Joint Commission International

Joint Commission International Accreditation Standards for Hospitals

Including Standards for Academic Medical Center Hospitals

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Joint Commission International Mission

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Summary of Changes to the Manual

Accreditation Participation Requirements (APR)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
APR.01.00	APR.1	ME 1 was added as scorable requirement on timely submission of data and information to JCI.		X
APR.02.00	APR.2	ME 1 was added as scorable requirement on providing accurate information throughout the accreditation process.		X
APR.03.00	APR.3	ME 1 was added as scorable requirement on informing JCI of any organization changes through organization's E-App.		X
APR.04.00	APR.4	ME 1 was added as scorable requirement on performance of JCI surveys.		X
APR.05.00	APR.5	ME 1 was added as scorable requirement on providing JCI official records and reports when requested.		X
APR.06.00	APR.7	Renumbered requirement and added ME 1 as scorable element focused on performance measures.		X
APR.07.00	APR.8	Renumbered requirement with two scorable measurable elements focused on accurate advertising of JCI accreditation.		X
APR.08.00	APR.9	Renumbered requirement with three scorable measurable elements focused on staff reporting safety or quality concerns without retribution.		X
APR.09.00	APR.11	Renumbered requirement with two measurable measurable elements focused on informing public on how to report concerns on patient safety and quality of care.		X
APR.10.00	APR.10	ME 1 was added as scorable requirement on providing qualified translator when applicable.		X
APR.11.00	APR.12	ME 1 was added as scorable requirement on providing safe environment.		X

Access to Care and Continuity of Care (ACC)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
ACC.01.00	ACC.1	Renumbered standard with six measurable elements similar to the 7th Edition.		
ACC.01.01	ACC.1	Renumbered standard with five measurable elements focused on patients with emergent, urgent, and immediate needs.		
ACC.01.02	ACC.1.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
ACC.02.00	ACC.2	Renumbered standard now with four measurable elements focused on patient flow processes.		
ACC.02.01	ACC.2.2	Renumbered standard with six measurable elements focused on patient education.		
		Moved PCC.4, ME 1 (7th Edition) to ACC.02.01, ME 4 (8th Edition).		
		Moved PCC.4, ME 2 (7th Edition) to ACC.02.01, ME 5 (8th Edition).		
		Moved PCC.4, ME 4 (7th Edition) to ACC.02.01, ME 6 (8th Edition).		
ACC.02.02	ACC.2.3	Renumbered standard with four measurable elements focused on criteria for specialized units/departments.		
ACC.03.00	ACC.3	Renumbered standard with six measurable elements similar to the 7th Edition.		
ACC.03.01	ACC.3.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
ACC.04.00	ACC.4	Renumbered standard with six measurable elements similar to the 7th Edition.		
ACC.04.01	ACC.4.1	Renumbered standard with five measurable elements focused on patient/family discharge education.		
ACC.04.02	ACC.4.2	Renumbered standard with five measurable elements similar to the 7th Edition.		
ACC.04.03	ACC.4.2.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
ACC.04.04	ACC.4.3	Renumbered standard with four measurable elements similar to the 7th Edition.		
ACC.04.05	ACC.4.4 ACC.4.4.1	Combined into one standard with six measurable elements focused on leaving against medical advice.		
ACC.05.00	ACC.5	Renumbered standard with six measurable elements similar to the 7th Edition.		
ACC.05.01	ACC.5.1	Renumbered standard with two measurable elements focused on transfer documentation.		
ACC.06.00	ACC.6	Renumbered standard with six measurable elements focused on transportation services.		

Assessment of Patients (AOP)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
AOP.01.00	AOP.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
AOP.01.01	AOP.1.1 AOP.1.2 AOP.1.2.1	Combined into one standard with nine measurable elements focused on the initial assessment.		
		ME 3 focuses on requirements of the initial assessment.		X
		ME 4 focuses on special populations that require assessment modifications.		X
AOP.01.02	AOP.1.3	Renumbered standard with three measurable elements focused on outside source assessments.		
AOP.01.03	AOP.1.4	Renumbered standard with five measurable elements focused on screening for nutritional, functional, or other special needs.		
AOP.01.04	AOP.1.5	Renumbered standard with five measurable elements focused on pain assessment.		
AOP.01.05	AOP.2	Renumbered standard with four measurable elements focused on reassessment intervals.		
AOP.02.00	IPSG.6 IPSG.6.1	Renumbered standard moved from IPSG chapter with four measurable elements focused on fall risk.		
AOP.03.00	AOP.5	Renumbered standard with three measurable elements focused on laboratory services.		
AOP.03.01	AOP.5.1	Renumbered standard with five measurable elements similar to the 7th Edition.		
AOP.03.02	AOP.5.2	Renumbered standard with five measurable elements similar to the 7th Edition.		
AOP.03.03	AOP.5.4	Renumbered standard with four measurable elements focused on reporting of lab results.		
		ME 4 focuses on corrective action when lab results are not reported correctly.		X
AOP.03.04	AOP.5.5	Renumbered standard with five measurable elements similar to the 7th Edition.		
AOP.03.05	AOP.5.6	Renumbered standard with five measurable elements focused on reagents and supplies for laboratory services.		
		ME 5 focuses on the information required for reagent records.		X
AOP.03.06	AOP.5.7	Renumbered standard with six measurable elements similar to the 7th Edition.		
AOP.03.07	AOP.5.8	Renumbered standard with five measurable elements similar to the 7th Edition.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
AOP.03.08	AOP.5.9 AOP.5.9.1	Combined into one standard with six measurable elements focused on laboratory service quality control and proficiency testing.		
AOP.03.09	AOP.5.10 AOP.5.10.1	Combined into one standard with five measurable elements focused on services provided by contracted laboratories.		
AOP.04.00	AOP.5.11	Renumbered standard with six measurable elements focused on blood bank and transfusion services.		
		ME 5 focuses on monitoring and improving utilization.		X
		ME 6 focuses on hemovigilance surveillance.		X
AOP.04.01	COP.3.4	New standard with five measurable elements focused on clinical guidelines for administration of blood and blood products.	X	
AOP.05.00	AOP.6	Renumbered standard with four measurable elements similar to the 7th Edition.		
AOP.05.01	AOP.6.1	Renumbered standard with six measurable elements similar to the 7th Edition.		
AOP.05.02	AOP.6.2	Renumbered standard with seven measurable elements focused on radiation and/or diagnostic imaging safety.		
		ME 6 focuses on the individual serving as the radiation safety officer.		X
AOP.05.03	AOP.6.3	Renumbered standard with four measurable elements focused on radiology and diagnostic imaging results.		
		ME 4 focuses on corrective action when results are not reported in the expected time frame.		X
AOP.05.04	AOP.6.4	Renumbered standard with five measurable elements similar to the 7th Edition.		
AOP.05.05	AOP.6.5	Renumbered standard with three measurable elements focused on quality control for radiology and diagnostic imaging services.		
AOP.05.06	AOP.6.6	Renumbered standard with five measurable elements focused on contracted services.		
		MEs 1 and 2 focus on maintaining a copy of licenses and certificates from a recognized authority.		X
AOP.06.00	N/A	New standard with five measurable elements focused on nuclear medicine safety.	X	

Anesthesia and Surgical Care (ASC)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
ASC.01.00	ASC.1 ASC.2	Combined into one standard with six measurable elements focused on the provision of sedation and anesthesia services.		
ASC.02.00	ASC.3	Renumbered standard with two measurable elements similar to the 7th Edition.		
ASC.02.01	ASC.3.1	Renumbered standard with three measurable elements focused on the qualifications of practitioners and staff responsible for procedural sedation.		
ASC.02.02	ASC.3.2	Renumbered standard with five measurable elements focused on the administration, monitoring, and documentation of procedural sedation according to professional practice guidelines.		
		ME 4 focuses on the presedation assessment performed by a qualified individual and the documentation.		X
ASC.02.03	ASC.3.3	Renumbered standard with three measurable elements similar to the 7th Edition.		
ASC.03.00	ASC.4	Renumbered standard with four measurable elements focused on the preanesthesia and preinduction assessments.		
		ME 4 focuses on the scope and content of the preanesthesia and preinduction assessment.		X
ASC.03.01	ASC.5	Renumbered standard with six measurable elements focused on discussing the anesthesia plan of care with the patient and/or decision-maker.		
		ME 6 focuses on anesthesia care according to professional practice guidelines and hospital policy.		X
ASC.03.02	ASC.6	Renumbered standard with three measurable elements similar to the 7th Edition.		
ASC.03.03	ASC.6.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
ASC.04.00	ASC.7 AOP.1.3.1	Renumbered standard with four measurable elements focused on the preoperative assessment.		
		Moved documentation requirement from AOP.1.3.1, ME 3 (7th Edition) to ASC.04.00, ME 1 (8th Edition).		X
		Moved Standard AOP.1.3.1 (7th Edition) to ASC.04.00, ME 2 (8th Edition).		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
ASC.04.01	ASC.7.1	Renumbered standard with two measurable elements focused on risks, benefits, and alternatives of surgical procedures.		
		Moved ASC.7.1, ME 2 (7th Edition) to ASC.04.01, ME 1 (8th Edition).		
ASC.04.02	ASC.7.2	Renumbered standard with three measurable elements similar to the 7th Edition.		
ASC.04.03	ASC.7.3	Renumbered standard with four measurable elements similar to the 7th Edition.		
ASC.04.04	ASC.7.4	Renumbered standard with five measurable elements focused on planning surgical care that includes implantable devices.		
		ME 3 focuses on the information the patient receives on the implantable device.		X

Care of Patients (COP)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
COP.01.00	COP.2 IPSG.2	Renumbered standard with six measurable elements focused on prescribing, documenting, and carrying out orders; and reporting results.		
		ME 3 moved from IPSG.2 (7th Edition).		X
		ME 6 moved from IPSG.2 (7th Edition).		X
COP.01.01	COP.2.2	Renumbered standard with four measurable elements focused on individualized patient care plans.		
COP.01.02	COP.3	Renumbered standard with five measurable elements similar to the 7th Edition.		
COP.02.00	COP.3.1	Renumbered standard with six measurable elements focused on clinical alarm safety.		
		ME 6 focuses on performance improvement efforts for clinical alarm safety.		X
COP.03.00	COP.3.2	Renumbered standard with four measurable elements similar to the 7th Edition.		
COP.04.00	COP.3.3	Renumbered standard with four measurable elements similar to the 7th Edition.		
		ME 4 focuses on expanded requirements for performance improvement related to resuscitation.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
COP.05.00	COP.3.5	Renumbered standard with seven measurable elements focused on care of suicidal patients.		
		ME 4 focuses on documentation of suicide screenings and assessments.		X
		ME 5 focuses on policies and procedures for staff competence and reassessment of patients.		X
		ME 6 focuses on follow-up care at discharge.		X
COP.06.00	COP.5 COP.5.1	Combined into one standard with eight measurable elements focused on delivery of nutrition services and nutrition therapy.		
COP.07.00	COP.6 PCC.2.2	Renumbered standard with four measurable elements similar to the 7th Edition; includes duplicative content from PCC.2.2.		
COP.08.00	COP.7 PCC.2.2	Renumbered standard with six measurable elements similar to the 7th Edition.		
COP.09.00	PCC.6	Moved and renumbered standard with four measurable elements focused on informing patients/families about organ donation.		
COP.09.01	PCC.6.1	Moved and renumbered standard with four measurable elements focused on provision of oversight of organ and tissue procurement program.		
COP.09.02	COP.8	Renumbered standard with three measurable elements similar to the 7th Edition.		
COP.09.03	COP.8.1 COP.8.2	Combined into one standard with seven measurable elements focused on qualified program leadership and interdisciplinary team with expertise in relevant transplant programs.		
COP.09.04	COP.8.3	Renumbered standard with four measurable elements similar to the 7th Edition.		
COP.09.05	N/A	New standard with seven measurable elements focused on organ, tissue, and cell transplant program responsibilities to include sharing of transplant data required by laws and regulations; and receipt, transport, handling, and storage of organs and tissues.	X	
COP.09.06	COP.8.5	Renumbered standard with five measurable elements similar to the 7th Edition.		
COP.09.07	COP.8.6	Renumbered standard with five measurable elements similar to the 7th Edition.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
COP.09.08	COP.8.7	Renumbered standard with six measurable elements focused on clinical practice guidelines and clinical criteria guiding selection of organ and tissue transplant recipients; standard language changed from 7th Edition.		
		ME 6 focuses on documentation of organ compatibility in patient records.		X
COP.10.00	COP.9	Renumbered standard with five measurable elements similar to the 7th Edition.		
COP.10.01	COP.9.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
COP.10.02	COP.9.2	Renumbered standard with six measurable elements similar to the 7th Edition.		
COP.10.03	COP.9.3	Renumbered standard with three measurable elements similar to the 7th Edition.		

International Patient Safety Goals (IPSG)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
IPSG.01.00	IPSG.1	Renumbered standard with three measurable elements similar to the 7th Edition, with expanded guidance for newborn naming conventions.		
IPSG.02.00	IPSG.2.1	Renumbered standard with four measurable elements focused on critical results reporting.		
IPSG.02.01	IPSG.2.2	Renumbered standard with three measurable elements similar to the 7th Edition.		
IPSG.03.00	IPSG.3	Renumbered standard with three measurable elements similar to the 7th Edition.		
IPSG.03.01	IPSG.3.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
		ME 3 expanded to include review of list of look-alike/sound-alike (LASA) medications at least annually.		
IPSG.03.02	IPSG.3.2	Renumbered standard with three measurable elements focused on safe storage of concentrated electrolytes.		
		ME 3 focuses on performing proactive risk assessments at least annually where concentrated electrolytes are stored.		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
IPSG.04.00	IPSG.4	Renumbered standard with three measurable elements focused on preoperative verification and site marking for safe surgery.		
		ME 1 expanded to include World Health Organization (WHO) recommendations.		
		ME 4 expanded to include requirement for alternative site marking process.		
IPSG.04.01	IPSG.4.1	Renumbered standard with four measurable elements focused on time-out/Universal Protocol for safe surgery.		
		ME 1 expanded to include WHO recommendations.		
		ME 4 new requirement to perform second time-out for separate procedures performed by different individuals during the same surgery episode.		X
IPSG.05.00	IPSG.5	Renumbered standard with three measurable elements similar to the 7th Edition; expanded requirement for ME 3 to collect and analyze data for hand hygiene program.		

Medication Management and Use (MMU)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
MMU.01.00	MMU.1	Renumbered standard with seven measurable elements focused on medication management processes.		
		ME 1 focuses on a qualified individual overseeing the medication management team.		X
		ME 3 focuses on members of the medication management team.		X
MMU.01.01	MMU1.1	Renumbered standard with eight measurable elements focused on antimicrobial stewardship.		
		ME 2 focuses on the antimicrobial stewardship program interdisciplinary team.		X
		ME 3 focuses on coordination of antimicrobial use throughout the hospital.		X
		ME 6 focuses on the program collecting, analyzing, and reporting data.		X
		ME 8 focuses on patient and family antimicrobial education.		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
MMU.01.02	MMU.3.2	Renumbered standard with six measurable elements focused on a medication recall system process.		
		ME 3 focuses on labeling and isolating recalled medication.		X
		ME 4 focuses on notifying patients of recalled medications.		X
		ME 5 focuses on the process to inform health care providers of medication recalls.		X
		ME 6 focuses on the process for documenting all actions related to medication recall.		X
MMU.01.03	N/A	New standard with three measurable elements focused on a process for handling expired medications.	X	
MMU.02.00	MMU.2	Renumbered standard with four measurable elements focused on a process for the selection and procurement of medications.		
		ME 1 focuses on interdisciplinary team collaboration to determine criteria for medication selection and procurement.		X
MMU.03.00	MMU.3	Renumbered standard with six measurable elements similar to the 7th Edition.		
MMU.03.01	MMU.3.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
MMU.04.00	MMU.4.1	Renumbered standard with two measurable elements similar to the 7th Edition.		
MMU.04.01	MMU.4.2	Renumbered standard with six measurable elements focused on safe prescribing, ordering, and transcribing practices and elements of a complete order or prescription.		
		ME 2 focuses on a diagnosis, condition, or indication for use for each medication ordered.		X
		ME 4 focuses on additional required elements of complete medication orders or prescriptions.		X
MMU.04.02	MMU.4	Renumbered standard with four measurable elements focused on a medication reconciliation process.		
		ME 4 focuses on when medication review is conducted.		X
MMU.05.00	MMU.5	Renumbered standard with six measurable elements focused on medication preparation and dispensing practices.		
		ME 4 focuses on visual inspection of medication.		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
MMU.05.01	N/A	New requirements with five measurable elements focused on a process for radiopharmaceuticals.	X	
MMU.05.02	MMU.5.1	Renumbered standard with seven measurable elements focused on medication appropriateness review.		
		ME 3 focuses on the process to conduct an appropriateness review for an order or prescription prior to dispensing.		X
		ME 7 focuses on clarifying concerns, issues, or questions with the provider prior to dispensing medication.		X
MMU.05.03	MMU.5.2	Renumbered standard with five measurable elements focused on a medication dispensing system.		
		ME 4 focuses on requirements in a policy for medication labeling practices.		X
MMU.06.00	MMU.6 MMU.6.1	Combined into one standard with six measurable elements focused on medication administration performed by qualified individuals.		
		ME 6 focuses on administering a radioactive pharmaceutical for diagnostic purposes.		X
MMU.06.01	MMU.6.2 MMU.6.2.1	Combined into one standard with four measurable elements focused on policies and procedures governing medication brought into the hospital, prescribed for patient self-administration, and medication samples.		
		ME 4 focuses on assessing the competence of the patient or family administering medication.		X
MMU.07.00	MMU.7	Renumbered standard with seven measurable elements focused on actual or potential adverse drug events and adverse drug reactions.		
		ME 2 focuses on a process to address prescriber notification for adverse drug events and reactions.		X
		ME 6 focuses on conducting a root cause analysis of data for adverse drug event patterns or undesirable trends.		X
MMU.07.01	MMU.7.1	Renumbered standard with five measurable elements focused on a process for medication errors and near miss events (or close calls).		
		ME 4 focuses on conducting a root cause analysis of data for medication error and near miss patterns or undesirable trends.		X

Patient-Centered Care (PCC)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
PCC.01.00	PCC.1	Renumbered standard with six measurable elements similar to the 7th Edition.		
PCC.01.01	PCC.1.1 PCC.1.2	Combined into one standard with five measurable elements focused on patients' rights to access care, have barriers removed, and have cultural and religious preferences respected.		
PCC.01.02	PCC1.3	Renumbered standard with five measurable elements similar to the 7th Edition.		
PCC.01.03	PCC.1.4	Renumbered standard with three measurable elements similar to the 7th Edition.		
PCC.01.04	N/A	New requirements with four measurable elements focused on protection of vulnerable populations.	X	
PCC.02.00	PCC.2	Renumbered standard with four measurable elements similar to the 7th Edition.		
PCC.02.01	PCC.2.1	Renumbered standard with six measurable elements similar to the 7th Edition.		
PCC.02.02	PCC.3	Renumbered standard with four measurable elements similar to the 7th Edition.		
PCC.02.03	PCC.3.1	Renumbered standard with five measurable elements focused on processes to manage patient complaints and disclosure of clinical errors.		
		ME 3 focuses on content of a policy for disclosure of clinical errors.		X
		ME 4 focuses on implementation of a policy on disclosure of clinical errors.		X
		ME 5 focuses on a process to analyze and prevent the error from recurring.		X
PCC.03.00	PCC.4 PCC.4.1 PCC.4.2 PCC.4.3 PCC.4.4	Combined into one standard with five measurable elements focused on informed consent policy and process for obtaining informed consent.		
PCC.04.00	PCC.5	Renumbered standard with four measurable elements similar to the 7th Edition.		
PCC.04.01	PCC.5.1 PCC.5.2	Combined into one standard with three measurable elements focused on identification of patient/family education needs and documentation of education.		

Facility Management and Safety (FMS)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
FMS.01.00	FMS.1	Renumbered standard with four measurable elements focused on leadership and planning for facility use.		
FMS.01.01	FMS.2	Renumbered standard with three measurable elements focused on oversight of the FMS structure.		
FMS.02.00	FMS.3 FMS.4	Combined into one standard with four measurable elements focused on risk assessment, reporting, and action by the governing entity.		
FMS.03.00	FMS.5	Renumbered standard with five measurable elements focused on the safety program.		
		ME 4 focuses on safety incidents within the facility.		X
		ME 5 focuses on safety incidents related to workplace violence.		X
FMS.04.00	FMS.6	Renumbered standard with nine measurable elements focused on a secure environment.		
		ME 4 focuses on equipment inspection.		X
		ME 5 focuses on education related to a safety event.		X
		ME 6 focuses on safety exercises.		X
		ME 7 focuses on an annual analysis of workplace violence.		X
		ME 8 focuses on investigation of security incidents.		X
		ME 9 focuses on investigation of workplace violence incidents.		X
FMS.05.00	FMS.7 FMS.7.1 FMS.7.2	Combined into one standard with seven measurable elements focused on hazardous materials and waste.		
		ME 7 focuses on staff demonstration of procedures.		X
FMS.06.00	FMS.8	Renumbered standard with three measurable elements focused on fire safety measures.		
FMS.06.01	FMS.8.1 FMS.8.2	Combined into one standard with six measurable elements focused on maintenance of fire safety equipment/building features.		
FMS.06.02	FMS.8.3	Renumbered standard with three measurable elements similar to the 7th Edition.		
FMS.06.03	FMS.8.4	Renumbered standard with three measurable elements similar to the 7th Edition.		
FMS.06.04	FMS.8.5	Renumbered standard with three measurable elements focused on patient and staff smoking habits.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
FMS.07.00	FMS.9 FMS.9.1	Combined into one standard with three measurable elements focused on medical equipment.		
		ME 2 combined concepts of previous FMS.9.1, MEs 2–4.		
FMS.07.01	FMS.9.2	Renumbered standard with three measurable elements similar to the 7th Edition.		
FMS.08.00	FMS.10 FMS.10.1	Combined into one standard with five measurable elements focused on utility systems management.		
FMS.08.01	FMS.10.2	Renumbered standard with three measurable elements focused on testing and evaluation of utility systems.		
FMS.08.02	FMS.10.3	Renumbered standard with four measurable elements focused on monitoring water quality.		
FMS.08.03	FMS.10.3.1	Renumbered standard with five measurable elements similar to the 7th Edition.		
FMS.08.04	PCI.10	Renumbered standard with three measurable elements focused on reducing the risk of infection through engineering controls.	X	
FMS.09.00	FMS.11	Renumbered standard with four measurable elements focused on the emergency management program.		
FMS.09.01	PCI.12.1 PCI.12.2	New standard with six measurable elements focused on emergency management for global communicable diseases.	X	
FMS.10.00	FMS.12 PCI.11	Renumbered standard with three measurable elements similar to the 7th Edition.		

Governance, Leadership, and Direction (GLD)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
GLD.01.00	GLD.1 GLD.1.1 GLD.1.2	Combined into one standard with five measurable elements focused on structure and oversight responsibilities of the governing entity.		
GLD.02.00	GLD.2	Renumbered standard with five measurable elements focused on the chief executive's qualifications and responsibilities.		
GLD.03.00	GLD.3	Renumbered standard with three measurable elements focused on hospital leaders' responsibility to carry out the hospital's mission.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
GLD.03.01	GLD.3.1	Renumbered standard with four measurable elements focused on hospital departments' planning of services, providing data, and communication to staff.		
		ME 4 focuses on implementing policies to provide uniform care to patients.		X
GLD.03.02	GLD.3.2	Renumbered standard with three measurable elements similar to the 7th Edition.		
GLD.04.00	GLD.4	Renumbered standard with seven measurable elements focused on implementation of hospitalwide quality and patient safety program.		
		ME 5 focuses on definition of patient safety events and reporting of sentinel events.		X
		Moved QPS.7, ME 2 (7th Edition) to GLD.04.00, ME 6 (8th Edition).		
		ME 7 focuses on supporting staff involved in an adverse event or a sentinel event.		X
GLD.04.01	GLD.4.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
GLD.04.02	GLD.5	Renumbered standard with four measurable elements focused on hospital leaders' use of data when identifying hospitalwide priorities and compliance to IPSGs.		
		ME 3 focuses on data collection and assessment of diagnostic error factors.		X
		ME 4 focuses on interventions to mitigate diagnostic errors.		X
GLD.05.00	GLD.6 GLD.6.1	Combined into one standard with six measurable elements focused on oversight of contract services and integration of contract management to the hospital's quality monitoring program.		
GLD.05.01	GLD.6.2	Renumbered standard with four measurable elements similar to the 7th Edition.		
GLD.05.02	GLD.7	Renumbered standard with four measurable elements focused on using data in resource decision-making.		
GLD.05.03	GLD.7.1	Renumbered standard with three measurable elements focused on establishing the hospital's supply chain strategy.		
		ME 1 combines the concepts of GLD.7.1, MEs 1–3 (7th Edition).		
GLD.06.00	GLD.8 GLD.9	Combined into one standard with four measurable elements focused on hospital department oversight, direction, and structure.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
GLD.06.01	GLD.11	Renumbered standard with four measurable elements similar to the 7th Edition.		
GLD.06.02	GLD.11.2	Renumbered standard with four measurable elements similar to the 7th Edition.		
GLD.07.00	GLD.12	Renumbered standard with six measurable elements focused on the hospital's ethical framework and conflict of interest disclosure.		
GLD.07.01	GLD.13 GLD.13.1	Renumbered standard with six measurable elements focused on culture of safety in the organization.		
		Moved GLD.13, ME 1 (7th Edition) to GLD.07.01, ME 4 (8th Edition).		
		Moved GLD.13.1, ME 5 (7th Edition) to GLD.07.01, ME 5 (8th Edition).		
		Moved GLD.13.1, ME 3 (7th Edition) to GLD.07.01, ME 6 (8th Edition).		
GLD.07.02	N/A	New standard with five measurable elements focused on workplace violence prevention program.	X	
GLD.08.00	GLD.14	Renumbered standard with five measurable elements similar to the 7th Edition.		
GLD.09.00	GLD.15	Renumbered standard with five measurable elements focused on human subjects research policies, patient information, consent forms, and indemnity insurance.		

Health Care Technology (HCT)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
HCT.01.00	MOI.11	Renumbered standard from MOI with four measurable elements similar to the 7th Edition.		
HCT.01.01	MOI.12	Renumbered standard from MOI with five measurable elements similar to the 7th Edition.		
HCT.01.02	N/A	New standard with four measurable elements focused on telehealth services.	X	
HCT.01.03	N/A	New standard with three measurable elements focused on clinical decision support tools and artificial intelligence.	X	
HCT.01.04	MOI.13	Renumbered standard from MOI with six measurable elements similar to the 7th Edition.		
HCT.01.05	N/A	New standard with three measurable elements focused on cybersecurity and cyber risk management.	X	
HCT.02.00	COP.4	Renumbered standard from COP with six measurable elements similar to the 7th Edition.		

Management of Information (MOI)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
MOI.01.00	MOI.1	Renumbered standard with three measurable elements focused on managing information.		
MOI.01.01	MOI.2	Renumbered standard with six measurable elements similar to the 7th Edition.		
MOI.01.02	MOI.2.1	Renumbered standard with five measurable elements focused on safety and security of information.		
		ME 5 focuses on cyberattacks.		X
MOI.01.03	MOI.3	Renumbered standard with three measurable elements similar to the 7th Edition.		
MOI.01.04	MOI.6	Renumbered standard with four measurable elements focused on information systems training.		
		ME 3 focuses on cybersecurity education.		X
MOI.02.00	MOI.7	Renumbered standard with four measurable elements focused on management of documents.		
		Split 7th Edition ME 1 into 8th Edition MEs 1 and 2.		
MOI.02.01	MOI.7.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
MOI.02.02	MOI.4	Renumbered standard with four measurable elements focused on use of abbreviations.		
MOI.02.03	MOI.5	Renumbered standard with three measurable elements focused on dissemination of data.		
MOI.03.00	MOI.8 MOI.8.1 MOI.9	Combined into one standard with five measurable elements focused on the integrity of the patient health record.		
MOI.03.01	MOI.10	Renumbered standard with five measurable elements similar to the 7th Edition.		

Prevention and Control of Infections (PCI)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
PCI.01.00	PCI.1	Renumbered standard with five measurable elements focused on qualifications of infection prevention and control leaders and oversight of the infection prevention and control program.		
PCI.01.01	PCI.2	Renumbered standard with five measurable elements focused on integration of the infection prevention and control program with all departments and services, and with the quality and patient safety program.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
PCI.01.02	PCI.3	Renumbered standard with three measurable elements focused on provision of adequate resources for the infection prevention and control program.		
PCI.02.00	PCI.5 PCI.5.1 IPSG.5.1	Combined into one standard with five measurable elements focused on risk assessments and evidence-based strategies for infection prevention and control.		
PCI.02.01	AOP.5.3.1	Renumbered standard moved to PCI chapter with four measurable elements similar to the 7th Edition.		
PCI.03.00	PCI.6	Renumbered standard with eight measurable elements similar to the 7th Edition.		
PCI.03.01	PCI.6	New standard with five measurable elements focused on a process to manage reuse of single-use devices.	X	
PCI.03.02	PCI.6	New standard with three measurable elements focused on a process to manage expired and damaged devices and supplies.	X	
PCI.04.00	PCI.7	Renumbered standard with four measurable elements similar to the 7th Edition.		
PCI.04.01	PCI.7.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
PCI.05.00	PCI.8	Renumbered standard with seven measurable elements focused on proper disposal and handling of infectious waste, sharps, and needles.		
		ME 7 focuses on a policy to direct chain of custody for all bodies and body parts handled by pathology, mortuary, and other postmortem areas.		X
PCI.05.01	PCI.8.1	Renumbered standard with seven measurable elements focused on protection from and response to blood and body fluid exposures.		
		ME 2 focuses on implementation of practices to reduce risk of exposures to blood and body fluids.		X
PCI.06.00	PCI.9	Renumbered standard with five measurable elements similar to the 7th Edition.		
PCI.07.00	PCI.12	Renumbered standard with five measurable elements focused on isolation precautions for communicable diseases and protection of immunosuppressed patients.		
		ME 2 focuses on staff education on management of infectious patients when negative air pressure rooms are not available.		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
PCI.07.01	PCI.13	Renumbered standard with six measurable elements focused on personal protective equipment and hand hygiene resources.		
		ME 2 focuses on ensuring that personal protective equipment and hand hygiene resources are readily available.		X
PCI.07.02	N/A	New standard with five measurable elements focused on preparedness and response for epidemiologically significant or high-impact pathogens, including novel pathogens.	X	
PCI.08.00	PCI.14	Renumbered standard with five measurable elements similar to the 7th Edition.		
PCI.08.01	PCI.15	Renumbered standard with five measurable elements focused on infection prevention and control education for staff and infection prevention and control program communication with leaders and governing board.		
		ME 5 focuses on communicating data and information from infection prevention and control program to governing board.		X

Quality and Patient Safety (QPS)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
QPS.01.00	QPS.1	Renumbered standard with six measurable elements focused on implementation of quality and patient safety program and quality and patient safety program leaders/staff qualifications.		
		ME 6 focuses on defining qualifications of quality and patient safety program leaders and staff.		X
QPS.02.00	QPS.2	Renumbered standard with four measurable elements similar to the 7th Edition.		
QPS.03.00	QPS.4	Renumbered standard with five measurable elements similar to the 7th Edition.		
QPS.03.01	QPS.6	Renumbered standard with three measurable elements focused on data validation.		
QPS.03.02	QPS.4.1	Renumbered standard with five measurable elements similar to the 7th Edition.		
QPS.03.03	QPS.5	Renumbered standard with three measurable elements similar to the 7th Edition.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
QPS.03.04	QPS.8	Renumbered standard with six measurable elements focused on mandatory data collection, intensive analysis when adverse events or trends occur, and reporting of data analyses.		
		ME 6 focuses on implementing measures intended to increase patient safety event reporting.		X
QPS.04.00	QPS.9	Renumbered standard with four measurable elements similar to the 7th Edition.		
QPS.04.01	QPS.10	Renumbered standard with six measurable elements focused on requirements for risk management programs.		
		ME 6 focuses on defining qualifications of risk management personnel.		X

Staff Qualifications and Education (SQE)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
SQE.01.00	SQE.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.01.01	SQE.1.1	Renumbered standard with four measurable elements focused on staff member responsibilities in the job description.		
		ME 2 focuses on requiring the job description to include defined staff member responsibilities.		X
SQE.01.02	SQE.2	Renumbered standard with four measurable elements similar to the 7th Edition.		
SQE.01.03	SQE.3 SQE.4	Combined into one standard with six measurable elements focused on staff qualifications and performance.		
		ME 2 focuses on performance-based staff evaluations.		X
		ME 5 focuses on a qualified individual conducting staff evaluations.		X
SQE.01.04	SQE.5	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.01.05	SQE.6 SQE.6.1	Combined into one standard with seven measurable elements focused on hospital staffing process.		
		ME 4 focuses on staffing process compliance with laws and regulations.		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
SQE.01.06	SQE.7	Renumbered standard with five measurable elements focused on staff orientation.		
		ME 5 focuses on documentation of completed orientation.		X
SQE.01.07	SQE.8	Renumbered standard with seven measurable elements focused on education and training.		
		ME 7 focuses on documentation of completed education and training.		X
SQE.01.08	SQE.8.1 SQE.8.1.1	Combined into one standard with seven measurable elements focused on staff competence in resuscitative techniques.		
SQE.02.00	SQE.8.2	Renumbered standard with five measurable elements focused on staff mental health.		
		ME 3 focuses on the evaluation and resources for elements of staff mental health.		X
		ME 5 focuses on actions taken for staff mental health prevention.		X
SQE.02.01	SQE.8.3	Renumbered standard with five measurable elements focused on a staff vaccination and immunization program.		
		ME 3 focuses on a process for staff vaccinations and immunizations.		X
SQE.02.02	N/A	New standard with three measurable elements focused on workplace violence prevention training.	X	
SQE.03.00	SQE.13	Renumbered standard with six measurable elements similar to the 7th Edition.		
SQE.03.01	SQE.14	Renumbered standard with five measurable elements focused on nursing staff credentials.		
		ME 1 focuses on nursing staff experience, training, and education applicability to their role.		X
		ME 2 focuses on nursing staff evaluation criteria.		X
SQE.03.02	SQE.14.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.04.00	SQE.15	Renumbered standard with five measurable elements similar to the 7th Edition.		
SQE.04.01	SQE.16	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.04.02	SQE.16.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.05.00	SQE.9	Renumbered standard with four measurable elements similar to the 7th Edition.		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
SQE.05.01	SQE.9.1	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.05.02	SQE.9.2	Renumbered standard with three measurable elements similar to the 7th Edition.		
SQE.06.00	SQE.10	Renumbered standard with five measurable elements focused on the process to grant medical staff membership and clinical privileges.		
		ME 2 focuses on criteria that determine scope of medical staff privileges.		X
		Moved PCC.4.3, ME 4 (7th Edition) to SQE.06.00, ME 5 (8th Edition).		X
SQE.06.01	N/A	New standard with six measurable elements focused on medical staff temporary clinical privileges.	X	
SQE.06.02	SQE.12	Renumbered standard with six measurable elements focused on medical staff membership and clinical privileges.		
		ME 4 focuses on notification of staff regarding the decision to grant privileges.		X
		ME 5 focuses on the process to disseminate all granting-related decisions to applicable parties.		X
SQE.07.00	SQE.11	Renumbered standard with five measurable elements focused on process for evaluating the care provided by the medical staff.		
		ME 4 focuses on hospitalwide and department/service data sources criteria used in medical staff ongoing evaluations.		X
SQE.07.01	N/A	New standard with five measurable elements focused on monitoring and evaluating medical staff professional performance.	X	

Global Health Impact (GHI)

All-new chapter and requirements. Did not exist in 7th Edition.

Human Subjects Research Programs (HRP)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
HRP.01.00	HRP.1 HRP.1.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
		Moved HRP.1.1, ME 2 (7th Edition) to HRP.01.00, ME 4 (8th Edition).		

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
HRP.01.01	HRP.2	Renumbered standard with five measurable elements similar to the 7th Edition.		
HRP.01.02	HRP.3 HRP.3.1	Renumbered standard with three measurable elements focused on a policy for sponsors of research.		
		Moved HRP.3, MEs 1–5 (7th Edition) to elements under HRP.01.02, ME 1 (8th Edition).		
		ME 2 focuses on leaders verifying sponsor qualifications.		X
		ME 3 focuses on documentation confirming sponsor responsibility and accountability.		X
HRP.01.03	HRP.3.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
HRP.01.04	HRP.4	Renumbered standard with six measurable elements similar to the 7th Edition.		
HRP.02.00	HRP.5	Renumbered standard with four measurable elements focused on managing conflict of interest with research conducted in hospitals.		
		ME 1 focuses on a conflict of interest policy for research in hospitals.		X
HRP.02.01	HRP.6	Renumbered standard with three measurable elements similar to the 7th Edition.		
HRP.02.02	HRP.7 HRP.7.1	Renumbered standard with four measurable elements similar to the 7th Edition.		
		Moved Standard HRP.7 (7th Edition) to HRP.02.02, ME 1 (8th Edition).		

Medical Professional Education (MPE)

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
MPE.01.00	MPE.1	Renumbered standard with five measurable elements similar to the 7th Edition.		
MPE.01.01	MPE.2	Renumbered standard with three measurable elements similar to the 7th Edition.		
MPE.01.02	MPE.3	Renumbered standard with three measurable elements similar to the 7th Edition.		
MPE.02.00	MPE.4	Renumbered standard with five measurable elements focused on the supervision of medical students and trainees.		
		ME 2 focuses on the participant roles and responsibilities of the professional education programs.		X

8th Edition Standard Number(s)	7th Edition (Previous) Standard Number(s)	Description of Changes	New Standard	New ME
MPE.02.01	MPE.5	Renumbered standard with four measurable elements similar to the 7th Edition.		
MPE.02.02	MPE.6	Renumbered standard with five measurable elements similar to the 7th Edition.		
MPE.02.03	MPE.7	Renumbered standard with three measurable elements similar to the 7th Edition.		

Introduction

This introduction presents Joint Commission International (JCI) and explains how *Joint Commission International Accreditation Standards for Hospitals*, 8th Edition, is organized. Like each of the seven previous editions, we have sought to reflect the most current thinking in patient safety practices and concepts to help accredited and nonaccredited organizations uncover their most pressing safety risks and advance their goals for continuous quality improvement. We hope to support your work of making health care as safe as possible.

Read this chapter first to understand the structure and the content of this manual. This introduction provides information on the following topics:

- The value of JCI accreditation
- The standards development process
- How the manual is organized
- Applying the standards in your organization
- How to use the standards manual
- General eligibility requirements

After you have a better understanding of how to use this manual, read the "General Eligibility Requirements" section of this introduction to check whether your organization is eligible for JCI accreditation. Then become familiar with the JCI standards chapters and how the standards make health care safer.

If you have questions about the standards or the accreditation process, please contact JCI at JCIAccreditation@jcrinc.com.

The Value of JCI Accreditation

JCI's Gold Seal of Approval® is a widely recognized benchmark representing the most comprehensive evaluation process in the health care industry. Joint Commission accreditation benefits your organization in the following ways:

- *Gives you a competitive advantage:* Achieving accreditation and specialty certification is a visible demonstration to patients and the community that your hospital is committed to providing the highest-quality services. It also sets you apart from other hospitals offering the same types of care, treatment, and services.
- *Assists with recognition from insurers, associations, and other third parties:* Many payers, regulatory agencies, government agencies, and managed care contractors require JCI accreditation for reimbursement, for certification or licensure, and as a key element of their participation agreements and reimbursement practices.
- *Helps organize and strengthen performance improvement efforts:* Accreditation encompasses state-of-the-art performance improvement concepts that help you continuously improve quality and standardize your processes of care, treatment, and services.
- *Helps health care organizations become high reliability organizations:* JCI offers numerous resources and information to help hospitals move toward high reliability—that is, to consistently perform at high levels of quality and safety across all services and to maintain these levels over long periods.

These resources help leaders commit to high reliability by making it a priority, establishing a safety culture throughout the organization that emphasizes trust and the reporting of unsafe conditions and opportunities for improvement.

- *Enhances staff education:* The accreditation process is designed to be educational. JCI surveyors share best practice approaches and strategies that may help your hospital better meet the intent of the standards and, more important, improve performance of day-to-day operations.
- *Provides access to experts in quality and safety:* JCI is committed to helping your hospital move toward highly reliable care, treatment, and services. Through JCI your hospital has access to a range of professionals eager to see you succeed. It starts with the assignment of an account manager specializing in hospitals to help in day-to-day accreditation activities. You also have ready access to the clinical and engineering experts in our Standards Interpretation Group (SIG) as well as professional surveyors who visit your organization for surveys.

Standards Development Process

The JCI standards development process represents a collaboration between JCI, accredited organizations, and global subject matter experts in patient quality and safety. This 8th edition considers developments in the science of quality improvement and patient safety as well as the experiences of the organizations that used the 7th edition hospital and academic medical center standards to improve the safety and quality of care in their organizations.

The JCI standards development team took the following actions in revising the standards for this edition:

- Conducted focus groups with leaders from JCI–accredited organizations and other health care experts representing a broad range of perspectives from around the world.
- Reviewed the literature for current evidence-based practice and processes, and authoritative sources for industry guidelines to support new and revised standards.
- Gathered input from experts and others with specific and relevant content knowledge, including JCI surveyors and consultants.
- Received guidance on the development and revision of the standards from the Technical Advisory Panel, an international panel composed of experts with extensive experience in various health care fields.
- Sent an online field review of the revised standards to all accredited hospitals and promoted public participation in the field review through social media and the JCI website.
- Overall, the standards revisions were influenced and guided by the following sources:
  - Suggestions identified in the focus groups, advisory panels and subject matter experts, and field review
  - Requests to clarify requirements and expectations for specific standards
  - Evolving health care practices, evidence-based guidelines, and the changing health care environment

Keep Current with Standard Changes

JCI gathers information and experience related to the standards on an ongoing basis. If a standard no longer reflects evidence-based health care practice, commonly available technology, and quality management practices, JCI will revise or delete the requirements. New and revised standards are published at least six months in advance of the effective date to provide time for organizations to come into full compliance with the revised standards by the time they are effective.

JCI Insight provides critical information about changes to standards and policies that are made throughout the year. Reading *JCI Insight* allows you to learn about initiatives underway to support your efforts to achieve and sustain performance excellence. **Note the changes because your organization is responsible for complying with all applicable JCI standards (new and revised), including any changes published in *JCI Insight*.**

Current and recent editions of *JCI Insight* are available on your organization's extranet (*JCI Direct Connect*) site, made available to organizations that are accredited or have applied for accreditation. Staff who don't have access to their organization's secure extranet site can "Request Guest Access" on JCI's website at https://www.jointcommissioninternational.org/resources/jcinsight-newsletter.

Effective Date of Standards

The *Joint Commission International Accreditation Standards for Hospitals*, 8th Edition, is effective 1 January 2025:

1. For currently accredited hospitals, this is the date by which you now must be in full compliance with all new and revised standards in the 8th edition.
2. For hospitals seeking accreditation for the first time, this is the date after which all surveys and accreditation decisions will be based on the standards of the 8th edition. If you apply for survey and are surveyed before 1 January 2025, the survey will assess compliance with the standards of the 7th edition.

How This Manual Is Organized

This manual includes all the hospital and academic medical center Accreditation Participation Requirements (APRs), standards, intents, and measurable elements (MEs). The standards are organized around the important functions common to all health care organizations—an approach widely used around the world, which has been validated by scientific study, testing, and application.

This manual contains five major sections:

1. Accreditation Participation Requirements (Section I) that outline specific requirements for participating in accreditation and maintaining an accreditation award
2. Standards related to providing patient care (Section II)
3. Standards related to providing a safe, effective, and well-managed organization (Section III)
4. Standards related to environmental, social, and governance that impacts health care organizations (Section IV)
5. For academic medical centers only, standards related to medical professional education and human subjects research programs (Section V)

The standards apply to the entire organization as well as to each department, unit, or service within the organization.

In addition to the accreditation requirements, this manual includes the following appendices:

- **Interim Measures:** Interim measures are actions taken to ensure the safety of the building's occupants during times when features and systems for fire safety are defective, compromised, or inoperable due to construction, maintenance, a breakdown, or repair. Interim measures may need to be implemented to ensure the safety of occupants until improvements or repairs can be completed.
- **Patient Safety Systems:** Informs and educates leaders about the importance and structure of an integrated patient safety system. This chapter is designed to clarify the relationship between JCI accreditation and patient safety. It does not contain new standards or requirements. Rather, the chapter describes how existing requirements can be applied to continually improve patient safety. It also provides approaches and methods that may be adapted to remove risk of patient harm.
- **Sentinel Event Policy:** Contains information on JCI's Sentinel Event Policy, including the definition of a sentinel event, the goals of the policy, the adverse events that constitute sentinel events, sentinel event–related standards, and the various activities that surround the policy.

The manual also includes "Summary of Changes to the Manual," "Introduction," a chapter describing the key accreditation policies, and a glossary.

The companion *Joint Commission International Survey Process Guide for Hospitals Including Academic Medical Centers*, 8th Edition, helps hospitals and academic medical centers learn about and prepare for the JCI accreditation survey. During the survey, surveyors gather standards compliance information throughout the entire organization. The accreditation decision is based on the organization's overall level of compliance with the standards in this manual.

Elements of a Standards Chapter

Each standards chapter in Sections II, III, IV, and V contains the following elements:

- *Overview:* The overview is located at the beginning of each chapter. The overview explains the chapter's purpose and the principles on which the standards were built.
- *Standards list:* This part shows how the chapter is laid out and provides a frame of reference for the numbering of standards.
- *Standards:* Standards (also known as requirements) are statements that define the performance expectations and/or structures or functions that must be in place for an organization to be accredited by JCI and to provide safe, high-quality care, treatment, and services. Standards are evaluated for compliance during the on-site survey.
- *Intent:* An intent helps explain the full meaning of a standard by providing additional background, justification, or other information. The intent describes the purpose or reason for the standard and how it fits into the overall program, setting parameters for what is required by the standard. The intent is considered advisory, and it is not scored.
- *Measurable elements (MEs):* MEs are statements that detail the specific performance expectations, structures, functions, or processes that must be in place for an organization to meet the standard and provide high-quality care, treatment, and services. MEs are reviewed during the on-site survey and assigned a score that determines an organization's overall compliance with a standard. Organizations can use MEs to bring clarity to standards, help the organization fully understand the requirements, guide the organization in accreditation preparation, and educate executive leaders, department/service leaders, health care practitioners, and staff about the standards.
- *Examples:* Examples are included in many standards' intents and MEs to better illustrate expectations for compliance. Examples are considered advisory and are not required or scored.
- *Notes:* Occasionally, notes are used to provide organizations and surveyors with additional or clarifying information. A note may provide applicability information, define a term, or explain a concept. (All key terms are defined in the "Glossary" in the back of this manual.)

Required Written Documentation

Joint Commission International's focus is on performance and implementation rather than documentation. The standards, consequently, require documentation only when it is essential. The documentation icon—Ⓓ—is used to identify data collection and documentation requirements that are in addition to information found in the medical record. For example, the documentation icon is applied to an ME that requires a written procedure, but the icon is not applied to an ME that lists the required components of the medical record. Other examples in which the documentation icon is applied are MEs that require a policy, a written plan, bylaws, a license, evidence of testing, data, performance improvement reports, medication labels, safety data sheets, and meeting minutes.

Documentation can be on paper or in an electronic format. Although documentation is important, the primary emphasis of the survey will be on how your hospital carries out the functions described in the standards. The surveyors may use a combination of data sources, including interviews with leaders of the hospital, staff, patients, and patients' family members; visits to patient care settings; and review of documentation to arrive at an assessment of your hospital's compliance with a standard.

The documentation icon is meant to be a guide. The names and format of specific documents may vary from organization to organization.

JCI Standards in the Public Domain

To help individual health care organizations and public agencies seeking to improve the quality of patient care, JCI hospital standards (but not the intent statements and MEs) are in the international public domain for viewing. A listing of JCI hospital standards can be downloaded at no cost from the JCI website at https://www.jointcommissioninternational.org. Organizations with questions about translating or using the JCI standards must request written permission by contacting permissions@jcrinc.com.

Applying the Standards in Your Organization

Although each standard in Sections II, III, and IV apply to all applicant hospitals, there are three special circumstances when considering how to apply standards in an individual hospital:

Adhering to the Stricter Standard

A hospital must establish policies and procedures that conform to national, regional, and local laws or regulations as well as JCI standards. When a concept is addressed by the JCI standards and by the laws or regulations of a national or local authority, JCI requires that an organization follow whichever body has set the *higher* or *stricter* requirement. For example, JCI requires that organizations use two patient identifiers in a variety of processes. If the hospital's national standard requires the use of three identifiers, the hospital must use three identifiers to meet the national standard, which is stricter than JCI's standard. However, if that same national standard allows the use of bed number as an identifier—a practice JCI explicitly prohibits—the organization is prohibited from doing so. In this case, the organization would need to use three identifiers (the stricter national requirement) and would be prohibited from using bed number as an identifier (the stricter JCI requirement).

Global Health Impact (GHI) Standards

The *Joint Commission International Accreditation Standards for Hospitals,* 8th Edition, introduces a new chapter on Global Health Impact (GHI) that focuses on environmental sustainability in health care organizations. Standards in the GHI chapter are developed in collaboration with the International Hospital Federation's Geneva Sustainability Centre.

Understanding that hospitals are in different stages of their environmental sustainability journey, this chapter will serve as a resource to standardize practices in the environmental sustainability initiatives of JCI-accredited hospitals. Standards in the GHI chapter will be scored but will not factor into the organization's JCI accreditation decision for organizations surveyed before 1 January 2026.

Academic Medical Center Standards

Although community medical centers, often called hospitals or acute care centers, provide a wide range of basic and specialized services for patients in their local communities, academic medical centers are also primary sites for medical education and health care research. JCI developed the academic medical center standards to recognize the unique resource such organizations represent for health professional education and human subjects research in their community and country.

JCI standards in Section V, the "Medical Professional Education" (MPE) and "Human Subjects Research Programs" (HRP) chapters, present a framework for including medical education and research into the quality and patient safety activities of academic medical centers.

Many health care organizations may consider themselves to be an academic medical center, but only organizations that meet JCI's definition are required to comply with the MPE and HRP standards presented in Section V of this manual.

JCI will consider an applicant hospital an eligible academic medical center if it meets the following three criteria:

1. It is *integrated* (by organization or administration) with a medical school.
2. It is the principal site for the *education* of both (a) medical students (that is, undergraduates) and (b) postgraduate medical specialty trainees (for example, residents or interns) from such medical school.
3. At the time of application, it conducts *medical research* with approval and oversight by an Institutional Review Board (IRB) or research ethics committee.

All hospitals meeting the academic medical center eligibility criteria must comply with the requirements in Section V (as well as the requirements detailed in Sections II and III) to achieve JCI accreditation.

Organizations with questions about their eligibility for academic medical center accreditation should contact JCI Accreditation's Central Office at JCIAccreditation@jcrinc.com.

Using the Standards Manual

Joint Commission International Accreditation Standards for Hospitals, 8th Edition, when paired with its companion book *Joint Commission International Survey Process Guide for Hospitals Including Academic Medical Centers*, 8th Edition, along with information on the organization's *JCI Direct Connect* extranet site, together contain all the information a hospital needs to achieve and maintain continuous compliance with JCI hospital accreditation standards.

Communicating critical information to staff and maintaining continuous compliance with JCI standards are keys to ensuring that safe, high-quality care is provided to patients—yet these goals present a real challenge for many organizations. Following are some helpful suggestions for successfully achieving continuous compliance with accreditation standards outlined in this accreditation manual:

- *Become familiar with the standards.* Review the important functions of a health care organization identified in the titles of the standards chapters. Become aware of those standards that all organizations must meet to be accredited by JCI and review the compliance expectations of the standards as well as those of the additional requirements found in the associated intents and MEs. Become familiar with the terminology used in the manual. Identify those standards that require documentation (also outlined in the *Joint Commission International Survey Process Guide for Hospitals Including Academic Medical Centers*, 8th Edition) and make sure you have the needed documentation to maintain compliance.
- *Visit your organization's extranet site.* Become aware of the accreditation policies and procedures and the accreditation process. Discover how to find the information you need about an upcoming survey or a revised requirement.
- *Use the standards to improve care, treatment, and services.* Hospitals should not view accreditation standards as rules that must be followed just for the JCI survey. Instead, incorporate tasks and processes that help integrate these concepts into your daily operations because they directly affect the safety of patients and the quality of care, treatment, and services you provide. As you self-assess your compliance with JCI surveys, identify follow-up actions needed to bring your organization into compliance and meet the needs of your patients for safe, high-quality care.

JCI's accreditation policies and procedures, as well as information about JCI's hospital accreditation process—including the presurvey, on-site survey, and postsurvey activities—can be found in their entirety on an accredited organization's secure *JCI Direct Connect* extranet site. They are also summarized in this manual.

General Eligibility Requirements

Any hospital may apply for JCI accreditation if it meets all the following criteria:

- The hospital is located outside of the United States and its territories.
- If required by law, the organization has a facility license or registration to conduct its scope of services.
- The hospital is currently operating as a health care provider in the country, is licensed to provide care and treatment as a hospital (if required), and, at minimum, does the following:
  - Provides a complete range of acute care clinical services—diagnostic, curative, and rehabilitative.
  - Provides services that are available 365 days per year; ensures that all direct patient care services are operational 24 hours per day, 7 days per week; and provides ancillary and support services as needed for emergent, urgent, and/or emergency needs of patients 24 hours per day, 7 days per week (such as diagnostic testing, laboratory, and operating theatre, as appropriate to the type of acute care hospital).
  - In the case of a specialty hospital, provides a defined set of services, such as pediatric, eye, dental, and psychiatry, among others.
- The hospital meets parameters for the minimum number of inpatients/volume of services required for organizations seeking initial or continued Joint Commission accreditation; that is, 10 inpatients served, with 1 active at the time of survey.
- The hospital provides services that can be evaluated by JCI accreditation standards for hospitals.
- The hospital assumes, or is willing to assume, responsibility for improving the quality of its care and services.
- The hospital is open and in *full operation*, admitting and discharging a volume of patients that will permit the complete evaluation of the implementation and sustained compliance with all current JCI accreditation standards for hospitals.
- The hospital meets the conditions described in the "Accreditation Participation Requirements" (APR) chapter.

In addition, academic medical center applicants must meet the additional following criteria:

- The applicant hospital is integrated (by organization or administration) with a medical school.
- The applicant hospital is the *principal site* for the education of both (1) *medical students* (undergraduates) and (2) postgraduate medical specialty *trainees* (for example, residents or interns) from such medical school.
- At the time of application, the applicant hospital is conducting *medical research* with approval and oversight by an Institutional Review Board (IRB) or research ethics committee.

Contact JCI at JCIAccrediation@jcrinc.com prior to submitting an electronic application (that is, E-App) to discuss the criteria and validate whether the hospital meets the above criteria as well as the definition for "in full operation" (in the sidebar "Understanding Terms" on page 8) at least six months or more prior to submitting its E-App and at its initial survey. JCI may request documentation of the hospital's utilization statistics prior to accepting the E-App or conducting the on-site survey. In addition, JCI will not begin a survey, may discontinue a survey, or may cancel a scheduled survey when it determines the hospital is not "in full operation."

Note: If in its reasonable discretion JCI determines that the applicant does not meet the eligibility criteria for the hospital/academic medical center accreditation program JCI will not accept or process the E-App and will notify the hospital of its decision.

Understanding Terms

Full Operation

Criteria indicating the organization's readiness for comprehensive evaluation against all relevant JCI standards, based on identification of the following in the organization's electronic application for survey (E-App):

1. A list of all clinical services currently provided for inpatients and outpatients. (Those clinical services that are planned, and thus not identified in the E-App, and begin operations at a later time will require a separate extension survey to evaluate those services.)
2. Utilization statistics for clinical services showing consistent inpatient and outpatient activity levels and types of services provided for at least four months or more prior to submission of the organization's electronic application.
3. All inpatient and outpatient clinical services, units, and departments. These locations must be available for a comprehensive evaluation against all relevant JCI standards for hospitals currently in effect, consistent with JCI's normal survey process for the size and type of organization, such as the following:
   - Patient tracer activities, including individual patient and system tracers
   - Open and closed medical record review
   - Direct observation of patient care processes
   - Interviews with patients
   - Interviews with medical students/trainees

Principal site

The location at which the hospital provides the majority of medical specialty programs for postgraduate medical trainees (for example, residents or interns) and not just one specialty, as in a single-specialty organization (for example, an ophthalmologic hospital, a dental hospital, or an orthopedic hospital).

Medical research

Basic, clinical, and health services research that includes many types of research studies, such as clinical trials, therapeutic interventions, development of new medical technologies, and outcomes research, among others. (Hospitals that primarily conduct non–human subjects research and/or research exempt from review by an Institutional Review Board or research ethics committee, such as medical record review studies, case studies, and research involving data/specimens without individually identifiable information, do not meet criterion 3 of the academic medical center eligibility criteria.)

Section I: Accreditation Participation Requirements

Accreditation Participation Requirements (APR)

Overview

This section consists of specific requirements for participation in the Joint Commission International (JCI) accreditation process and for maintaining an accreditation award.

For a hospital seeking accreditation for the first time, compliance with many of the APRs is assessed during the initial survey. For the already-accredited hospital, compliance with the APRs is assessed throughout the accreditation cycle, through surveys, the Strategic Improvement Plan (SIP), and periodic updates of hospital-specific data and information.

When a hospital does not comply with certain APRs, the hospital may be asked to submit an SIP, go through a for-cause survey, or be placed in Preliminary Denial of Accreditation. Refusal to permit performance of survey activities, such as limiting or denying access to authorized JCI staff (APR.04.00) will lead to immediate Denial of Accreditation. Consequences of noncompliance with the requirement are noted with each APR.

Requirements

The following is a list of all accreditation participation requirements. They are presented here for your convenience without their rationales, consequences of noncompliance, and measurable elements. For more information about these standards, please see the next section in this chapter, Requirements, Rationales, and Measurable Elements. JCI reserves the right to update its Accreditation Participation Requirements (APRs) and recognizes the *JCI Direct Connect* website as the official location for the posting of all current APRs.

APR.01.00 The hospital submits information to Joint Commission International (JCI) as required.

APR.02.00 The hospital provides accurate information throughout the accreditation process.

APR.03.00 The hospital reports any changes in the information provided in the application for accreditation and any changes made between surveys.

APR.04.00 The hospital permits the performance of a survey at JCI's discretion.

APR.05.00 The hospital allows JCI to request (from the hospital or outside agency) and review an original or authenticated copy of the results and reports of external evaluations from publicly recognized bodies.

APR.06.00 The hospital selects and uses measures as part of its quality improvement measurement system.

APR.07.00 The hospital accurately represents its accreditation status and the programs and services to which JCI accreditation applies. Only hospitals with current JCI accreditation may display the Gold Seal.

APR.08.00 Any individual hospital staff member (clinical or administrative) can report concerns about patient safety and quality of care to JCI without retaliatory action from the hospital.

APR.09.00 The hospital notifies the public it serves about how to contact its hospital management and JCI to report concerns about patient safety and quality of care.

APR.10.00 Translation and interpretation services arranged by the hospital for an accreditation survey and any related activities are provided by qualified translation and interpretation professionals who have no relationship to the hospital.

APR.11.00 The hospital provides patient care, treatment, services, and an environment that pose no risk of an "Immediate Threat to Health or Safety."

Requirements, Rationales, and Measurable Elements

JCI reserves the right to update its Accreditation Participation Requirements (APRs) and recognizes the *JCI Direct Connect* website as the official location for the posting of all current APRs.

Requirement APR.01.00

The hospital submits information to Joint Commission International (JCI) as required.

Rationale for APR.01.00

There are many points in the accreditation process at which data and information are required. Some examples include the completion of the electronic application (E-App); annual updates to the E-App; submission of a Strategic Improvement Plan (SIP); any changes in hospital executive leadership, such as a change in ownership; Office of Quality and Patient Safety (OQPS) requests for information; JCI Accreditation requests for verification of information received from a regulatory or other authority; or timely notification of intent to appeal an accreditation decision. Relevant accreditation policies and procedures inform the hospital of what data and/or information are required and the time frame for submission.

Consequences of Noncompliance with APR.01.00

If the hospital consistently fails to meet the requirements for the timely submission of data and information to Joint Commission International, the hospital will be required to undergo a follow-up survey. Failure to resolve this issue at the time of the follow-up survey may result in an accreditation decision change.

These consequences address only compliance with the requirement itself and not the content of the hospital's submissions to JCI. For example, if information in a hospital's E-App leads to inaccuracies in the appropriate length of the survey and a longer survey is required, the hospital will incur the additional costs of the longer survey. In addition, if there is evidence that the hospital has falsified or withheld the information or intentionally deleted information submitted to JCI, the requirement at APR.02.00 and its consequences will apply.

Measurable Elements of APR.01.00

1. The hospital meets all requirements for timely submissions of data and information to Joint Commission International. (*See also* APR.02.00, ME 1)

Requirement APR.02.00

The hospital provides accurate information throughout the accreditation process.

Rationale for APR.02.00

JCI requires each hospital seeking accreditation or already accredited to engage in the accreditation process with honesty, integrity, and transparency. This type of engagement in the accreditation process is evident by providing complete and accurate information during all phases of the three-year cycle of the accreditation process.

Hospitals provide information to JCI in any of the following ways:

- Verbally
- Direct observation by, or in an interview or any other type of communication with, a JCI employee
- Electronic or hard-copy documents submitted to JCI or through a third party, such as the media, or a government report

For the purpose of this requirement, *falsification of information* is defined as the fabrication, in whole or in part, of any information provided by an applicant or accredited organization to JCI. Falsification may include redrafting, reformatting, or deleting document content or submitting false information, reports, data, or other materials.

Consequences of Noncompliance with APR.02.00

If JCI is reasonably convinced that the hospital has submitted inaccurate or falsified information to JCI or has presented inaccurate or falsified information to surveyors, the hospital may be required to undergo a for-cause survey. Failure to resolve this issue in a timely manner or at the time of the for-cause survey may result in Denial of Accreditation.

Measurable Elements of APR.02.00

1. The hospital provides accurate and complete information throughout the accreditation process. (*See also* APR.01.00, ME 1)

Requirement APR.03.00

The hospital reports any changes in the information provided in the application for accreditation and any changes made between surveys.

Rationale for APR.03.00

JCI collects core information regarding each hospital's profile in its E-App to understand ownership, licensure, scope and volume of patient services, and types of patient care facilities, among other factors. When any of these factors change, JCI must evaluate the change to determine if the change is within or outside of the scope of a planned initial survey or the scope of a current accreditation award.

Thus, the hospital notifies JCI within 30 days of the effective date of the change for the following:

- A change in the organization's ownership
- Requesting to change hospital accreditation to academic medical center accreditation
- A merger or acquisition; the organization has merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable JCI standards.
- The revocation or restriction of operational licenses or permits, any limitations or closure of patient care services, any sanctions of professional or other staff, or other actions under laws and regulations brought by relevant health authorities
- New biomedical equipment for patient care that are used to expand the types and volume of patient care services 25% or more than was stated in the most recent E-App
- Changes in use of patient care buildings, construction of new or expansion of patient care buildings, or the occupation of buildings that are used to expand the types and volume of patient care services 25% or more than was stated in the most recent E-App, or was not reported as a patient care location, or was not included in the scope of the previous accreditation survey

- Temporary cessation of services and/or significant reduction of patient care services/volume due to extenuating circumstances
- Intentional expansion of the organization's capacity to provide services in the absence of new, renovated, or expanded facilities by 25% or greater, as measured by patient volume, scope of services, or other relevant measures
- The addition of one or more types of health care services (for example, addition of a dialysis unit)
- Implementation of a higher level of service (for example, adding inpatient invasive diagnostic cardiology when originally providing only outpatient cardiac rehabilitation)

JCI does not automatically extend accreditation to new services and facilities. Based on the change, JCI may request additional information or documents; for example, policies, floor plans, fire safety plan, credentials of new staff for a new service. When JCI is unable to fully evaluate the changes with the additional information or documents provided, an extension survey may be necessary for all or a portion of the hospital again or for the first time in the case of new facilities or services.

Consequences of Noncompliance with APR.03.00

If the hospital does not provide notification to JCI within 30 days of the effective date of any change(s), the hospital may be denied accreditation.

Measurable Elements of APR.03.00

1. Ⓓ The hospital reports within 30 days of the effective date of any change(s) in the hospital's profile (electronic database) or information provided to JCI via the E-App before and between surveys.

Requirement APR.04.00

The hospital permits the performance of a survey at JCI's discretion.

Rationale for APR.04.00

Achieving JCI accreditation implies to the public, governmental agencies, and payment sources, among others, that the hospital is in compliance with JCI standards and accreditation policies at all times. Thus, it is important that JCI has the right to enter all or any portion of the hospital on an announced or unannounced basis to confirm standards and accreditation policy compliance and/or evaluate patient safety and quality concerns at any time during all phases of accreditation. Surveyors will always present an official letter of introduction and at least one other form of identification as a JCI representative when the visit is unannounced.

Consequences of Noncompliance with APR.04.00

JCI will deny or withdraw the accreditation of a hospital that refuses or limits access to authorized JCI staff to perform an evaluation.

Measurable Elements of APR.04.00

1. The hospital permits evaluations of standards and policy compliance or verification of quality and safety concerns, reports, or regulatory authority sanctions at the discretion of JCI.

Requirement APR.05.00

The hospital allows JCI to request (from the hospital or outside agency) and review an original or authenticated copy of the results and reports of external evaluations from publicly recognized bodies.

Rationale for APR.05.00

In order to conduct a thorough accreditation survey, JCI collects information on many aspects of hospital operations. External bodies other than JCI evaluate areas related to safety and quality—for example, fire safety inspections, staff working conditions inspections, and evaluation of safety incidents or quality complaints by local authorities. These evaluations complement accreditation reviews but may have a different focus or emphasis. These evaluations may produce information JCI needs to make accreditation decisions.

When requested, the hospital provides JCI with all official records, reports, and recommendations of outside agencies, such as licensing, examining, reviewing, government, or planning bodies. JCI may also request such reports directly from the outside agency. The reports can be requested during any phase of accreditation, including during an accreditation survey or as part of the evaluation of a quality concern or incident.

Consequences of Noncompliance with APR.05.00

When the hospital fails to provide an official report when requested during an on-site survey, relevant standards will be scored out of compliance and the hospital may be required to undergo a for-cause survey to review the report and the relevant standards. When the hospital fails to provide a requested report during other phases of accreditation, a for-cause survey may be required.

Measurable Elements of APR.05.00

1. Ⓓ When requested, the hospital provides JCI with all official records and reports of licensing, examining, reviewing, or planning bodies.

Requirement APR.06.00

The hospital selects and uses measures as part of its quality improvement measurement system.

Rationale for APR.06.00

Collection, analysis, and use of data are important for any quality improvement system and are at the core of the JCI accreditation process. Many JCI standards specify that organizations must collect data as part of their quality improvement system. To comply with these standards, the organization's leaders select well-defined, evidence-based measures that are applicable to the organization's patient populations and services. The organization analyzes measurement data, and the data are used to inform and propel quality improvement activities in the organization.

Organizations may choose any well-defined, evidence-based measures and measurement approaches that address process and outcomes for which the data will guide improvement in the delivery of patient care. Acceptable measures are those developed by any one or combination of the following:

- The organization's quality leaders and team
- A municipal, regional, or national health authority
- Internationally recognized health care quality authorities, such as Joint Commission International, the Institute for Healthcare Improvement, or the US-based Agency for Healthcare Research and Quality

Consequences of Noncompliance with APR.06.00

A Strategic Improvement Plan (SIP) will be required when a hospital is found to be not compliant with this requirement.

Measurable Elements of APR.06.00

1. Ⓓ The hospital selects and uses performance measures from among those available that are relevant to the service(s) it provides to the population(s) it serves.

Requirement APR.07.00

The hospital accurately represents its accreditation status and the programs and services to which JCI accreditation applies. Only hospitals with current JCI accreditation may display the Gold Seal.

Rationale for APR.07.00

The hospital's website, advertising and promotion, and other information made available to the public accurately reflect the scope of programs and services that are accredited by JCI.

The hospital does not engage in any false or misleading advertising about its accreditation award. For example, the organization's website displaying the JCI Gold Seal of Approval® may not include the contracted clinics and/or services that were not included in the accreditation survey or services that will be offered in the future but that the organization is not currently providing or acquisition of an unaccredited site, service, or program for which there are applicable JCI standards.

Consequences of Noncompliance with APR.07.00

When the hospital fails to correct inaccurate information, a for-cause survey may be required.

Measurable Elements of APR.07.00

1. The hospital's advertising accurately reflects the scope of programs and services that are accredited by JCI.
2. The hospital does not engage in any false or misleading advertising about its accreditation award.

Requirement APR.08.00

Any individual hospital staff member (clinical or administrative) can report concerns about patient safety and quality of care to JCI without retaliatory action from the hospital.

Rationale for APR.08.00

To create a "safe" reporting environment, the hospital educates all staff that concerns about the safety or quality of patient care provided in the hospital may be reported to JCI. The hospital also informs its staff that it will take no disciplinary (for example, demotions, reassignments, or change in working conditions or hours) or punitive (for example, harassment, isolation, or abuse) actions because a staff member reports safety or quality-of-care concerns to JCI. (*See also* GLD.07.01)

Methods of notice may include distribution of information about JCI, including contact information in published materials such as brochures and/or posting this information on the hospital's website.

Consequences of Noncompliance with APR.08.00

Confirmed reports of retaliatory actions to staff who reported a quality and patient safety issue to JCI may cause a Denial of Accreditation and a for-cause survey may be conducted.

Measurable Elements of APR.08.00

1. The hospital educates its staff, medical staff, and other individuals who provide care, treatment, and services that concerns about the safety or quality of care provided in the organization may be reported to JCI.
2. The hospital informs its staff and medical staff that it will take no disciplinary or punitive action because an employee, physician, or other individual who provides care, treatment, and services reports safety or quality-of-care concerns to JCI.
3. The hospital takes no disciplinary or punitive action against employees, physicians, or other individuals who provide care, treatment, and services when they report safety or quality-of-care concerns to JCI.

Requirement APR.09.00

The hospital notifies the public it serves about how to contact its hospital management and JCI to report concerns about patient safety and quality of care.

Rationale for APR.09.00

Methods of notice may include but are not limited to distribution of information about JCI, including contact information in published materials such as brochures and/or posting this information on the hospital's website.

The following link is provided to report a patient safety or quality-of-care concern to JCI: https://www.jointcommissioninternational.org/contact-us/report-a-quality-and-safety-issue/.

Hospitals seeking initial accreditation should be prepared to discuss their plan on how compliance with this APR will be achieved when accredited. JCI standards require hospitals to have a mechanism to receive and respond to complaints, conflicts, and other patient care quality and safety concerns in a timely manner. The hospital needs to inform the public it serves about how to access this process. (*See also* PCC.02.03)

The hospital also needs to inform the public about how to report concerns about patient safety and quality of care to JCI, in particular when the hospital process has not been effective in resolving the concern.

Consequences of Noncompliance with APR.09.00

A Strategic Improvement Plan (SIP) will be required when a hospital is found to not meet this requirement.

Measurable Elements of APR.09.00

1. Ⓓ The hospital informs the public it serves about how to contact its management to report concerns about patient safety and quality of care. (*See also* GLD.07.01, ME 1)
2. Ⓓ The hospital informs the public it serves about how to contact JCI to report concerns about patient safety and quality of care.

Requirement APR.10.00

Translation and interpretation services arranged by the hospital for an accreditation survey and any related activities are provided by qualified translation and interpretation professionals who have no relationship to the hospital.

Rationale for APR.10.00

The integrity of the on-site evaluation process, as well as the integrity of the outcome, depend on the surveyor(s) obtaining an unbiased, accurate understanding of their conversations with staff; and the hospital's staff communicating effectively in their language with the surveyor(s). To ensure this accurate, unbiased exchange, translation and interpretation is provided by individuals qualified to provide translation and interpretation services, with evidence of experience in health care translation and/or interpretation services. Individuals providing translation and interpretation services are not current or former staff of the hospital and do not have any conflicts of interest, such as immediate family members or staff of an affiliated hospital. Individuals providing translation and interpretation services have not served in any consultation capacity to the hospital in relation to accreditation or accreditation preparation, with the possible exception of assistance in translating the documents required by JCI to be in English or providing translation and interpretation services at a previous survey.

Qualified translators and interpreters provide to the hospital and JCI documentation of their experience in translation and interpretation. The documentation may include but is not limited to the following:

- Evidence of advanced education in English and in the language of the host hospital
- Evidence of translation and interpretation experience, preferably in the medical field

- Evidence of employment as a professional translator or interpreter, preferably full-time
- Evidence of continuing education in translation and interpretation, preferably in the medical field
- Translation and interpretation certifications, when applicable
- Other relevant translation and interpretation credentials

In some cases, JCI can provide organizations with a list of translators and interpreters who meet the requirements listed above.

JCI Accreditation staff will obtain a signed conflict of interest statement from each translator. For unannounced surveys, the surveyor and/or JCI Accreditation staff will evaluate the credentials of the translators.

Consequences of Noncompliance with APR.10.00

When translators are found to be unqualified due to lack of professional experience and/or other qualifications, or no signed conflict of interest statement is provided, the survey will be stopped until a suitable replacement can be found. The hospital is responsible for any additional costs related to the delay, including rescheduling of survey team members when necessary.

Measurable Elements of APR.10.00

1. Ⓓ When applicable, the hospital submits the résumés of the selected translators no later than eight (8) weeks prior to the start of any JCI survey.

Requirement APR.11.00

The hospital provides patient care, treatment, services, and an environment that pose no risk of an "Immediate Threat to Health or Safety."

Rationale for APR.11.00

Patients, staff, and the public trust hospitals to be low-risk, safe places. Thus, hospitals maintain that trust with ongoing vigilant review and supervision of safety practices.

Consequences of Noncompliance with APR.11.00

Immediate threats discovered during a survey interrupt the survey until the threat can be resolved or until the hospital, survey team, and JCI Accreditation staff can mediate the issue. Until the issue is resolved, the hospital is placed in Preliminary Denial of Accreditation and a follow-up survey is conducted.

Measurable Elements of APR.11.00

1. The hospital provides care, treatment, services, and an environment that pose no risk of an "Immediate Threat to Health or Safety."

Section II: Patient-Centered Standards

Access to Care and Continuity of Care (ACC)

Overview

Health care organizations are pursuing a more comprehensive and integrated approach toward delivering health care. This approach is characterized by a high degree of collaboration and communication among health care practitioners. Hospitals need to consider the care provided as part of an integrated provider system of services, health care practitioners, and levels of care, which make up a continuum of care. The goal is to correctly match the patient's health care needs with the services available, to coordinate timely and high-quality services provided to the patient in the organization, and then to plan for referral, transfer, or discharge and follow-up. The result is improved patient care outcomes and more efficient use of available resources.

Information is essential for making correct decisions about the following:

- Which patient needs can be met by the health care organization
- Prioritization for patients presenting with urgent or immediate needs
- Efficient flow of services to the patient
- Access to intensive care or specialized services
- Coordination and continuity of care
- Referral, transfer, or discharge of the patient to their home or to another care setting
- Safe patient transportation

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Admission to the Hospital

ACC.01.00 Patients admitted to the hospital or who seek outpatient services are screened to identify if their health care needs match the hospital's mission, scope of care, and resources.

ACC.01.01 Patients with emergent, urgent, or immediate needs are given priority for assessment and treatment.

ACC.01.02 The hospital considers the clinical needs of patients and informs patients when there are unusual delays for diagnostic and/or treatment services.

Patient Flow

ACC.02.00 The hospital has a process for managing the flow of patients throughout the hospital that includes the admission and registration of patients, as applicable to the patient care setting.

ACC.02.01 At the time of admission, the patient and family receive education and orientation to the patient care area, information on the proposed care and any expected costs for care, and the expected outcomes of care.

ACC.02.02 The hospital establishes criteria for admission to and discharge from units or departments providing specialized services.

Continuity of Care

ACC.03.00 The hospital provides continuous patient care services and coordination among health care providers.

ACC.03.01 There is a qualified individual responsible for the patient's care.

Discharge, Referral, and Follow-Up

ACC.04.00 The hospital develops and implements a discharge planning and referral process based on the patient's readiness for discharge.

ACC.04.01 The hospital's discharge process includes patient and family education related to the patient's ongoing need for continuing care, treatment, and services.

ACC.04.02 The complete discharge summary is prepared for all patients and is included in the patient's medical record.

ACC.04.03 Emergency care is documented.

ACC.04.04 Medical records contain patient profiles.

ACC.04.05 The hospital has a process for the management of patients who leave against medical advice.

Transfer of Patients

ACC.05.00 The hospital has a process to transfer patients to other health care organizations based on the patient's status and the hospital's ability to meet those needs.

ACC.05.01 The receiving organization is given a written summary of the patient's clinical condition and the interventions provided by the hospital, and the process is documented in the patient's medical record.

Transportation

ACC.06.00 The hospital's transportation services comply with relevant laws and regulations and meet requirements for high-quality, safe transport.

Standards, Intents, and Measurable Elements

Admission to the Hospital

Standard ACC.01.00

Patients admitted to the hospital or who seek outpatient services are screened to identify if their health care needs match the hospital's mission, scope of care, and resources.

Intent of ACC.01.00

Matching patient needs with the hospital's mission, scope of care, and available resources depends on obtaining information on the patient's needs and condition through screening. Decisions to treat, to transfer, or to refer are made only after the results of screening evaluations are available.

Screening for patient needs and condition may be conducted through various means, including the following:

- Triage criteria in the emergency department or outpatient urgent/immediate care clinic
- Visual evaluation

- Physical examination
- Previous physical, psychological, clinical laboratory, or diagnostic imaging evaluations

The screening may occur at various points of contact, including the following:

- At a referring source (for example, primary care visit)
- During emergency transport
- Upon arrival at the hospital

If patients qualify for admission, their care needs are identified and prioritized. These needs may include the following:

- Preventive services
- Diagnostics services
- Curative or treatment services
- Rehabilitative services
- Palliative services

The patient is admitted to the service or unit that meets the patient's most urgent needs.

When the hospital does not have the clinical capability to provide the needed services, the patient is transferred, referred to, or assisted in identifying sources of services to meet their needs. The transferring hospital must provide and document stabilizing treatment within its capacity prior to transfer.

Measurable Elements of ACC.01.00

1. Screening results determine if patients are accepted or admitted to the hospital, dependent on patient needs matching the hospital's mission, scope of care, and available resources.
2. Patients outside of the hospital's mission, scope of care, or available resources are assessed and stabilized within the capacity of the hospital prior to transfer.
3. The hospital transfers, refers, or assists the patient or family in identifying and/or obtaining appropriate sources of care if their needs do not match the hospital's mission, scope of care, or available resources.
4. Patients are admitted to the service or unit that meets their most urgent needs.
5. Ⓓ Assessments and treatments completed prior to transfer are documented in a record maintained by the transferring hospital. (*See also* ACC.03.00, ME 4)
6. There is a process to provide the results of diagnostic tests to those responsible for determining if the patient is to be admitted, transferred, or referred.

Standard ACC.01.01

Patients with emergent, urgent, or immediate needs are given priority for assessment and treatment.

Intent of ACC.01.01

The hospital identifies which patients need emergent, urgent, or immediate care and prioritizes care.

Patients with emergent, urgent, and immediate care needs are identified and prioritized through the use of a recognized triage process, such as Emergency Severity Index or Canadian Triage and Acuity Scale. Staff responsible for identifying and prioritizing patient needs are trained in the selected triage process.

The triage process includes early recognition of the signs and symptoms of communicable diseases. Patients identified as having, or suspected of having, potential communicable diseases are segregated and/or isolated.

The triage process includes identifying patients who require clinical observation. The clinical observation period allows appropriate clinicians to determine whether a patient requires admission or is safe to discharge from the hospital. There is a defined process for clinical observation prior to admission to or discharge from the hospital.

Certain screenings or diagnostic tests may be required for every patient being admitted, or the hospital may identify specific screenings and tests for particular patient populations based on risk. Examples include the following:

- Screening patients with active diarrhea for *Clostridioides difficile* (*C. diff*)
- Screening patients from other health care organizations for methicillin-resistant *Staphylococcus aureus* (MRSA)

The triage process used by the hospital organization meets the following criteria:

- Is based on evidence or established by a professional organization.
- Is appropriate for the patient population (for example, pediatric vs. adult triage tools, obstetric tools).

The clinical observation process includes the following:

- Criteria for admission to or discharge from the hospital
- A time limit on the observation period
- Identification of who determines whether the patient is admitted or discharged from the hospital

Screenings and diagnostic tests required for admission are based on the following:

- Current trends in health care and current scientific evidence
- Risks specific to patient population cared for by the organization
- Risks specific to the environment and geographic region

Measurable Elements of ACC.01.01

1. Ⓓ The hospital selects and uses an evidence-based triage process, appropriate to its patient population, to identify and prioritize patients with emergent, urgent, and immediate needs.
2. The hospital has identified which specific screenings or diagnostic tests must be completed prior to admitting or registering patients.
3. The triage process includes early recognition of communicable diseases.
4. Staff are trained to use the triage process, including the early recognition of communicable diseases.
5. There is a process for holding patients for observation when clinically indicated.

Standard ACC.01.02

The hospital considers the clinical needs of patients and informs patients when there are unusual delays for diagnostic and/or treatment services.

Intent of ACC.01.02

Delays for diagnostic services and treatment may negatively impact patient condition, particularly when a patient's condition or treatment is time sensitive. Patients have a right to know and understand the potential impact of these delays on their health.

Patients are informed when there are known long delays for diagnostic and/or treatment services or when obtaining planned care may require placement on a waiting list. Examples of such delays include the following:

- Waiting for an organ transplant
- A delay in obtaining a diagnostic test due to limited appointments
- Waiting for an elective surgical procedure due to limited availability of operating theatres

Patients are informed of the associated reasons for the delay and are informed of alternatives, if available.

This requirement applies to inpatient and outpatient care and/or diagnostic services. This requirement does not apply to minor, usual, or expected waiting periods for outpatient care or inpatient care. Examples of such delays include the following:

- When a provider is behind schedule in a clinic
- When the emergency department and its waiting room are full

- When a delay is consistent with regional norms for specialized services, such as oncology treatment or organ transplant

These are reasonable examples for delays, but patients and/or their families should still be informed of delays and the reason for them. Appropriate and timely communication is essential to address anxiety and demonstrate genuine empathy for patients and/or their families.

Unusual delays require documentation in the patient's medical record. Documentation of unusual delays includes the reason for the delay, so the hospital and health care provider understand how it impacted patient care. Examples of unusual delays include the following:

- Insufficient staffing
- Miscommunication
- Rejected laboratory specimen

Measurable Elements of ACC.01.02

1. Patients are informed when there will be a delay in care and/or treatment.
2. Patients are informed of the reasons for the delay and provided with information on available alternatives consistent with their clinical needs.
3. The information on unusual delays and reasons for the delay are documented in the patient's medical record.

Patient Flow

Standard ACC.02.00

The hospital has a process for managing the flow of patients throughout the hospital that includes the admission and registration of patients, as applicable to the patient care setting.

Intent of ACC.02.00

Managing the flow of patients throughout the hospital improves the coordination of care, patient safety, and health outcomes. It is essential to minimize boarding of patients in the emergency department or other temporary areas in the hospital.

Patient flow is the movement of patients throughout the hospital from the point of admission to the point of discharge or from the point of registration to the point of disposition. Effective management of processes that support patient flow can minimize delays in the delivery of care. Patient flow includes the following:

- Admission and discharge of patients
- Scheduled, elective, and emergent admissions
- Assessment and treatment of patients
- Patient transfers between units or other levels of care
- Availability of staff and resources

The hospital has a process to manage patient flow. Components of the process include the following:

- Available inpatient beds in appropriate care areas
- Availability of appropriately trained and credentialed staff
- Expected patient progression and movement through all care areas, including the following:
  - Emergency department
  - Inpatient units
  - Operating theatres and procedure areas
  - Diagnostic testing areas
- Availability and efficiency of nonclinical services that support patient care, including housekeeping and transportation

Hospitals must prepare for patient overflow when patient flow does not progress as expected, and when there is an influx of patients. Preparation plans address patient and staff requirements to provide safe care to patients boarding in the emergency department or held in other temporary locations.

The hospital has a process to manage overflow patients boarding in the emergency department and other temporary areas. This process includes the following:

- Facility plans for allocation of space, utilities, equipment, medical equipment, and supplies
- Staffing plans
- Clinical resource availability and access, including the following:
  - Overflow or boarded patients receive the same level of care as admitted patients.
  - Overflow or boarded patients have the same access to clinical services as admitted patients.
  - Overflow or boarded patients have the same access to nonclinical services as admitted patients.
- An established timeline for transferring patients from temporary holding areas or the emergency department to appropriate inpatient beds

Staff from throughout the hospital can contribute to understanding and resolving problems in patient flow. The hospital establishes measures and goals to review the effectiveness of the patient flow process. These measures and goals are monitored and inform strategies to improve patient flow. The effectiveness of process improvements to patient flow is evaluated.

Measurable Elements of ACC.02.00

1. The hospital implements a patient flow process, including the following:
   - Availability of appropriate beds
   - Properly trained staff
   - Expected movement and progression throughout care areas
   - Availability of nonclinical services
2. The hospital has an admission process for patients, regardless of their origin of arrival, including a registration process for patients who do not require admission.
3. The hospital plans and provides for the care of patients who are boarded in the emergency department and other temporary holding areas, including the following:
   - Allocation of space, utilities, equipment, medical equipment, and supplies
   - Staffing plans
   - Availability of clinical resources
   - Availability of nonclinical resources
   - Provision of timely and equivalent care to meet patient needs
   - A time limit on boarding patients in the emergency department and other temporary holding areas and a process for managing patients when temporary boarding periods exceed this time limit
4. Ⓓ The patient flow processes are reviewed for effectiveness, and process improvements are identified and implemented.

Standard ACC.02.01

At the time of admission, the patient and family receive education and orientation to the patient care area, information on the proposed care and any expected costs for care, and the expected outcomes of care.

Intent of ACC.02.01

Orientation to the care environment, including equipment related to the care and services provided, is an essential component of patient safety. Patients and their families receive sufficient information to make knowledgeable decisions. Patients and clinical staff understand the scope and limits of the general consent (if used by the hospital) to protect patient autonomy and rights.

The patient and their family receive information about the proposed care, the expected outcomes of care, and any expected cost for the care when not paid for by a public or private source. This information can be provided as a written document or through verbal explanation. It must also be noted in the patient's medical record.

The hospital seeks ways to minimize any financial barriers for the patient. Examples include the following:

- Providing applications for financial aid
- Identifying sources of charitable funding for health care
- Providing prescriptions for generic rather than branded medications

When used, general consents include the following:

- The scope of the general consent (for example, which tests and treatments are covered by the general consent)
- What tests and treatments require additional informed consent
- How patients receive information (for example, via patient portal or text messaging)

The hospital specifies how the general consent is documented in the patient's medical record.

The hospital may rely on implied consent or obtain a general consent for treatment when the patient is admitted or registered for the first time. Hospitals are not required to use a general consent unless required by laws and regulations. Regardless of whether general consent is obtained, all patients are informed about what tests and treatments require additional informed consent.

All patients are informed about the likelihood of students participating in their care; for example, medical students, nursing students, physical therapy students, respiratory therapy students.

Measurable Elements of ACC.02.01

1. The patient and family receive education and orientation to the patient care area.
2. The patient and family receive information on the proposed care, treatment, and services, including expected outcomes.
3. The patient and family receive information on any expected costs related to the proposed care, treatment, and services.
4. Patients and families are informed as to the scope of a general consent, if used by the hospital. (*See also* PCC.03.00, ME 3)
5. Ⓓ The hospital defines, in writing, how a general consent is documented in the patient's medical record, if used by the hospital. (*See also* PCC.03.00, ME 1)
6. All patients receive information about the likelihood of students and trainees participating in care processes.

Standard ACC.02.02

The hospital establishes criteria for admission to and discharge from units or departments providing specialized services.

Intent of ACC.02.02

Specific criteria for admission to and discharge from intensive care or specialized units or departments ensures that patients are receiving an appropriate level or type of care and encourages the efficient use of these limited resources.

Units or departments that provide intensive or specialized care are costly, use many resources, and usually are limited in space and staffing. Hospitals should restrict admission to these units or departments to ensure the appropriate use of these areas and resources. The hospital must establish criteria regarding which patients require the level and type of care provided by these specialized units or departments. Criteria must be

consistently implemented throughout the hospital and among clinical staff determining patient disposition. Examples of these units or departments and their admission criteria include the following:

- Criteria for admission to a burn unit may include a specific percentage of the burned body surface and/or whether the burn is a second- or third-degree burn.
- Criteria for admission to an intensive care unit may require that patients are intubated, need close monitoring for critical changes, or require additional equipment (for example, IV lines and pumps, feeding tubes, drains and catheters).
- Admission to a postanesthesia care unit vs. surgical intensive care unit may be determined by whether the patient remains intubated, is on vasopressors, or requires complex wound care.

The criteria are used to determine direct admission to the unit or department (for example, directly from the emergency department). The criteria are also used to determine admission into the unit or department from another clinical area within the hospital or transferred from another hospital.

Patients admitted to a specialized unit or department require periodic reassessment to determine when a patient continues to meet criteria for specialized services. Examples of patients no longer meeting criteria include the following:

- A patient admitted to an intensive care unit whose physiological status has stabilized and no longer requires continuous monitoring
- A patient whose physiological status has deteriorated, and care goals are redirected to comfort or palliative care, requiring less intensive monitoring

Whenever possible, criteria for intensive or specialized units and departments meet the following requirements:

- Use prioritization or severity-of-illness criteria.
- Are based on diagnostic and/or objective parameters.
- Use physiologic-based criteria for medical and surgical services.
- Use psychological-based criteria for psychiatric services.
- Include required lifesaving or life-sustaining technology, interventions, and medications. Examples of such technology, interventions, and medications include the following:
  - Ventilators or other respiratory support
  - Vasopressors or other medications requiring frequent or continuous monitoring
  - Frequency of direct observation of the patient
  - Frequency and complexity of wound care

Intensive or specialized units or departments establish criteria for reassessment of admitted patients, which include the following:

- When and how often patients should be reassessed for continued care or transfer to a different level of care
- Diagnostic and/or objective parameters for safe transfer to a different level of care
- Physiologic-based and/or psychological-based criteria
- Frequency and type of technology, interventions, and medications for de-escalation of treatment

Measurable Elements of ACC.02.02

1. Ⓓ The hospital has established written admission criteria, based on prioritization, diagnostic, and/or objective parameters, for specialized units or departments.
2. Ⓓ The hospital has established written discharge and/or transfer criteria from specialized units or departments to a different level of care.
3. The medical records of patients who are admitted to specialized units or departments contain evidence that they meet the criteria for care, treatment, and services. (*See also* GLD.06.00, ME 3)
4. The medical records of patients who are transferred or discharged from specialized units or departments contain evidence that they meet criteria for discharge. (*See also* ACC.03.00, ME 1; ACC.05.00, ME 1; GLD.06.00, ME 4)

Continuity of Care

Standard ACC.03.00

The hospital provides continuous patient care services and coordination among health care providers.

Intent of ACC.03.00

Care coordination and continuity among health care practitioners improves patient safety and outcomes. Coordination is accomplished through access to patient information that is imperative to these processes. Therefore, health care practitioners who are part of the patient's care, treatment, and services are provided access to relevant information.

Patients are transferred within the hospital between various services and units or departments. The hospital identifies individuals for coordinating patient care and services. Many health care practitioners care for patients throughout the hospital. Throughout all phases of care, patient needs are matched with required level of care and resources for care. When necessary, patients are transferred or referred to resources or services outside the hospital. The hospital establishes criteria or policies to determine appropriateness of transfers within and from the hospital.

Continuity is enhanced when all health care practitioners have the information needed from the patient's current and past medical experiences to make decisions about the patient's care. When multiple decision-makers are providing care, these decision-makers agree on the care and services to be provided.

The hospital implements processes for continuity and coordination of care among physicians, nurses, and other health care practitioners in all settings, including the following:

- Emergency services and inpatient admission
- Diagnostic services
- Surgical and nonsurgical treatment services
- Outpatient care programs
- Other organizations and other care settings

The patient's medical record is a primary source of information for patient care and is an essential communication tool. The medical record must contain current information and be available during inpatient care and for outpatient visits. Medical, nursing, and other patient care notes are available to all the patient's health care practitioners who need them for patient care.

The patient's complete health care record is transferred with the patient when changing care teams or settings within the hospital so treatments, medications, and other interventions may continue without interruption. When a patient is transferred to an outside organization, the hospital provides the care team receiving the patient with a copy of the patient's medical record or a summary of essential information from the patient's health care record.

When transferring a patient to an outside organization, the hospital may transfer a copy of the patient's medical record or send a transfer summary with the patient. The transfer summary contains the following information from the patient's health care record:

- Chief complaint(s)
- Significant findings
- Diagnosis
- Procedures performed
- Medications
- Other treatments
- Patient condition at time of transfer

Care coordination and continuity processes are supported by the following:

- Guidelines
- Clinical pathways
- Referral forms
- Checklists

Measurable Elements of ACC.03.00

1. Ⓓ Hospital leaders implement processes that support the continuity and coordination of care across all care settings. (*See also* ACC.02.02, ME 4; ACC.05.00, ME 1; GLD.06.00, ME 4)
2. The patient's medical record is available to those practitioners who are authorized to have access and need it for the care of the patient. (*See also* MOI.01.01, ME 4)
3. The patient's medical record is up to date with the patient's latest information.
4. The patient's medical record or a summary of patient care information is transferred with the patient to another service or unit in the hospital. (*See also* ACC.01.00, ME 5)
5. Ⓓ The written transfer summary of the patient's medical record contains, at minimum, the following:
   - The reason for admission
   - Significant findings and test results
   - Diagnosis
   - Procedures performed
   - Medications administered during hospitalization, including last time of administration and current medications (*See also* MMU.04.02, ME 2)
   - Other treatments
   - Patient condition at time of transfer
6. Care coordination and continuity are supported using various tools, such as care plans, guidelines, or protocols.

Standard ACC.03.01

There is a qualified individual responsible for the patient's care.

Intent of ACC.03.01

A clearly identified individual overseeing a patient's entire hospital stay improves continuity, coordination, patient satisfaction, quality, and clinical care outcomes.

The individual with responsibility for the patient's overall care coordination is clearly identified, for all the different phases of patient care. This individual may be a physician or another qualified individual. The individual responsible is identified in the patient's medical record. This individual collaborates and communicates with the other health care practitioners. When more than one individual is responsible for coordination of care, there is a higher likelihood of uncertainty and a lack of effective coordination. Hospital policy defines the process for the transfer of responsibility to another individual during vacations, holidays, and other periods.

The hospital creates a policy that guides the process for patient oversight, including the following:

- Identifying the individual overseeing all phases of patient care; for example, a physician or other advanced provider
- Defining the process for transfer of oversight responsibility during off days; for example, vacations, sick days, holidays
- Identifying consultants, on-call physicians, locum tenentes, or others who take responsibility
- Defining how transfer of responsibility occurs and what documentation is required to ensure coordination and documentation of their participation or coverage; for example, when a patient moves from one phase of care to another

Measurable Elements of ACC.03.01

1. A qualified individual responsible for the coordination of the patient's care is available through all phases of inpatient care and is identified in the patient's medical record.
2. There is a process for transferring the responsibility for coordination of care.
3. Ⓓ The process identifies how transferred responsibility is assumed, and the participation or coverage is documented.

Discharge, Referral, and Follow-Up

Standard ACC.04.00

The hospital develops and implements a discharge planning and referral process based on the patient's readiness for discharge.

Intent of ACC.04.00

Effective and early discharge planning can decrease the risk of hospital readmission, improve recovery, ensure safe medication practices, and help prepare patients and/or families in having safe, posthospital care.

Discharge planning is a process used to help determine what types of continued care and services a patient may need after leaving the hospital. Improvements in hospital discharge planning significantly improve outcomes for patients as they move to the next level of care. Early initiation of the discharge planning process is paramount to maximizing outcomes. The discharge planning process includes assessing and identifying the patient's need for continuing care or services. The patient's principal health care provider determines readiness for referral or discharge.

Referring or discharging a patient to a health care provider outside the hospital, another care setting, home, or family is based on the patient's health status and readiness for discharge. The hospital identifies any needs the patient may have for psychosocial or physical care, treatment, and services after discharge or transfer. An organized process is required to ensure that any continuing needs are met.

Patients not directly referred or transferred to another health care practitioner receive clear instructions on where and how to receive continuing care. This is essential to ensure that all care needs are met. The instructions include the name and location of sites for continuing care, any return to the hospital for follow-up, and when urgent care should be obtained. The process includes referring patients to sources of care outside the region when required.

The hospital begins to plan for the continuing needs as early in the care process as possible. The discharge planning process begins with the initial assessment and is updated throughout the care process as the patient's discharge needs become clearer. Discharge planning includes any special education the patient may require related to continuing care outside of the hospital. The patient, the patient's family, health care practitioners, and others involved in the patient's care participate in planning the patient's discharge or transfer.

The hospital establishes a method to determine a patient's readiness for discharge. This includes the use of the following:

- Relevant criteria
- Clinical indications
- Clinical guidelines/protocols

The hospital establishes a process to ensure that patients receive any continuing care or support services they need following discharge. Continuing care needs include the following:

- Referral to a medical specialist
- Rehabilitation services

- Admission to a long-term care facility
- Home care services
- Psychological services
- Social services
- Home medical supplies or equipment
- Education related to continuing care needs

Patients discharged home are provided with at least the following information:

- Name and location of a site(s) for continuing care; for example, ambulatory care clinic, rehabilitation center, nearest emergency department
- Written instructions regarding any follow-up visits or care
- When and how to obtain urgent or emergent care

Discharge planning and instruction are documented in the patient's medical record and provided to the patient in writing.

Measurable Elements of ACC.04.00

1. The patient's discharge and/or referral is consistent with relevant criteria, indications, or guidelines.
2. The discharge planning process begins with the initial assessment and includes care, treatment, equipment, and services that meet the continuing needs of the patient.
3. Patients not directly referred or transferred are provided with the name and location of a site(s) for continuing care.
4. Patients not directly referred or transferred are provided instructions, in writing, on when to return to the hospital for continued care, treatment, and service, and when and how to obtain urgent care.
5. Patients, family as appropriate, and staff involved in the patient's care participate in the discharge planning process.
6. Discharge planning and instructions are documented in the patient's medical record and provided to the patient in writing.

Standard ACC.04.01

The hospital's discharge process includes patient and family education related to the patient's ongoing need for continuing care, treatment, and services.

Intent of ACC.04.01

Patient and family education is an important component of the discharge plan and supports the patient's return to previous functional levels and maintenance of optimal health.

The discharge process addresses the patient's and family's need for education on how to manage the patient's continuing care needs at home or for education on how to support the patient's continuing care needs in another setting. Standardized materials and processes are used to educate patients on topics related to their ongoing care and treatment after discharge. Patient education and follow-up instructions are provided to the patient in a form and language the patient understands.

Based on the patient's identified continuing care needs, discharge education and instructions may include but are not limited to the following topics:

- Review of all medications to be taken at home
- Safe and effective use of all medications, including potential medication side effects
- Potential interactions between prescribed medications and other medications (including over-the-counter preparations) and food
- Diet and nutrition
- Pain management

- Safe and effective use of medical equipment
- Rehabilitation activities and services

Patient education and follow-up instructions are provided to the patient in a form and language the patient understands. It is recommended that education and instructions are provided in writing to the patient and family, so they can refer to these materials as needed. However, not all patients and families have even basic reading skills. If education and instructions are provided in other forms, this must be documented in the patient's medical record. Education and instructions may be provided in the following forms:

- In writing (recommended method)
- Verbally
- Media (for example, videos, photographs, pictograms)

Measurable Elements of ACC.04.01

1. Ⓓ Patients and families are provided with a complete written list of medications to be taken at home and are educated on their safe use, including the following:
   - Potential side effects
   - Potential interactions between medications
   - Potential interactions between medications and foods
2. Patients and families are educated about proper diet and nutrition.
3. Patients and families are educated about pain management. (*See also* COP.07.00, ME 3)
4. Patients and families are educated about safe and effective use of medical equipment and rehabilitation activities and services.
5. Patient and family education is documented in the patient's medical record and includes the following:
   - What information and education were provided
   - How the information and education was delivered (for example, in writing, verbally, by demonstration)
   - Confirmation that the patient and/or family understood the information and education provided

   (*See also* PCC.04.01, MEs 2 and 3)

Standard ACC.04.02

The complete discharge summary is prepared for all patients and is included in the patient's medical record.

Intent of ACC.04.02

The discharge summary provides an overview of the patient's care and is intended to be used by the health care provider(s) caring for the patient following discharge.

A summary of the patient's care is prepared prior to discharge from the hospital. Any qualified individual can compile the discharge summary, such as the patient's physician or a house officer. A copy of the discharge summary is provided to the practitioner who will be responsible for the continuing or follow-up care of the patient.

A copy is to be given to the patient when indicated by hospital policy or when required by local laws or regulations. When the provider responsible for follow-up care is unknown (for example, patients who are visiting from a different region or country), a copy of the discharge summary is given to the patient or family. The expectation is that the patient provides the copy of their discharge summary to their primary care or general practitioner responsible for their care.

A copy of the discharge summary is included in the patient's medical record.

The hospital has a process to provide a copy of the discharge summary to the health care provider responsible for the patient's continuing or follow-up care.

The hospital has defined situations when a patient will be given a copy of the discharge summary. Examples include the following:

- When required by hospital policy
- When required by local laws or regulations
- When the health care provider responsible for the patient's follow-up care is unknown

The summary includes the following:

- Reason for admission, diagnoses, and comorbidities
- Significant physical and other findings
- Diagnostic and therapeutic procedures performed
- Medications at time of discharge, including last date/time administered
- All medications to be taken at home
- Therapeutic equipment at time of discharge (for example, nebulizers, glucometer, ambulation devices)
- The patient's condition at the time of discharge (examples include "condition improved," "patient at baseline condition")
- Follow-up instructions

Measurable Elements of ACC.04.02

1. A discharge summary is prepared by a qualified individual.
2. The discharge summary contains at least the following:
   - Reason for admission, diagnoses, and comorbidities
   - Significant physical and other findings
   - Diagnostic and therapeutic procedures performed
   - Medications at time of discharge, including date/time of last dose given while hospitalized
   - All medications to be taken at home
   - Therapeutic equipment at time of discharge
   - The patient's condition at the time of discharge
   - Follow-up instructions
3. A copy of the discharge summary is provided to the health care provider responsible for the patient's continuing or follow-up care.
4. The patient or caregiver is provided with a copy of the discharge summary.
5. A copy of the completed discharge summary is included in the patient's medical record at the time of discharge.

Standard ACC.04.03

Emergency care is documented.

Intent of ACC.04.03

Emergency care is documented to ensure continuity of care and to permit providers at the next level of care to understand the emergency services provided.

The record of each patient receiving emergency care includes the arrival and departure times. This information is captured for all emergency department patients, including those who are discharged from the hospital, transferred to another facility, or admitted as inpatients. Departure time may be when the patient physically leaves the emergency department to go home or to another facility, or the time at which the patient is moved to another unit as an inpatient. For patients discharged from the emergency department, the medical record includes conclusions following completion of emergency treatment, the patient's condition at discharge, and follow-up care instructions.

Measurable Elements of ACC.04.03

1. The medical records of all emergency patients include arrival and departure times.
2. The medical records of patients discharged from the emergency department include conclusions following completion of treatment.
3. The medical records of patients discharged from the emergency department include the patient's condition at discharge.
4. The medical records of patients discharged from the emergency department include any follow-up care instructions.

Standard ACC.04.04

Medical records contain patient profiles.

Intent of ACC.04.04

Patient profiles provide a summary of a patient's condition and treatments and are available to all members of the patient's health care team across the continuum of care. Patient profiles provide a "snapshot" of the patient and their care.

The hospital creates patient profiles or similar brief overviews for all patients, including inpatients and outpatients, as part of the patient medical record. A profile makes updated critical information quickly and easily available to health care providers, particularly when there are multiple providers involved in the patient's care. Patient profiles are particularly helpful when patients have complex diagnoses and care, multiple problems, or multiple care teams. Because a health care occurrence is dynamic, the patient profile must be kept up to date and current with patient information as any changes occur. The profile summary should be available within one document for efficient access by any health care provider.

A patient profile is required for both electronic and hard-copy medical records.

The process for creating patient profiles includes defining what information is part of the patient profile. Examples of such information include the following:

- Patient age, weight, height
- Active problem list
- Past medical and surgical history
- Current treatment information
- Allergies

Additional considerations include creating a format that is easy for clinicians to retrieve and review and evaluating the process to verify that the profile meets the needs of the clinicians.

The patient profile may be structured differently or contain different information between care areas to meet clinician needs; however, the profile must be consistent within care areas, as in the following examples:

- Inpatient and outpatient profiles may be structured differently, but all inpatient and outpatient profiles are consistent.
- Medical and surgical patient profiles may be structured differently but all medical and surgical patient profiles are consistent.
- Psychiatric and physical rehabilitation patient profiles may be structured differently, but all psychiatric patient physical rehabilitation profiles are consistent.

Measurable Elements of ACC.04.04

1. All patient medical records contain a patient profile or similar overview.
2. Ⓓ The hospital identifies necessary information to be included in the profiles.
3. The patient profile is easy to access and review and is consistent within care areas.
4. The process is evaluated to ensure that the implementation is consistent with the policy and provides clinicians with an accurate overview of the patient.

Standard ACC.04.05

The hospital has a process for the management of patients who leave against medical advice.

Intent of ACC.04.05

Patients leaving against medical advice are at risk of inadequate treatment, which may result in permanent harm or death. The hospital must have a process to manage patients leaving against medical advice and to inform them of the risks related to this decision.

"Leaving against medical advice" means leaving the hospital after an examination has been completed and a treatment plan has been recommended. Leaving against medical advice also includes patients who do not complete or return for complex or lifesaving treatments in the outpatient setting.

Inpatients and outpatients, including patients from the emergency department, have the right to refuse medical treatment and to leave the hospital against medical advice. However, these patients may be at risk of inadequate treatment, which may result in permanent harm or death.

When a competent patient requests to leave the hospital without medical approval, the risks must be explained by the provider recommending the treatment plan or their designee, and the conversation should be documented in the medical record. If the patient allows it, normal discharge procedures should be followed. Patients leaving against medical advice do not leave the facility without receiving information on their medical care. Health care providers attempt to identify why the patient is choosing to leave against medical advice to improve communication and identify potential process improvements. When a patient leaves the hospital against medical advice without notifying anyone or does not return for treatment, the hospital must try to contact the patient to inform them of potential risks.

If the patient has a documented primary care provider, they must be notified of the patient's decision to leave against medical advice. When applicable, the hospital reports cases of infectious disease and provides information regarding patients who may harm themselves or others to local and national health authorities as required.

If the patient is at risk of self-harm or harming others, the hospital should restrain the patient from leaving if allowed by local laws and regulations.

The hospital may develop a process to allow patients to leave the hospital for a defined period (such as on a weekend "pass") if approved by the patient's attending physicians and permitted by local laws and regulations. Such a temporary absence is not considered leaving against medical advice.

The hospital designs this process to be consistent with applicable laws and regulations. The process for managing patients who leave against medical advice includes the following:

- Inpatients who leave with or without informing hospital staff
- Patients who have absconded
- Patients receiving complex treatment who do not complete or do not return for treatment ("no shows")

The process includes contacting the following individuals:

- The patient (if possible) to inform them of the potential risks of leaving against medical advice
- The patient's family or caregivers, as applicable
- The patient's primary care provider if one is known
- Local and national health authorities, as required, if the patient has a known or suspected reportable infectious disease
- Local authorities, as required, if the patient is at risk for harming themselves or others

The process defines expectations for documenting "leaving against medical advice," patient absconded, and no shows.

The process includes the following:

- Permitting patients to leave for a defined period of time during the planned course of treatment
- Identifying clinical criteria for patients to leave. Examples of criteria include the following:
  - Physical status
  - Mental status
  - Patient's ability to care for themselves or the family's ability to care for the patient
- Including the treatment team, the patient, and the patient's family (if applicable) in the decision

Measurable Elements of ACC.04.05

1. Ⓓ There is a written process for managing patients who leave against medical advice; this process includes the following:
   - Inpatients who leave with and without informing hospital staff
   - Patients who have absconded
   - Patients receiving complex treatment who do not complete or do not return for treatment ("no shows")
   - Documentation requirements
2. There is a process to inform the patient of the medical risks of inadequate treatment.
3. The patient is discharged according to the hospital discharge process.
4. There is a process to notify the patient's primary care provider if a patient leaves against medical advice.
5. The process is consistent with applicable laws and regulations, including requirements for reporting cases of infectious disease and when patients may be a threat to themselves or others.
6. When consistent with regional laws and regulations, the hospital develops a process for allowing patients to leave the hospital during the planned course of treatment for a defined period of time.

Transfer of Patients

Standard ACC.05.00

The hospital has a process to transfer patients to other health care organizations based on the patient's status and the hospital's ability to meet those needs.

Intent of ACC.05.00

Transferring a patient to an outside organization is based on the patient's status and need for continuing health care services. Criteria help to identify when a transfer is necessary to ensure that the patient's needs are met.

Transfer may be in response to a patient's needs. Examples of needs include the following:

- Specialized consultation and treatment
- Urgent services
- Less intensive services (such as subacute care or long-term rehabilitation)
- Patient or family request

The hospital must determine if the receiving organization provides services to meet the patient's needs and has the capacity to receive the patient. This advance determination ensures continuity of care and that the patient's care needs will be met. Transfer requirements are described in formal or informal affiliations or agreements. However, transfers may occur to other specialized treatment or services without formal or informal agreements.

A consistent process for patients is required to ensure that patients are transferred between health care organizations safely.

The condition and status of the patient determine the required qualifications of the staff member monitoring the patient and the type of medical equipment needed during transfer.

The hospital evaluates the quality and safety of the transfer process to ensure that patients are transferred with qualified staff and the correct medical equipment for the patient's condition.

The patient transfer process specifies the following:

- How and when responsibility is transferred between providers and organizations
- Criteria for when transfer is necessary to meet the patient's needs
- Who is responsible for the patient during transfer
- Qualifications of the staff caring for the patient during transfer
- What medications, supplies, and medical equipment are required during transport
- Follow-up mechanism that provides information regarding the condition of the patient during transfer and upon arrival to the receiving organization
- What is done when transfer to another source of care is not possible

Measurable Elements of ACC.05.00

1. Ⓓ The hospital develops a written transfer process based on patients' needs for continuing care and ensures that the receiving organization meets the needs of the patient to be transferred. (*See also* ACC.02.02, ME 4; ACC.03.00, ME1; GLD.06.00, ME 4)
2. The transfer process addresses how and when responsibility for continuing care is moved to another provider.
3. The transfer process identifies who is responsible for monitoring the patient during transfer and the staff qualifications required for the type of patient being transferred.
4. The transfer process identifies the medications, supplies, and medical equipment required during transport.
5. The transfer process addresses a follow-up mechanism that provides information about the patient's condition upon arrival to the receiving organization.
6. The transfer process addresses the situations in which transfer is not possible.

Standard ACC.05.01

The receiving organization is given a written summary of the patient's clinical condition and the interventions provided by the hospital, and the process is documented in the patient's medical record.

Intent of ACC.05.01

To ensure continuity of care, patient information is transferred with the patient.

The receiving organization needs to understand any patient care provided before and during transfer. Without this information, there is a risk that vital patient information will not be communicated or that interventions, treatments, or medications are repeated or omitted. A copy of the written clinical or discharge summary is provided to the receiving organization with the patient. The patient's medical record contains documentation of the transfer.

The written clinical or discharge summary includes at least the following:

- Patient's clinical condition or status
- Procedures and other interventions provided
- Patient's continuing needs and reason for transfer

The transfer documentation includes the following:

- Name of the health care organization and the name of the individual agreeing to receive the patient
- Reason(s) for the transfer

- Any serious changes in the patient's condition or status during transfer
- Any other documentation required by hospital policy (for example, a signature of the receiving nurse or physician, the name of the individual who monitored the patient during transport)

Measurable Elements of ACC.05.01

1. Ⓓ A written clinical summary is transferred with the patient and includes at least the following:
   - Patient's condition or status
   - Procedures and other interventions provided
   - Patient's continuing needs and reason for transfer
2. Ⓓ The transfer documentation includes at least the following:
   - Name of the service provider and the name of the individual agreeing to receive the patient
   - Reason(s) for the transfer
   - Changes in the patient's condition or status
   - Other documentation required by hospital policy

Transportation

Standard ACC.06.00

The hospital's transportation services comply with relevant laws and regulations and meet requirements for high-quality, safe transport.

Intent of ACC.06.00

Patients may require transportation at the time of discharge or transfer; the hospital is responsible for assessing patients' transportation needs and arranging safe transportation when necessary.

Assessing patients' transportation needs and ensuring safe transportation for those patients who require assistance is the hospital's responsibility. Transportation services may be provided by the following:

- Hospital-owned service
- A contracted transportation service
- The Ministry of Health
- Other entity

The hospital has a process for assessing patients' transportation needs at the time of discharge or transfer. A patient's transportation needs may change from admission to discharge. Examples of these changes may include change in their physical or mental condition or use of sedation during a same-day procedure.

The required equipment, supplies, and medications for transport are determined by the type of patient and the patient's condition at the time of transport. The hospital determines the staff qualifications and level of monitoring required based on the type of patient and the patient's condition at the time of transport.

The hospital identifies transportation situations that have a risk of infection and implements strategies to reduce infection risk.

The hospital ensures that transportation services meet all applicable laws and regulations related to their operation, condition, and maintenance. The hospital evaluates the quality and safety of transportation, including complaints about the transportation services.

Depending on hospital policy and the laws and regulations of the region, the cost of the transportation may or may not be the responsibility of the hospital.

The hospital has a process to evaluate transportation needs of its patients. This includes the following:

- Identifying which patients require transportation

- Identifying which type of transportation is needed (for example, ambulance, air transfer, another vehicle)
- Defining staff qualifications for transportation
- Defining what equipment, supplies, and medications are needed for transportation
- Defining criteria for patient monitoring during transportation

The hospital has a process to ensure the safety and quality of transportation services. This includes the following:

- Ensuring that transportation services comply with local and regional laws and regulations
- Identifying infection risks and implementing strategies to reduce the infection risks (transportation services are part of the hospital's infection prevention and control program)
- Evaluating the quality and safety of services provided by the hospital or others, including receiving, evaluating, and responding to complaints about the transportation services provided or arranged

Note: If transportation services are not provided by the hospital, the hospital has a process to provide feedback about safety and quality to the responsible organization.

Measurable Elements of ACC.06.00

1. The process for discharging or transferring patients includes an assessment of patient transportation needs.
2. Transportation services, including contracted services, and transport vehicles owned by the hospital meet relevant laws and regulations and the hospital's requirements for high-quality and safe transport.
3. All vehicles used for transportation, contracted or hospital owned, comply with the hospital's infection prevention and control program.
4. All vehicles used for transportation, contracted or hospital owned, have appropriate medical equipment, supplies, and medications to meet the needs of the patient being transported.
5. The transportation provided or arranged is appropriate to the needs and condition of the patient.
6. There is a process in place to monitor the quality and safety of transportation provided or arranged by the hospital, including a complaint process.

Assessment of Patients (AOP)

Overview

The goal of assessment is to determine the care, treatment, and services that will meet the patient's initial and continuing needs. An effective patient-assessment process results in decisions about the patient's treatment needs for emergency, elective, or planned care, even when the patient's condition changes. Patient assessment is an ongoing, dynamic process that takes place in many inpatient and outpatient settings and departments and clinics. Patient assessment consists of three primary processes:

1. Collecting information and data on the patient's physical, psychological, and social status, and health history
2. Analyzing the data and information, including the results of laboratory testing, diagnostic imaging, and physiologic monitoring, to identify the patient's health care needs
3. Developing a plan of care to meet the patient's identified needs

Patient needs must be reassessed throughout the course of care, treatment, and services. Reassessment is key to understanding the patient's response to the care, treatment, and services provided and is essential in identifying whether care decisions are appropriate and effective.

Assessment activities may vary between settings, as defined by the hospital's leaders. Information gathered at the patient's first contact may indicate the need for more data or a more intensive assessment. At a minimum, the need for further assessment is determined by the care, treatment, and services sought and the patient's presenting condition(s).

Patient assessment is appropriate when it considers the patient's condition, age, health needs, and requests or preferences. These processes are most effectively carried out when the various health care practitioners responsible for the patient work together.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Patient Assessment

AOP.01.00 All patients have their health care needs identified through an assessment process that has been defined by the hospital.

AOP.01.01 Each patient's initial assessment includes a health history and an assessment of the patient's physical, psychological, spiritual/cultural, social, and economic needs.

AOP.01.02 The hospital has a process for accepting initial assessments from outside sources.

AOP.01.03 Patients are screened for nutritional, functional, and other special needs and are further assessed when indicated by the screening.

AOP.01.04 All patients are screened for pain and assessed when pain is present.

AOP.01.05 All patients are reassessed at intervals based on their condition and treatment.

Patient Falls

AOP.02.00 The hospital develops and implements a process to reduce the risk of falls, and patient harm resulting from falls.

Laboratory Services

AOP.03.00 Laboratory services are available to meet patient needs, and all laboratory services meet applicable local and national standards, laws, and regulations.

AOP.03.01 A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff are qualified to perform the tests and interpret the results.

AOP.03.02 The hospital has defined requirements for the oversight and supervision of the point-of-care testing program.

AOP.03.03 Laboratory results are reported within time frames defined by hospital policy.

AOP.03.04 All laboratory testing equipment is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.

AOP.03.05 Essential reagents and supplies are available, and all reagents are evaluated to ensure accuracy and precision of results.

AOP.03.06 Procedures for collecting, identifying, handling, safely transporting, and disposing of specimens are established and implemented.

AOP.03.07 Established norms and ranges are used to interpret and to report clinical laboratory results.

AOP.03.08 The hospital has implemented processes for quality control and proficiency testing of laboratory services.

AOP.03.09 The hospital ensures the quality of services provided by contracted laboratories.

Blood Bank and/or Transfusion Services

AOP.04.00 A qualified individual(s) is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice.

AOP.04.01 Clinical guidelines and procedures are implemented for the handling and administration of blood and blood products.

Radiology and Diagnostic Imaging Services

AOP.05.00 Radiology and diagnostic imaging services are available to meet patient needs, and all services meet applicable local and national standards, laws, and regulations.

AOP.05.01 A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services, and individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results.

AOP.05.02 A radiation and/or diagnostic imaging safety program for patients, staff, and visitors is implemented and is compliant with applicable professional standards, laws, and regulations.

AOP.05.03 Radiology and diagnostic imaging study results are available in a timely way as defined by hospital policy.

AOP.05.04 All equipment used to conduct radiology and diagnostic imaging studies is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.

AOP.05.05 The hospital has implemented quality control procedures for radiology and diagnostic imaging services.

AOP.05.06 The hospital ensures the quality of services provided by all outside contracted sources of radiology and diagnostic imaging services.

Nuclear Medicine Services

AOP.06.00 When applicable, the hospital establishes and implements a nuclear medicine safety program that complies with applicable professional standards, laws, and regulations.

Standards, Intents, and Measurable Elements

Patient Assessment

Standard AOP.01.00

All patients have their health care needs identified through an assessment process that has been defined by the hospital.

Intent of AOP.01.00

The effective assessment process drives decisions about the patient's needs for care, treatment, and services. Because decisions are made based on assessments, the assessment process is dynamic and ongoing throughout the patient care continuum.

Patient assessments determine care needs, even when the patient's condition changes. Patient assessment includes three primary processes:

- Collecting information and data on the patient's health history and their physical, psychological, and social needs
- Analyzing the assessment data, including any diagnostic tests, to identify the patient's health care needs
- Using the information to develop a plan of care specific to the patient's needs

When a patient is admitted to or registered for care, whether inpatient or outpatient care/treatment, a complete assessment needs to be performed related to the reason for care. The information required depends on the patient's needs and the setting in which care is being provided (for example, inpatient or outpatient care). Hospital policies define the minimum content of assessments for clinical staff to include in their assessments and in all care settings. The hospital identifies any specific assessment data that must be included by various clinical staff.

Assessments are performed by each discipline within its scope of practice, licensure, applicable laws and regulations, or certification. Only qualified individuals conduct the assessments.

All the content from assessments must be available when treatment is initiated.

Measurable Elements of AOP.01.00

1. Ⓓ Hospital policy defines, in writing, the minimum content of assessments for inpatients for each clinical discipline that performs assessments. (*See also* AOP.01.01, ME 2)
2. Ⓓ Hospital policy defines, in writing, the minimum content of assessments for outpatients for each clinical discipline that performs assessments. (*See also* AOP.01.01, ME 2)
3. Only qualified individuals permitted by licensure, applicable laws and regulations, or certification perform the assessments. (*See also* AOP.01.01, ME 3)
4. The hospital identifies the information to be documented for the assessments.

Standard AOP.01.01

Each patient's initial assessment includes a health history and an evaluation of the patient's physical, psychological, spiritual/cultural, social, and economic needs.

Intent of AOP.01.01

The initial patient assessment is critical to identifying patient needs and planning the patient's care.

A complete assessment is performed related to the chief complaint at the time of admission or registration. Hospital policies define what information is needed at the time of admission or registration, who is responsible for obtaining and documenting this information, and how this information is documented.

The initial assessment provides information to do the following:

- Understand the care the patient is seeking.
- Select the best care setting for the patient.
- Form an initial diagnosis.
- Understand the patient's response to any previous care.

Hospital policy outlines what assessments and history are required as part of the initial assessment.

Common elements of an initial assessment include the following:

- Physical evaluation
- Health history
- Medication history and allergies
- Psychological assessment
- Social and economic assessment
- Cultural and spiritual assessment

The psychological assessment determines the patient's perception, thought processes, and emotional status. The social and economic assessment is not intended to "classify" the patient; it is used to identify possible barriers to access and paying for care.

A patient's social, cultural, spiritual, family, and economic factors can influence their response to illness and treatment. Families can be very helpful in these areas of assessment and in understanding the patient's wishes and preferences.

Hospital policy also states the following:

- What parts of the initial assessment each discipline is responsible for completing
- The minimum content for the initial medical assessment
- The minimum content for the initial nursing assessment
- The minimum content for other assessments (for example, physical therapy, speech therapy)
- The time frame for completion of the initial assessment
- The documentation requirements for the initial assessment

The initial assessment of the patient does not need to be completed by one person. Hospital policies define which disciplines are responsible for which parts of the initial assessment. Hospital policies outline the minimum content of the initial medical and nursing and other assessments, the time frame for completion of assessments, and the documentation requirements for assessments.

The initial assessment of some patient populations requires that the assessment process be modified. The modification is based on the unique characteristics or needs of each patient population. Each hospital identifies those special patient populations and modifies the assessment process to meet their special needs. The assessment of these patients responds to their needs and condition in a culturally acceptable and confidential manner. The assessment of special populations is modified to be consistent with local laws and regulations and professional standards.

The assessment is complete, available to those caring for the patient, and results in an initial diagnosis and an understanding of the patient's medical and nursing needs so care and treatment can begin.

In an emergency, the initial medical and nursing assessments may be limited to the patient's apparent needs and condition. In cases in which an emergency patient requires surgery, a brief note and the preoperative diagnosis are documented before surgery.

The hospital must identify, in writing, special populations that it serves and require a modified assessment process. Examples of special patient populations include the following:

- Infants, children, and adolescents
- Frail elderly
- Terminally ill/dying patients
- Patients with intense or chronic pain
- Women in labor or experiencing terminations in pregnancy
- Patients with emotional or psychiatric disorders
- Patients suspected of drug and/or alcohol dependency
- Victims of abuse or neglect
- Patients with infectious or communicable diseases
- Patients whose immune systems are compromised

The hospital requires the patient's initial assessment be completed and documented within 24 hours of admission. The hospital may identify situations in which an assessment may be needed sooner, or a limited assessment is acceptable. These situations include the following:

- When a patient's condition indicates, for example, an unstable patient, a patient scheduled for surgery in less than 24 hours after admission, or when a transfer is imminent
- Immediate assessment of emergency patients or other groups identified by the hospital
- When an emergency patient is sent for emergent surgery

Measurable Elements of AOP.01.01

1. Ⓓ All patients have an initial assessment that is consistent with the requirements defined in hospital policy.
2. The assessment includes the following:
   - Physical examination
   - Health history
   - Medication history and known allergies
   - Initial psychological assessment as indicated by the patient's condition
   - Initial social and economic assessment, when indicated by the patient's needs
   - Initial spiritual and cultural assessment, when indicated by the patient's needs

   (*See also* AOP.01.00, MEs 1 and 2)
3. Ⓓ The hospital outlines requirements about who is responsible for the initial assessment and the timeliness of the assessment, including the following:
   - What parts of the initial assessment each discipline is responsible for completing
   - Minimum content for the initial medical assessment
   - Minimum content for the initial nursing assessment
   - Minimum content for other assessments (for example, physical therapy, speech therapy, social services)
   - Time frame for completion of the initial assessment
   - Documentation requirements for the initial assessment

   (*See also* AOP.01.00, ME 3)
4. Ⓓ The hospital identifies, in writing, those patient groups and populations it serves that require modifications to their initial assessment.
5. The initial assessment for special patient populations is modified to reflect their needs.
6. The initial nursing assessment is completed within 8 hours, and the medical assessment is completed within 24 hours of admission to the hospital.
7. The initial assessment results in an initial diagnosis or diagnoses that require treatment and monitoring.
8. The initial nursing assessment results in a list of specific nursing needs or conditions that require nursing care, interventions, or monitoring.
9. Preoperative diagnosis is documented for patients requiring emergency surgery.

Standard AOP.01.02

The hospital has a process for accepting initial assessments from outside sources.

Intent of AOP.01.02

There must be a process to accept initial assessments from outside sources that includes validation of the information included in the assessment because correct and current information is needed to provide safe patient care.

An initial assessment may be conducted by an outside source. Examples of outside sources include the following:

- Health care practitioner's office
- Primary care or ambulatory care center
- Consulting or referring practitioner

Common reasons for initial assessments by outside sources include the following:

- Referral to a specialist employed by the hospital
- Direct or scheduled admissions to the hospital
- Referral for a scheduled outpatient or same-day procedure

The initial assessment completed by an outside source must be within the previous 30 days.

When an assessment is partially or entirely completed by an outside source, the information in the assessment is reviewed and verified by a qualified individual. If there are any changes to the assessment, the medical record is updated and identifies any additional testing that may be needed related to the change.

If the initial assessment is greater than 30 days old at the time of admission or registration, the medical history must be updated and the physical examination repeated.

For initial assessments performed and documented 30 days or less prior to admission or registration, the information in the history and assessment is reviewed and verified. This review includes the following:

- Patient's medical history and assessment findings
- Laboratory and other diagnostic test results
- Proposed plan of care and treatments

Any changes in the patient's condition since the assessment, or "no change" if appropriate, are documented at admission.

Measurable Elements of AOP.01.02

1. Initial medical assessments accepted are less than or equal to 30 days old.
2. For initial assessments less than or equal to 30 days old, the assessment is reviewed and validated; any changes in the patient's condition since the assessment or "no change" are documented in the patient's medical record at the time of admission or registration.
3. If the initial assessment is greater than 30 days old at the time of admission or registration, the medical history is updated and the initial assessment is repeated in accordance with the hospital's initial assessment policy.

Standard AOP.01.03

Patients are screened for nutritional, functional, and other special needs and are further assessed when indicated by the screening.

Intent of AOP.01.03

Initial screenings for nutritional, functional, and other special needs identify patients who may require additional interventions for safe, high-quality care.

These screenings may be conducted at the initial medical or nursing assessment. The hospital uses a screening tool to screen patients for nutritional, functional, and other special needs. The information gathered through the screening determines if the patient needs further assessment.

The screening process is very simple and high level and identifies whether a risk or problem exists. If the screening identifies a risk or a problem, an assessment is then completed. The hospital refers the patient for further assessments, either within the hospital or through the community, to address risks or problems identified by the screening.

The screening tools are implemented consistently throughout the hospital and are used by trained clinical staff.

The screening tools are developed by qualified individuals able to further assess any identified risks. Various clinical staff may be trained on how to use the tools and complete screenings with patients. When indicated by the screening, qualified individuals complete the assessment and identify interventions or a plan to address the patient's needs. Examples include the following:

- Nutritional risk
  - An evidence-based screening tool for nutritional risk may be developed by the hospital's nurses.
  - Nurses, physicians, and dietitians are trained to use the tools.

    - Dietitians then complete a nutritional assessment and supply the recommended dietary intervention.
    - Nutritionists integrate nutritional needs identified by the assessment with the other needs of the patient.
- Functional status
    - An evidence-based functional screening tool, including physical ability, vision, and hearing, may be developed by the hospital's occupational therapists.
    - Nurses and occupational, physical, and speech therapists are trained use the screening tool.
    - Occupational, physical, and speech therapists complete a functional assessment.
    - Physical medicine and rehabilitation physician orders functional therapy to address the needs identified in the assessment.

Other specialized needs may be identified through routine care; for example, clinical staff may observe that a patient has difficulty seeing or hearing and refer the patient for the necessary assessments.

Assessments are completed using evidence-based tools and used by trained clinical staff to determine the level of risk or severity of a problem and to develop specific interventions to address the risk or problem.

A screening tool is used to evaluate for the presence of a risk or a problem and generally results in a "yes or no" response.

Screening tools can be developed by a qualified individual to screen for a risk or problem. Creating a brief questionnaire for the patient is a useful screening tool, as in the following examples:

- Asking a patient "Have you lost or gained more than 2 kg in the past 30 days?" to screen for nutritional risk
- Asking a patient "Are you able to complete daily hygiene tasks without difficulty or assistance?" to screen for functional risk
- Asking a patient to complete a brief whisper test to screen for hearing deficits

Assessment tools are used to complete an in-depth assessment of patient risk or problems and are used to develop specific interventions to address the risk or problem.

Assessment tools meet the following criteria:

- Are appropriate to the risk or problem being evaluated.
- Are appropriate to the patient population being evaluated (for example, pediatric, adult, geriatric).
- Are based on evidence and validated in the population being evaluated.

Measurable Elements of AOP.01.03

1. Evidence-based screening tools are used to identify patients who require further nutritional assessment, and the tools are implemented consistently throughout the hospital.
2. Patients whose screening indicates a nutritional risk or problem receive a nutritional assessment.
3. Screening tools are used to identify patients who require further functional assessment, and the tools are implemented consistently throughout the hospital.
4. Patients whose screening indicates a functional risk or problem receive a functional assessment.
5. When the need for additional specialized assessments is identified, patients are referred within the hospital or outside the hospital.

Standard AOP.01.04

All patients are screened for pain and assessed when pain is present.

Intent of AOP.01.04

Pain greatly impacts a patient's quality of life, affects healing, and can impact physical, psychological, and social well-being.

Screening identifies those at risk or potentially in need of a further, more specialized assessment. The screening has a narrow scope, whereas the scope of assessment is more comprehensive. An assessment is a systemic process done to evaluate needs that can then be fulfilled, or a plan made around them on how to meet those needs, thus the individual conducting the assessment should have an expertise or specialty in the field being assessed.

Screening tools have a more narrow, superficial scope and are beneficial for identifying those at risk. A screening tool is used to identify patients with pain. The screening process is simple, is high level, and identifies whether a risk or problem related to pain exists. If the screening identifies a risk or a problem, an assessment is then completed. A screening for pain may consist of one or more simple questions that can be asked by trained clinical staff. The results of the pain screening are documented in the patient's medical record.

The information gathered through the screening determines if the patient needs further assessment. The assessment is then used to match the individual's needs with the appropriate type and level of care, treatment, or services.

If the planned care, treatment, or services may result in pain, this would also indicate the need for a pain assessment.

The pain assessment is appropriate to the patient, including the following:

- Patient age
- Patient condition (for example, sedated or alert)
- Any barriers (for example, inability to speak or hear or developmental delays)

The pain assessment is a more in-depth evaluation of the patient's pain and is used to develop specific interventions to address the pain. The pain assessment is documented in the patient's medical record.

The patient's pain is addressed immediately and may include referral or transfer to a different care setting. For example, an outpatient with severe pain may be admitted as an inpatient to further assess and treat their pain, or an inpatient in the general medical unit may need to be transferred to an intensive care unit for monitoring if an epidural is needed to treat their pain.

A screening tool is used to evaluate for the presence of a risk or a problem and generally results in a "yes or no" response. Examples of questions that may be used in a screening include the following:

- Are you having pain right now?
- Does pain keep you from sleeping at night?
- Does pain keep you from participating in activities?
- Do you experience pain every day?

Evidence-based tools are used to measure the severity of the patient's pain. Examples of pain severity scales include the following:

- Wong-Baker Faces Scale
- FLACC (Face, Legs, Activity, Cry, Consolability)
- COMFORT Scale
- Behavior Pain Scale
- Newborn Infant Pain Scale

The pain assessment also evaluates pain intensity and quality, including the following:

- Pain character (for example, sharp, dull, or burning)
- Frequency
- Location
- Duration

- Pain history (for example, when did the pain start, what activities cause the pain, what treatments has the patient tried to relieve the pain)
- What makes pain better or worse
- What are the patient's goals for pain relief (for example, zero pain or enough relief to complete or participate in specific activities)

Pain assessments, including which assessment tool is used, are documented in the patient's medical record to allow the care team to easily identify trends in the patient's pain and pain relief interventions.

Measurable Elements of AOP.01.04

1. All inpatients are screened for pain, and the screening is documented.
2. Outpatients whose condition, diagnosis, or situation may indicate that they are at risk for pain are screened for pain.
3. Ⓓ When pain is identified by the screening, a pain assessment is performed and documented. (*See also* COP.07.00, ME 1)
4. Patients are reassessed for pain following any pain management interventions.
5. If needed, the patient is referred or transferred to a care setting that has the capabilities and resources to treat the patient's pain.

Standard AOP.01.05

All patients are reassessed at intervals based on their condition and treatment.

Intent of AOP.01.05

Reassessment is key to understanding how patients respond to treatment and to understand if care decisions are effective.

Patients are reassessed throughout the care process at intervals based on their condition and treatment as defined in hospital policies. The results of these reassessments are documented in the patient's medical record.

Hospital policy defines how often reassessments occur by various members of the health care team. A physician must assess patients with acute care needs at least daily, including weekends, and when there is a significant change in the patient's condition.

Hospital policy defines how often patients are reassessed by a nurse. This will vary greatly based on the patient's needs, condition, and treatment. For example, newly intubated patients may require a nursing reassessment every hour, whereas a stable, chronically ill patient with an established airway may require a nursing reassessment every four hours.

Hospital policy defines how often patients are reassessed by other members of the care team, including the following:

- Respiratory therapists
- Physical, occupational, and speech therapists
- Social workers or other social services

Reassessments occur in accordance with hospital policy. Reassessments are completed and results are documented in the patient's medical record in the following instances:

- At defined intervals by various members of the care team, including physicians, nurses, and others
- Daily by a physician for acute care patients
- In response to a significant change in the patient's condition
- If the patient's diagnosis has changed and the care needs require revised planning
- To determine if medications and other treatments have been successful and the patient can be transferred or discharged

Some nonacute patients may not need daily physician assessments (for example, a stable psychiatric patient receiving group therapy sessions, or a patient who is past the acute phase of illness or surgery and who is receiving only rehabilitative treatment). Hospital policy identifies patients who do not require daily physician assessments.

Measurable Elements of AOP.01.05

1. Ⓓ Hospital policy defines, in writing, how often patients are reassessed by various members of the health care team and other circumstances when a reassessment is required, including the following:
   - Defined intervals by various members of the care team, including physicians, nurses, and other clinical staff (for example, therapists, social workers)
   - When there has been a significant change in patient condition
   - When the diagnosis has changed and plan of care needs to be revised (*See also* COP.01.01, ME 3)
   - To determine if the patient is ready for transfer or discharge
2. A physician reassesses patients at least daily, including weekends, during the acute phase of their care and treatment.
3. Ⓓ Hospital policy identifies, in writing, patient populations who may not require a daily assessment and defines the minimum reassessment interval for these patients.
4. Reassessments are documented in the patient's medical record.

Patient Falls

Standard AOP.02.00

The hospital develops and implements a process to reduce the risk of falls, and patient harm resulting from falls.

Intent of AOP.02.00

Many injuries in hospitals to both inpatients and outpatients are a result of falls, so a comprehensive falls prevention program is needed to prevent injuries to patients.

The risk for falls is related to the patient, the situation, and/or the location. Risks associated with patients include but are not limited to the following:

- Age
- Medical history
- Patient history of falls
- Medication use
- Substance consumption
- Other comorbidities
- Gait or balance disturbances
- Visual impairments
- Altered mental status
- Environmental hazards (for example, slippery floors, poor lighting, cluttered rooms)

Patient falls are a significant safety concern and can result in serious injuries such as fractures, head injuries, lacerations, and death.

Patients who have been initially assessed to be at low risk for falls may have a change in fall risk during hospitalization or between outpatient visits. Reasons for change in fall risk include the following:

- Surgery and/or anesthesia
- Sudden changes in patient condition
- Adjustment in medications

Many patients require reassessment during their hospitalization due to these changes in condition and fall risk. Fall risk criteria screenings and assessments identify the patients who are considered at high risk for falls. Screenings, assessments, and any interventions applied are documented in the patient's medical record.

The hospital establishes a fall risk reduction program based on appropriate policies and/or procedures. If a fall occurs, the hospital evaluates the fall, takes action to reduce the risk of future falls, and reduces the risk of injury. A fall risk reduction program includes risk assessment and periodic reassessment of a particular patient population and/or of the environment in which care and services are provided (such as those conducted during periodic safety tours). Measures and interventions are implemented to reduce fall risk for patients, situations, and locations assessed to be at risk.

Specific situations can pose a risk for falls. For example, a patient arriving at the outpatient department from a long-term care facility by ambulance for a radiologic examination may be at risk for falls in that situation when transferring from ambulance cart to exam table or when changing positions while lying on the narrow exam table.

Specific locations may present higher fall risks because of the services provided. For example, a physical therapy department (inpatient or outpatient) has many types of specialized equipment used by patients that may increase the risk for falls, such as parallel bars, freestanding staircases, and exercise equipment. When specific locations are identified as areas at higher risk for falls, hospitals may determine that all patients visiting those locations are considered at risk for falls and implement general measures to mitigate fall risks that are applicable to all patients.

All inpatients are assessed for fall risk using evidence-based assessment tools and/or methods appropriate for the hospital's patient population(s). For example, pediatric patients require a pediatric fall risk assessment tool, such as the Humpty Dumpty Score or GRAF-PIF tool. Specialized units may prefer tools that are geared toward their specific populations (for example, the Obstetric Fall Risk Assessment System for women on a maternity ward or the Edmonson Psychiatric Fall Risk Assessment Tool (EPFRAT) for psychiatric patients.

Hospital leaders conduct a risk assessment to identify high-risk services and patient populations to screen for fall risk in the outpatient department(s). However, the hospital may either choose to screen all outpatients, or those in departments that are inherently higher risk for fall, based on condition, diagnosis, situation, and/or location. Examples could include the following:

- All patients in a physical therapy outpatient department
- All patients arriving from long-term care facilities by ambulance for outpatient procedures
- Patients scheduled for outpatient surgery involving procedural sedation or anesthesia
- Patients with gait or balance disturbances or who use an ambulation device
- Patients with visual impairments
- Pediatric patients under the age of 2

If fall risk is indicated from the screening, evidence-based interventions are implemented to reduce fall risk for those patients.

Screening generally involves performing a simple evaluation of the patient to determine if they are at risk for a fall. Screening tools are commonly used and include questions or items that are used to identify fall risk patients. For example, the questions may require a simple yes/no answer, or the tool may involve assigning a score to each item based on the patient's responses. Hospitals may determine how the screening process occurs. For example, screening may be performed by registration clerks, or patients may be allowed to self-screen, such as at a kiosk upon entering the outpatient department. Examples of simple screening questions may include "Do you feel unsteady when standing or walking?"; "Do you worry about falling?"; and "Have you fallen in the past year?"

Measurable Elements of AOP.02.00

1. The hospital screens all inpatients for fall risk and uses evidence-based screening tools appropriate for the patient population.
2. The hospital screens all outpatients whose condition, diagnosis, situation, or location may put them at risk for falls and uses screening tools appropriate for the patients being served.
3. The hospital implements a process for the assessment and, when applicable, reassessment of patients who may become at risk for falls due to a change in condition or are already at risk for falls based on the documented assessment.
4. Interventions to reduce fall risk are implemented for those identified patients, situations, and locations within the hospital assessed to be at risk, and the interventions are documented.

Laboratory Services

Note: Laboratories that are required to have specific recognition by local laws and regulations (for example, ISO 15189) may present verification of this recognition as evidence of compliance with relevant requirements to surveyors during the JCI hospital accreditation survey. Evidence of compliance must include all specialties and subspecialties provided by the hospital laboratory. JCI survey includes laboratory specialties and subspecialties (for example, blood bank) that are not within the scope of the existing laboratory recognition.

Standard AOP.03.00

Laboratory services are available to meet patient needs, and all laboratory services meet applicable local and national standards, laws, and regulations.

Intent of AOP.03.00

Laboratory services are essential to the diagnostic and treatment process and therefore must meet requirements to ensure the quality of data from laboratory tests.

The hospital has a system for providing laboratory services based on patient needs.

The laboratory services are organized and provided in a way that meets applicable local and national standards, laws, and regulations. Laboratory services are available after normal hours for emergencies.

Laboratory services may be provided within the hospital, by agreement with another organization (for example, contracted laboratory), or both. The hospital identifies and contacts experts in specialized diagnostic areas, such as parasitology, virology, or toxicology, when needed.

Outside sources are convenient for the patient to access. The hospital selects outside sources based on the recommendation of the laboratory's leader or other individual responsible for laboratory services. Outside sources of laboratory services meet applicable laws and regulations and have an acceptable record of accurate, timely services. Patients are informed when an outside source of laboratory services is owned by the referring physician.

Measurable Elements of AOP.03.00

1. Laboratory services, including outside sources of laboratory services, meet applicable local and national standards, laws, and regulations.
2. Ⓓ Laboratory services meet the needs of the patients and other services the hospital provides, including a process to access laboratory services after hours and for emergency needs.
3. Experts in specialized diagnostic areas are contacted when needed. (*See also* GLD.05.00, ME 1)

Standard AOP.03.01

A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff are qualified to perform the tests and interpret the results.

Intent of AOP.03.01

Clinical laboratory services are managed by an individual who is qualified to ensure that the laboratory and its services meet patient needs, laws, and regulations. Qualified laboratory staff perform tests and interpret results to ensure that the data collected through laboratory services are accurate.

Clinical laboratory services are under the direction of an individual who is qualified through documented education, training, experience, and the requirements of laws and regulations. This individual is responsible for the laboratory facility, the services provided in the laboratory, and tests performed outside the laboratory, including point-of-care testing.

The oversight of services outside the laboratory does not include daily supervision of those activities. Daily supervision remains the responsibility of the leaders of the department or unit in which the testing is conducted. When this individual provides clinical consultation or medical opinion, they are a physician, preferably a pathologist. Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals.

Laboratory staff are oriented to their work and are given work assignments consistent with their training and experience. The laboratory implements a staffing program that allows staff to perform tests promptly and to ensure laboratory staffing during all hours of operation and for emergencies.

The hospital identifies a qualified laboratory leader to oversee laboratory services. Oversight responsibilities include those services that are provided within and outside the laboratory.

The oversight of services outside the laboratory includes ensuring consistent hospitalwide policies and practices, including the following:

- Training
- Supply management
- Inspection and maintenance of equipment
- Oversight of the point-of-care-testing program

Laboratory staffing requirements include the following:

- Education, training, qualifications, and experience of laboratory staff members performing and interpreting laboratory tests
- Identifying staff approved to perform point-of-care testing
- Identifying staff who direct or supervise other staff who perform testing

Measurable Elements of AOP.03.01

1. The clinical laboratory, and other laboratory services throughout the hospital, are under the direction and oversight of one or more qualified individuals. (*See also* GLD.06.00, ME 1)
2. Responsibilities of the qualified laboratory leader include the following:
   - Developing, implementing, and maintaining policies and procedures
   - Administrative oversight of laboratory services
   - Maintaining any necessary quality control programs
   - Developing and implementing a staffing program
   - Recommending outside sources of laboratory services
   - Monitoring and reviewing all laboratory services
3. All laboratory staff have the required qualifications to perform and interpret tests.
4. Ⓓ A laboratory staffing program is implemented so staff can perform tests promptly and provide staffing during all hours of operation and during emergencies.
5. Laboratory supervisory staff are identified and have the proper qualifications and experience for the role.

Standard AOP.03.02

The hospital has defined requirements for the oversight and supervision of the point-of-care testing program.

Intent of AOP.03.02

The hospital must have a clearly defined and well-structured approach to point-of-care testing to ensure that it is performed safely and correctly and that the results generated are accurate and reliable.

Point-of-care testing (POCT) is testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to the patient.

The individual responsible for laboratory services or other qualified designee is responsible for the oversight and supervision of POCT.

The hospital develops a program for POCT that includes the following:

- Selecting tests to be performed
- Identifying staff who perform the test(s)
- Establishing a protocol for reporting abnormal test results
- Determining a process for reporting critical results
- Defining a process to include representatives of clinical staff in developing and evaluating the POCT program

Staff performing POCT require training for each test being performed. Staff must complete a competency evaluation for each test to confirm that they know how to perform the test and to ensure that results are accurate. Staff performing POCT understand the process to report abnormal and critical results.

Quality control tests and their documentation are required to be performed according to manufacturers' guidelines. All staff performing POCT adhere to quality control procedures and know what actions to take if a quality control sample is out of the test range specified by the manufacturer. The results of the quality control testing and any corrective actions are documented.

POCT is monitored and evaluated to ensure that the program is meeting the needs of patients and health care providers.

Point-of-care tests include those performed and interpreted at or near the patient. Examples of point-of-care tests include the following:

- POCT blood glucose tests
- POCT blood gas tests

- Pregnancy test
- Urinalysis
- Fecal occult tests
- Rapid infection tests, including strep and COVID

POCT does not include tests that are performed at or near the patient but are processed or interpreted in another location.

Quality control testing occurs based on manufacturers' guidelines. Examples of when quality control testing occurs include the following:

- Once daily
- Once per week
- Between new batches of test kits

POCT evaluation may be accomplished by one or more of the following methods:

- Developing and monitoring quality improvement measures
- Interviewing patients or conducting surveys
- Reviewing quality control and proficiency test results
- Reviewing utilization reports.

Measurable Elements of AOP.03.02

1. The person responsible for managing the laboratory services, or a designee, provides oversight and supervision of the POCT program.
2. Staff performing POCT have the required qualifications and training and are competent to perform POCT.
3. Ⓓ The POCT program includes a defined process for reporting abnormal test results, including reporting critical results. (*See also* IPSG.02.00, ME 1)
4. Ⓓ The POCT program includes requirements for quality control performance and documentation.
5. Ⓓ The POCT program is monitored, evaluated, and included in quality improvement activities.

Standard AOP.03.03

Laboratory results are reported within time frames defined by hospital policy.

Intent of AOP.03.03

Timely result reporting is vital to the prompt assessment and diagnosis of patients.

The hospital defines the time frame for reporting laboratory test results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergent or stat tests and after-hours and weekend testing needs are included.

The hospital monitors whether results are reported within the time frame. Results from stat tests are given special attention in the quality measurement process. If the results are not reported in accordance with the hospital's time frame, the hospital identifies barriers to meeting this goal and implements corrective actions.

In addition, when laboratory services are by contract with an outside organization, the reports are also timely, as set forth by hospital policy or the contract.

Measurable Elements of AOP.03.03

1. Ⓓ The hospital has a written policy that establishes the expected report time for routine and stat test results.
2. The hospital monitors whether stat tests are reported within the expected time frame.
3. The hospital monitors whether routine laboratory results are reported within the expected time frame.
4. When laboratory results are not reported within the expected time frame, the hospital takes corrective action.

Standard AOP.03.04

All laboratory testing equipment is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.

Intent of AOP.03.04

The proper maintenance and calibration of laboratory equipment is essential to ensuring accuracy of test results.

Laboratory staff ensure that all equipment, including medical devices used for point-of-care testing, function properly. The laboratory implements a program to manage equipment. Testing, maintenance, and calibration frequency are completed according to the manufacturer's guidelines or more frequently based on the laboratory's use of the equipment and documented history of service.

The program to manage laboratory equipment includes the following:

- Selecting and acquiring laboratory equipment and medical equipment
- Identifying and taking inventory of laboratory equipment and medical equipment
- Assessing laboratory equipment use through inspection, testing, calibration, and maintenance
- Monitoring and acting on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failures
- Documenting the management program

Measurable Elements of AOP.03.04

1. Ⓓ The laboratory manages laboratory equipment with a written process for how equipment is selected and acquired.
2. Ⓓ There is an inventory of all laboratory equipment. (*See also* FMS.07.00, ME 2)
3. Ⓓ Laboratory equipment is inspected and tested when new and according to manufacturers' guidelines; the inspections are documented.
4. Ⓓ Laboratory equipment is calibrated and maintained according to manufacturers' guidelines, and the calibration and maintenance are documented.
5. The hospital monitors and acts on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failures. (*See also* FMS.07.01, ME 1)

Standard AOP.03.05

Essential reagents and supplies are available, and all reagents are evaluated to ensure accuracy and precision of results.

Intent of AOP.03.05

Reagents are a necessary component of laboratory testing, so the hospital creates a policy to ensure that essential reagents are available and meet their purpose for laboratory tests. The hospital has identified reagents and supplies necessary to provide laboratory services to its patients. There is a process to order or secure essential reagents and supplies.

The laboratory develops and implements guidelines for the periodic evaluation of all reagents, to provide for accuracy and precision of laboratory test results. Reagent performance and adequacy are verified before use. All essential reagents are evaluated according to manufacturers' directives or packaging instructions. Hospital policy requires the complete and accurate labeling of reagents and solutions.

Measurable Elements of AOP.03.05

1. Essential reagents and supplies are identified and available, and there is a process to address when essential reagents are not available. (*See also* FMS.05.00, ME 2)
2. All reagents are stored and dispensed according to manufacturers' instructions.
3. Ⓓ The laboratory establishes and follows the hospital's written policy for the evaluation of all reagents to ensure accuracy and precision of results.
4. All reagents undergo quality control testing as required by the manufacturer.
5. Ⓓ Records for reagents include the following information:
   - Identity of the reagent
   - Date of receipt or preparation
   - Lot number
   - Expiration date
   - Date put into use

   (*See also* FMS.05.00, ME 2)

Standard AOP.03.06

Procedures for collecting, identifying, handling, safely transporting, and disposing of specimens are established and implemented.

Intent of AOP.03.06

Proper management of specimens is required to ensure that test results accurately represent patient condition; specimens must be properly labeled to match the specimen and results to the correct patient.

Procedures are established and implemented for the following:

- Ordering laboratory tests
- Collecting and identifying specimens
- Transporting, storing, and preserving specimens
- Receiving, logging, and tracking specimens
- Disposal of specimens

These procedures are observed for specimens sent to contracted laboratory services for testing.

Measurable Elements of AOP.03.06

1. Ⓓ Procedures are established and implemented for the ordering of tests.
2. Ⓓ Procedures are established and implemented for the collection and identification of specimens.
3. Ⓓ Procedures are established and implemented for the transport, storage, and preservation of specimens.
4. Ⓓ Procedures are established and implemented for the receipt and tracking of specimens.
5. Ⓓ Procedures are established and implemented for the disposal of specimens.
6. The procedures are followed when contracted laboratory services are used.

Standard AOP.03.07

Established norms and ranges are used to interpret and to report clinical laboratory results.

Intent of AOP.03.07

Norms and ranges are needed to interpret test results; these norms and ranges are included with the test results so health care providers can interpret test results.

The laboratory establishes reference intervals or "normal" ranges for each test performed. The range is included in the medical record, either as part of the report or by including a current listing of such values approved by the laboratory leader. Ranges are provided when a contracted laboratory service performs the test. The reference ranges are appropriate to the hospital's geography and patient demographics. The reference ranges are reviewed and updated when testing methods change and to reflect current scientific evidence.

Measurable Elements of AOP.03.07

1. Ⓓ The laboratory establishes reference ranges for each test performed.
2. The range is included in the medical record at the time test results are reported.
3. Ranges are provided when tests are performed by contracted laboratory services.
4. Ranges are appropriate to the hospital's geography and patient demographics.
5. The laboratory reviews and updates ranges as needed.

Standard AOP.03.08

The hospital has implemented processes for quality control and proficiency testing of laboratory services.

Intent of AOP.03.08

Well-designed quality control processes and proficiency testing are essential to providing accurate laboratory services.

Quality control procedures are used to validate test methods and results. Quality control also includes daily surveillance to ensure that testing is completed according to procedure. Rapid corrective actions are implemented when deficiencies are identified.

The laboratory participates in an approved proficiency testing program or external quality assessment when available. Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methods. Proficiency testing can identify performance problems not recognized by internal mechanisms.

Quality control processes include the following:

- Validation of the test methods used for accuracy, precision, and reportable range
- Daily surveillance of results by qualified laboratory staff
- Rapid corrective action when a deficiency is identified
- Documentation of results and corrective actions

If an approved proficiency testing program or external quality assessment is not available, the laboratory exchanges samples with a laboratory in another hospital for purposes of peer comparison. Proficiency testing, or an alternative, is carried out for all specialty laboratory programs.

The laboratory maintains documentation of participation in a proficiency testing program.

Measurable Elements of AOP.03.08

1. Ⓓ The hospital establishes and implements a written quality control program for the clinical laboratory.
2. The program includes the validation of test methods for accuracy, precision, and reportable range.
3. The program includes the daily surveillance and documentation of test results.
4. The program includes rapid correction and documentation of deficiencies.
5. The laboratory participates in a proficiency testing program or an alternative for all laboratory tests when external quality assessments are not available.
6. The laboratory's proficiency testing results meet satisfactory performance criteria in accordance with laws and regulations.

Standard AOP.03.09

The hospital ensures the quality of services provided by contracted laboratories.

Intent of AOP.03.09

The hospital has a responsibility to ensure that any service provided by contracted services meets all licensing and legal requirements and meets quality expectations developed by the hospital.

If the hospital uses the services of a contracted laboratory, the hospital has a responsibility to make certain that the contracted laboratory is licensed, accredited, or certified by recognized authorities.

Contracted laboratories must participate in proficiency testing to determine how the contracted laboratory's results compare with other laboratories that use the same testing methods.

The hospital identifies measures to monitor the quality of services provided by all contracted laboratories. Qualified individuals review and act on the results of quality monitoring. This information is used to identify potential process improvements and to make decisions about future contracts with the contracted laboratories.

To be certain the contracted laboratory is licensed and accredited or certified, and participates in an outside proficiency testing program, the hospital must obtain a copy of a license from a recognized licensing authority and of the certificate or letter of accreditation or certification from a recognized laboratory accreditation or certification program.

The hospital defines what measures the contracted laboratory is required to collect and submit to the hospital, as well as how often data are submitted to the hospital. Examples of measures collected to evaluate contracted laboratories include the following:

- Turnaround times for tests, meaning the time it takes for the laboratory to report a result following receipt of the specimen
- Critical results reporting
- Problems with specimens such as missing identifiers or specimen rejections

Measurable Elements of AOP.03.09

1. Ⓓ The hospital maintains a copy of the license and the certificate or letter of accreditation or certification, from a recognized authority, for all contracted laboratories used by the hospital.
2. Ⓓ The hospital maintains documentation that any contracted laboratory used by the hospital participates in a proficiency testing program.
3. The hospital determines the frequency and type of performance expectation data from contracted laboratories. (*See also* GLD.05.00, MEs 4 and 5)
4. The individual responsible for the laboratory or a designee reviews the performance data from contracted laboratories and takes action based on the results. (*See also* GLD.05.00, MEs 4 and 5)
5. Ⓓ An annual report of the data from contracted laboratories is provided to the leaders responsible for the management and renewal of contracts.

Blood Bank and/or Transfusion Services

Standard AOP.04.00

A qualified individual(s) is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice.

Intent of AOP.04.00

Blood bank and/or transfusion services have unique risks to staff and patients.

Blood bank and/or transfusion services are under the direction of a qualified individual(s). This individual assumes professional responsibility for all aspects of blood bank and transfusion services provided in the hospital.

Quality control processes for all blood bank and transfusion services are implemented and documented to ensure the safety and efficacy of blood bank and transfusion services. Blood donor and transfusion services are guided by laws and regulations and recognized standards of practice.

The hospital monitors its use of blood products, outcomes, and availability of blood products. Many hospitals have implemented patient blood management programs to do this. Patient blood management programs include various clinical staff across disciplines and generally include staff from quality and risk management and infection prevention and control.

The hospital implements blood surveillance procedures known as hemovigilance. Hemovigilance covers the entire blood transfusion process, from donation of blood products through follow-up care for the blood product recipient. Monitoring includes any adverse events or near miss events involving the blood bank and/or transfusion services. When an event is discovered, the hospital is responsible for taking corrective action to prevent a repeat occurrence.

The oversight of blood bank and/or transfusion services includes implementation and documentation of the processes for blood administration.

A formal patient blood management program may make oversight of the above processes more efficient. However, the hospital determines how its blood bank and/or transfusion services are monitored and how changes are implemented. The hospital monitors blood bank and/or transfusion services and makes improvements on processes to do the following:

- Ensure optimal use of blood products.
- Ensure optimal patient outcomes.
- Maintain the supply of blood products.

As noted, hemovigilance processes include monitoring any adverse events or near miss events. When an adverse or near miss event is discovered that involves blood bank and/or transfusion services, the event is investigated and reported to all required authorities (for example, hospital risk management committee or the local or regional blood bank).

The hospital then takes corrective action based on monitoring data to prevent any future adverse or near miss events. Examples of these events include the following:

- Transfusion to the wrong patient
- Mislabeled blood product
- Contaminated blood product

Measurable Elements of AOP.04.00

1. A qualified individual(s) is responsible for blood bank and/or transfusion services. (*See also* GLD.06.00, ME 1)
2. Ⓓ The blood bank has implemented and documented processes for the following:
   - Blood donor selection
   - Blood screening for disease
   - Blood collection
   - Blood storage
   - Compatibility testing
   - Blood distribution
3. Ⓓ Quality control measures for all blood bank and transfusion services are implemented and documented.
4. The blood bank and transfusion services comply with applicable laws and regulations and recognized standards of practice.
5. The hospital has a process to monitor and improve blood product utilization throughout the hospital, including the following:
   - Optimal use of blood products
   - Safe transfusion practices
   - Availability of blood products
6. Ⓓ The hospital has a hemovigilance surveillance program to monitor, investigate, and report any adverse events and near miss events involving blood bank and/or transfusion services. (*See also* QPS.03.04, ME 3)

Standard AOP.04.01

Clinical guidelines and procedures are implemented for the handling and administration of blood and blood products.

Intent of AOP.04.01

Proper oversight is required to minimize risks and to ensure optimal use of blood products. Additional guidance for this key requirement is explained below.

In addition to oversight of the blood bank and transfusion services, the hospital identifies who is permitted to administer blood and blood products according to local laws and regulations and uniformly implements clinical guidelines and procedures for the handling and administration of blood and blood products. The hospital provides and documents training for all clinical staff permitted to administer blood and blood products. This training is overseen by an individual with education, knowledge, and expertise related to blood and blood products administration. Uniform training ensures that processes, procedures, and clinical guidelines for transfusions are implemented throughout the hospital.

Training for clinical staff permitted to administer blood and blood products includes the following:

- How to obtain consent
- How to obtain blood and blood products from the blood bank or blood storage areas
- How to verify patient identification
- Administration procedures, including special considerations for special patient populations (for example, neonates, trauma patients)
- Documentation requirements
- How to monitor for and respond to transfusion reactions

The hospital has a process to monitor and investigate any adverse events and near miss events involving the administration of blood and blood products. This process includes the following:

- Clinical staff involved in the event
- The individual(s) who oversees blood and blood product administration training

- The individual(s) who oversees the blood bank and transfusion services
- An individual(s) from the quality and risk management program
- Others as identified

Measurable Elements of AOP.04.01

1. The hospital identifies who is permitted to administer blood and blood products in accordance with laws and regulations.
2. Individuals permitted to administer blood and blood products must have the education, knowledge, and clinical expertise to do so safely.
3. Ⓓ The hospital provides and documents training of practices associated with administering blood and blood products.
4. Clinical guidelines and procedures are uniformly implemented for the handling and administration of blood and blood products.
5. Clinical guidelines and procedures address the processes for the following:
   - Patient consent for administration
   - Procurement of blood from the blood bank or blood storage area
   - Patient identification
   - Blood administration
   - Monitoring of the patient
   - Identification of and response to signs of potential transfusion reactions

Radiology and Diagnostic Imaging Services

Standard AOP.05.00

Radiology and diagnostic imaging services are available to meet patient needs, and all services meet applicable local and national standards, laws, and regulations.

Intent of AOP.05.00

Safe and accurate radiology and diagnostic services are needed to make accurate patient diagnoses and treatment plans.

The hospital has a process for providing radiology and diagnostic imaging services required by its patient population and scope of services. Radiology and diagnostic imaging services meet all applicable local and national standards, laws, regulations, and professional standards.

Radiology and diagnostic imaging services, including those required for emergencies, may be provided within the hospital, by agreement with another organization, or both. Radiology and diagnostic imaging services are available after normal hours for emergencies. In addition, the hospital may identify and contact experts in specialized diagnostic areas, and the hospital maintains a list of such experts. Examples of these specialized areas include the following:

- Radiation physics
- Radiation oncology
- Nuclear medicine
- Interventional radiology
- Neurointerventional radiology
- Cardiac catheterization

Outside sources are convenient for the patient to access, and reports are received in a timely way to support patient care. The hospital selects outside sources based on the recommendation of the individual responsible for radiology and diagnostic imaging services. Outside sources of radiology and diagnostic imaging services

meet applicable laws and regulations and have an acceptable record of accurate, timely services. Patients are informed when an outside source of services is owned by the referring physician.

Measurable Elements of AOP.05.00

1. Radiology and diagnostic imaging services meet applicable professional standards local and national laws and regulations.
2. Radiology and diagnostic imaging services are available to meet the needs related to the hospital's patient population, scope of services, and emergency needs, including after normal hours.
3. Ⓓ The hospital maintains a list of experts in specialized diagnostic areas and ensures that the list is accessible to staff who need it.
4. Outside sources are selected based on recommendations of the individual responsible for radiology and diagnostic imaging services and have an acceptable record of timely performance and compliance with applicable laws and regulations.

Standard AOP.05.01

A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services, and individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results.

Intent of AOP.05.01

Radiology and diagnostic imaging services are managed by an individual who is qualified to ensure that services meet patient needs, laws, and regulations. Qualified radiology and diagnostic imaging staff are needed to perform tests and interpret results to ensure that the data collected through these services are accurate.

Radiology and diagnostic imaging services, provided at any location in the hospital, are under the direction of an individual who is qualified by documented education, training, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the radiology and diagnostic imaging facility, the equipment, and the services provided.

When this individual provides clinical consultation or medical opinion, they are a physician, preferably a radiologist. When special services are provided, they are under the direction of appropriately qualified individuals. Examples of special services include the following:

- Radiation therapy
- Nuclear medicine
- Interventional radiology
- Neurointerventional radiology
- Cardiac catheterization

The radiology and diagnostic imaging leader's responsibilities include the following:

- Developing, implementing, and maintaining policies and procedures
- Overseeing administrative tasks
- Overseeing quality control
- Developing and implementing a staffing program
- Recommending outside sources of radiology and diagnostic imaging services
- Monitoring and reviewing all radiology and diagnostic imaging services

The hospital identifies which radiology and diagnostic imaging staff members perform diagnostic and imaging studies; are qualified to interpret the results or to verify and report results; and direct or supervise the processes.

Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their responsibilities. Technical staff members are given work assignments consistent with their training and experience. In addition, there is a sufficient number of staff to perform, to interpret, and to report

studies within a time frame defined by hospital policy and to provide necessary staffing during all hours of operation and for emergencies.

Measurable Elements of AOP.05.01

1. Radiology and diagnostic imaging services are under the direction of one or more qualified individuals. (*See also* GLD.06.00, ME 1)
2. Responsibilities of the individual managing radiology and diagnostic imaging services include the following:
   - Developing, implementing, and maintaining policies and procedures
   - Overseeing administrative tasks
   - Overseeing quality control
   - Developing and implementing a staffing program
   - Recommending outside sources of radiology and diagnostic imaging services
   - Monitoring and reviewing all radiology and diagnostic imaging services
3. Staff with proper qualifications and experience perform diagnostic and imaging studies.
4. Staff with proper qualifications and experience interpret study results and verify and report the results within the time frame defined by hospital policy.
5. There is an adequate number of staff to meet patient needs and the hospital's scope of services.
6. Radiology and diagnostic imaging supervisory staff have proper qualifications and experience for the role.

Standard AOP.05.02

A radiation and/or diagnostic imaging safety program for patients, staff, and visitors is implemented and is compliant with applicable professional standards, laws, and regulations.

Intent of AOP.05.02

Radiation exposure can pose potential risk of long-term damage, so the hospital has a responsibility to implement a radiation safety program to protect patients, staff, and visitors from unnecessary or excessive exposure to radiation.

Risks of long-term damage depend on the dose of radiation delivered and the length and frequency of exposure to radiation. The higher the radiation dose, the greater the risk for long-term damage, and repeated doses have a cumulative effect presenting greater risks. The diagnostic procedures most commonly associated with avoidable radiation doses are computed tomography (CT), nuclear medicine, and fluoroscopy. A radiation safety program is important in the safe use of ionizing radiation, including radioactive materials (RAM) and radiation producing machines.

Health care providers weigh the medical necessity of the exposure to radiation for diagnosis or treatment against the risks. Unnecessary exposure to radiation should be avoided. The hospital follows the principles of ALARA (maintain all radiation exposures as low as reasonably achievable).

Diagnostic imaging, such as magnetic resonance imaging (MRI) and ultrasonography (US), does not use ionizing radiation, and therefore the risks from radiation are not present. There are other risk-related diagnostic imaging services that need to be addressed. Hazards from MRI include the following:

- Exposure to a strong magnetic field
- Presence of cryogenic gases used to cool the magnets of the MRI
- Exposure to acoustic noise

The hospital has a radiation and diagnostic imaging safety program that includes all components of the hospital's radiology and diagnostic imaging services, including radiation oncology and the cardiac catheterization laboratory. The safety program addresses the risks and hazards encountered and implements safety practices and prevention measures for radiology and diagnostic imaging staff, patients, and visitors. The program is coordinated with the hospital's facility management and infection prevention and control programs.

As noted, the hospital follows the principles of ALARA (maintain all radiation exposures as low as reasonably achievable), which include the following:

- Minimizing the amount of time staff, patients, and visitors are exposed to radiation
- Increasing the distance between the radiation source and any staff, patients, and visitors
- Using lead or other shields to reduce exposure to radiation

Hospitals must implement measures to address these hazards from diagnostic imaging. For example, MRI safety measures may include the following:

- Clearly marking safety zones in the MRI area to indicate who can have access and what safety precautions are necessary in each zone
- Ensuring proper ventilation and appropriate staff training to address hazards related to cryogenic gases
- Protecting ears to decrease discomfort and harm from acoustic noise during MRI examinations
- Restricting access to the MRI magnetic field area to only authorized staff and to patients accompanied by those staff
- Posting signs in and around the area to identify hazards
- Completing a preimaging checklist to identify any risks or exclusion criteria for patients undergoing MRI (for example, metal implants, shrapnel, pacemaker in place)
- Ensuring that only special non-ferromagnetic equipment enters the MRI environment

The radiation safety management program includes the following:

- Compliance with applicable professional standards, laws, and regulations
- Orientation of all radiology and diagnostic imaging staff to safety procedures and practices
- Training and ongoing education for new procedures, new equipment, and newly acquired or recognized hazardous materials
- Availability of safety protective equipment and devices appropriate to the practices and hazards encountered; in radiology, protective devices and equipment include lead aprons, lead lining in the walls, and radiation badges (for staff), among others.
- Compliance with standards addressing facility management and infection prevention and control programs

Measurable Elements of AOP.05.02

1. Ⓓ A radiation and/or diagnostic imaging safety program for patients, staff, and visitors is implemented and is compliant with applicable professional standards, laws, and regulations.
2. Radiology and diagnostic imaging staff are oriented to safety requirements and receive ongoing education and training for any new procedures, equipment, and hazardous materials. (*See also* SQE.01.07, ME 1)
3. Safety protective equipment and devices appropriate to the practices and hazards encountered from radiation and diagnostic imaging are available to staff, patients, and visitors, and in the area in which radiology and diagnostic imaging services are provided.
4. Radiation safety education includes the principles of ALARA and implementation of protocols that identify the maximum dose of radiation for each type of study.
5. Hazards from magnetic resonance imaging are addressed using industry standards and evidence-based guidelines.
6. The hospital designates an individual to serve as the radiation safety officer who is responsible for the following:
   - Ensuring that radiologic services are provided in accordance with laws, regulation, and organizational policies
   - Monitoring compliance with established radiation safety practices (including oversight of dosimetry monitoring)
7. The radiation and/or diagnostic imaging safety program is part of the organization's facility management and infection prevention and control programs and provides reports to those programs at least annually and when any safety events and infection control events occur.

Standard AOP.05.03

Radiology and diagnostic imaging study results are available in a timely way as defined by hospital policy.

Intent of AOP.05.03

Timely reporting of radiology and diagnostic imaging results is vital to the prompt assessment and diagnosis of patients.

The hospital defines the time frame for reporting diagnostic radiology and diagnostic imaging study results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergent or stat imaging and after-hours and weekend imaging needs are included.

The hospital monitors whether radiology and diagnostic imaging study results are reported within the time frame. Results from urgent or emergent radiology and diagnostic imaging studies are given special attention in the quality measurement process. If the results are not reported in accordance with the hospital's time frame, the hospital identifies barriers to meeting this goal and implements corrective actions.

Radiology and diagnostic imaging studies performed by outside contractors of services are reported according to hospital policy or contract requirement.

Measurable Elements of AOP.05.03

1. Ⓓ The hospital has a written policy that establishes the expected report time for diagnostic imaging results.
2. The hospital monitors whether urgent or emergent radiology and diagnostic imaging results are reported within the expected time frame.
3. The hospital monitors whether routine radiology and diagnostic imaging results are reported within the expected time frame.
4. When radiology and diagnostic imaging results are not reported within the expected time frame, the hospital takes corrective action.

Standard AOP.05.04

All equipment used to conduct radiology and diagnostic imaging studies is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.

Intent of AOP.05.04

The proper maintenance and calibration of radiology and diagnostic imaging equipment is essential to ensure accuracy of test results.

Radiology and diagnostic imaging staff ensure that all equipment used for radiology and diagnostic imaging programs functions properly. The hospital has a program to manage radiology and diagnostic imaging equipment. Testing, maintenance, and calibration frequency are completed according to the manufacturer's guidelines or more frequently based on the use of the equipment and documented history of service.

The program to manage radiology and diagnostic imaging equipment includes the following:

- Selecting and acquiring radiology and diagnostic imaging equipment and medical equipment
- Identifying and taking inventory of radiology and diagnostic imaging equipment
- Assessing radiology and diagnostic imaging equipment use through inspection, testing, calibration, and maintenance
- Monitoring and acting on radiology and diagnostic imaging equipment hazard notices, recalls, reportable incidents, problems, and failures
- Documenting the management program

Measurable Elements of AOP.05.04

1. Ⓓ The hospital develops and implements a written program to manage radiology and diagnostic imaging equipment, including how radiology equipment is selected and acquired.
2. Ⓓ There is a documented inventory of all radiology and diagnostic imaging equipment. (*See also* FMS.07.00, ME 2)
3. Ⓓ Radiology and diagnostic imaging equipment is inspected and tested when new and according to age, use, and each manufacturer's recommendations; the inspections are documented.
4. Ⓓ Radiology and diagnostic imaging equipment is calibrated and maintained according to each manufacturer's recommendations, and the calibration and maintenance is documented.
5. The hospital has a system in place for monitoring and acting on radiology and diagnostic imaging equipment hazard notices, recalls, reportable incidents, problems, and failures. (*See also* FMS.07.01, ME 1)

Standard AOP.05.05

The hospital has implemented quality control procedures for radiology and diagnostic imaging services.

Intent of AOP.05.05

Well-designed quality control processes and proficiency testing are essential to providing accurate radiology and diagnostic imaging services. Quality control also includes daily surveillance to ensure that testing is completed according to procedure. Rapid corrective actions are implemented when deficiencies are identified.

Quality control processes include the following:

- Review of image quality
- Accuracy of interpretation of imaging
- Daily surveillance of results by qualified radiology and diagnostic imaging staff
- Rapid corrective action when a deficiency is identified
- Documentation of results and corrective actions

Measurable Elements of AOP.05.05

1. Ⓓ The hospital establishes and implements a written quality control program for the radiology and diagnostic imaging services.
2. Quality control includes validating test methods for accuracy and precision.
3. Quality control includes rapid correction and documentation when a deficiency is identified.

Standard AOP.05.06

The hospital ensures the quality of services provided by all outside contracted sources of radiology and diagnostic imaging services.

Intent of AOP.05.06

The hospital has a responsibility to ensure that any service provided by a contracted service meets all licensing and legal requirements and meets quality expectations developed by the hospital.

If the hospital uses the services of a contracted radiology or diagnostic imaging service, the hospital has a responsibility to make certain that the radiology or diagnostic imaging service is licensed and accredited or certified by recognized authorities.

The hospital identifies measures to monitor the quality of services provided by all contracted radiology and diagnostic imaging services. Qualified individuals review and act on the results of quality monitoring. This

information is used to identify potential process improvements and to make decisions about future contracts with the contracted radiology and diagnostic imaging services.

The hospital defines what measures the contracted radiology or diagnostic imaging service is required to collect and submit to the hospital, as well as how often data are submitted to the hospital. Examples of measures collected to evaluate contracted radiology or diagnostic imaging service include the following:

- Turnaround times for tests, meaning the time it takes for the radiology or diagnostic imaging to receive an order, obtain the imaging, and report the results
- Critical results reporting
- Problems with images such as missing identifiers or specimen rejections

Measurable Elements of AOP.05.06

1. Ⓓ The hospital maintains a copy of the license from a recognized authority for all contracted radiology and diagnostic imaging services used by the hospital.
2. Ⓓ The hospital maintains a copy of the certificate or letter of accreditation or certification from a recognized authority for all contracted radiology and diagnostic imaging services used by the hospital.
3. The hospital determines the frequency and type of quality data from contracted radiology and diagnostic imaging services. (*See also* GLD.05.00, MEs 4 and 5)
4. The individual responsible for the radiology and diagnostic imaging services or a designee reviews the performance measure data from contracted radiology and diagnostic imaging services and takes action based on the results. (*See also* GLD.05.00, MEs 4 and 5)
5. Ⓓ An annual report of the data from contracted radiology and diagnostic imaging services is provided to those who make decisions about management and renewal of contracts.

Nuclear Medicine Services

Standard AOP.06.00

When applicable, the hospital establishes and implements a nuclear medicine safety program that complies with applicable professional standards, laws, and regulations.

Intent of AOP.06.00

Nuclear medicine is a branch of medical imaging and treatment that uses small amounts of radioactive materials, known as radiopharmaceuticals, to diagnose and treat various diseases. Due to the use of radiation, strict safety standards and guidelines are in place to ensure the well-being of patients, health care professionals, and the general public.

Nuclear medicine practices are regulated by various national and international organizations, such as the International Atomic Energy Agency (IAEA), the Nuclear Regulatory Commission (NRC) in the United States, and the European Medicines Agency (EMA) in Europe. These bodies establish and enforce safety standards, including licensing requirements, training guidelines, and equipment regulations. Medical professionals working with radioactive materials in nuclear medicine, such as nuclear medicine physicians, radiologists, and technologists, must undergo specialized training to ensure that they have the necessary knowledge and skills to handle radioactive materials safely. They should be trained in radiation safety, radiation protection, and proper handling and disposal of radioactive waste.

Nuclear medicine facilities are designed to minimize radiation exposure to staff and the public. Shielding materials, such as lead and concrete, are used to contain radiation within designated areas. Proper ventilation systems, monitoring equipment, and radiation shielding barriers are required to ensure safety. Quality assurance programs are established to ensure the accuracy and safety of nuclear medicine procedures. Regular

equipment calibration, performance testing, and quality control measures are undertaken to maintain the reliability and effectiveness of imaging and treatment equipment.

Patients scheduled for nuclear medicine procedures receive specific instructions regarding preparation, such as fasting requirements or discontinuation of certain medications. Patients are educated about the benefits, risks, and safety precautions associated with the procedure. Informed consent is obtained, and patient concerns or questions are addressed. Radiation exposure is monitored for both patients and health care professionals involved in nuclear medicine procedures. Personal dosimeters are worn to measure the amount of radiation received. Regular monitoring helps ensure that radiation doses are within acceptable limits and that appropriate safety measures are followed.

Proper disposal of radioactive waste is crucial to prevent environmental contamination and ensure public safety. Nuclear medicine facilities follow strict protocols for the collection, storage, and disposal of radioactive materials and waste. These procedures are in accordance with local laws, regulations, and guidelines.

Measurable Elements of AOP.06.00

1. A qualified individual(s) is responsible for overseeing nuclear medicine services, and relevant staff members are properly trained, qualified, and certified to perform their respective roles in nuclear medicine safety and procedures.
2. The hospital implements radiation safety protocols, including the use of appropriate shielding, personal protective equipment (PPE), and monitoring devices for both patients and staff.
3. Radiation doses administered to patients are optimized for diagnostic and therapeutic purposes, and the procedure includes monitoring and minimizing radiation exposure while obtaining the necessary diagnostic information or therapeutic effect.
4. The procurement, storage, handling, and disposal of radiopharmaceuticals complies with laws, regulations, professional standards, and manufacturers' guidelines.
5. Patients and family are informed about the procedures and safety precautions.

Anesthesia and Surgical Care (ASC)

Overview

The use of surgical anesthesia, procedural sedation, and surgical interventions are common and complex processes in a health care organization. They require complete and comprehensive patient assessment, integrated care planning, continued patient monitoring, and criteria-determined transfer for continuing care, rehabilitation, and eventual transfer and discharge. As individual patient response may move along that continuum, general anesthesia and procedural sedation use should be organized in an integrated manner. Thus, this chapter addresses moderate and deep sedation/analgesia to general anesthesia where the patient's protective reflexes needed for a patent airway and ventilatory function maintenance are at risk. This chapter does not address the use of minimal sedation for the purposes of anxiolysis or sedation required in the intensive care unit for ventilator tolerance.

Procedural sedation is defined as the administration of sedatives or dissociative agents with or without analgesics to an individual, in any setting, by any route, to induce an altered state of consciousness that allows the patient to tolerate painful or unpleasant procedures while maintaining cardiorespiratory function. Definitions of four levels of sedation and anesthesia include the following:

Minimal sedation (*anxiolysis):* A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate sedation/analgesia (*"conscious sedation"):* A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained without supportive measures.

Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure. Indications for monitored anesthesia care include the need for deeper levels of analgesia and sedation than can be provided by moderate sedation, including potential conversion to a general or regional anesthetic.

Deep sedation/analgesia: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained without supportive measures.

General Anesthesia: General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because surgery carries a high level of risk, information about the surgical procedure and care after surgery is carefully planned, based on the patient's assessment, and documented. Special consideration is given to surgery that involves implanting a medical device, including the reporting of devices that malfunction, as well as a process for follow-up with patients in the event of a recall.

Note: The anesthesia and surgery standards are applicable in whatever setting anesthesia and/or procedural sedation are used and where surgical and other invasive procedures that require consent are performed. Such settings include hospital operating theatres, day surgery or day hospital units, endoscopy, interventional radiology, dental and other outpatient clinics, emergency services, intensive care areas, or elsewhere.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Organization and Management

ASC.01.00 The hospital provides sedation and anesthesia services to meet patient needs, and in accordance with laws and regulations.

Sedation Care

ASC.02.00 The administration of procedural sedation is standardized throughout the hospital.

ASC.02.01 Practitioners responsible for procedural sedation and staff responsible for monitoring patients receiving procedural sedation are qualified.

ASC.02.02 Procedural sedation is administered and monitored according to professional practice guidelines and documented in the patient's medical record.

ASC.02.03 The risks, benefits, and alternatives related to procedural sedation are discussed with the patient, their family, or those who make decisions for the patient.

Anesthesia Care

ASC.03.00 A qualified individual conducts a preanesthesia assessment and preinduction assessment.

ASC.03.01 Each patient's anesthesia plan of care is discussed with the patient and/or those who make decisions for the patient and documented in the patient's medical record.

ASC.03.02 Each patient's physiological status during anesthesia and surgery is monitored according to professional practice guidelines and documented in the patient's medical record.

ASC.03.03 Each patient's postanesthesia status is monitored, and the patient is discharged from the recovery area by a qualified individual or by using established criteria.

Surgical Care

ASC.04.00 Each patient's surgical care is planned based on the results of the preoperative assessment and documented in the patient's medical record.

ASC.04.01 The risks, benefits, and alternatives are discussed with the patient and their family or those who make decisions for the patient.

ASC.04.02 Information about the surgical procedure is documented in the patient's medical record to facilitate continuing care.

ASC.04.03 Patient care after surgery is planned and documented.

ASC.04.04 Surgical care that includes the implanting of a medical device is planned with special consideration for how standard processes must be modified.

Standards, Intents, and Measurable Elements

Organization and Management

Standard ASC.01.00

The hospital provides sedation and anesthesia services to meet patient needs, and in accordance with professional practice standards and laws and regulations.

Intent of ASC.01.00

With the complexities involved in sedation and anesthesia care, the hospital must have a system in place for providing such services reflective of its patient population, clinical services offered, and health care practitioners' needs. Sedation and anesthesia are commonly viewed as a continuum from minimal sedation to full anesthesia. Sedation and anesthesia use are complex processes that must be integrated into patient care planning encompassing the stages of sedation and anesthesia. Sedation and anesthesia require a complete and comprehensive patient assessment (presedation/preanesthesia), continued patient monitoring (intraprocedure/intraoperative sedation/anesthesia), and objective recovery criteria (postprocedure/postoperative sedation/anesthesia). These services are provided according to professional practice standards for care, meet all applicable local and national laws and regulations, and must be available at all times for emergencies. It is the recommendation of the Association of periOperative Registered Nurses (AORN, 2022) that the hospital provides the same standard of care (that is, patient monitoring and equipment) for patients who are receiving procedural sedation/analgesia and anesthesia in non-operating room anesthesia locations (for example, interventional cardiology, endoscopy, dental, radiology, office-based surgery) as for patients receiving moderate sedation/analgesia and anesthesia in the operating room.

Sedation and anesthesia services may be provided by the hospital, by agreement with a contracted service (for example, an individual anesthesiologist or anesthesia group practice), or both. Any use of contract anesthesia services is based on the recommendation of the qualified individual(s) responsible for managing the sedation and anesthesia services. Sedation and anesthesia services are under the direction of one or more individuals who are qualified by documented training, expertise, and experience, which are consistent with applicable laws and regulations. This individual(s) assumes professional and some management responsibilities for the anesthesia services provided.

Measurable Elements of ASC.01.00

1. The hospital provides sedation and anesthesia services that meet the needs of the patients the hospital serves.
2. The hospital provides sedation and anesthesia services that comply with laws and regulations.
3. The hospital provides sedation and anesthesia services that comply with professional practice standards for care.
4. A qualified individual(s) assumes professional responsibility for the anesthesia services provided regardless of the location at the hospital. Responsibilities include the following:
   - Developing, implementing, and maintaining policies and procedures
   - Providing administrative oversight
   - Maintaining any necessary quality improvement programs
   - Monitoring and reviewing all sedation and anesthesia services
5. This qualified individual(s) is responsible for managing the sedation and anesthesia services, including ensuring the following:
   - Sedation and anesthesia services are uniform throughout the hospital.
   - Sedation and anesthesia services are available at all times for emergencies.
   - The responsibilities for monitoring and reviewing all sedation and anesthesia services are defined and carried out.
6. Ⓓ The hospital has a process for the selection of contract anesthesia services that includes the following:
   - An updated contract anesthesia service list must be used to select contract anesthesia services approved by hospital leaders and the qualified individual(s) professionally responsible for anesthesia services.
   - The contract anesthesia service must have acceptable records of performance and follow applicable laws and regulations.
   - The hospital must have a record of all the completed training and education for each contract anesthesia staff as required by the hospital.
   - There is a current contract in place when contract anesthesia services are used.

   (*See also* GLD.05.00, ME 3)

Sedation Care

Standard ASC.02.00

The administration of procedural sedation is standardized throughout the hospital.

Intent of ASC.02.00

Procedural sedation is often performed in many areas of the hospital outside of the operating theatre. Clinical practice guidelines and standardization of practices have demonstrated improvement in outcomes; in particular, processes that include protocols and checklists, which have proven to reduce patient harm through standardization and communication. As a result, standardized processes optimize moderate procedural sedation practices regardless of the site where the service is performed; guide appropriate patient selection; decrease the risk of adverse patient outcomes (for example, apnea, airway obstruction, respiratory arrest, cardiac arrest, death); promote sedation education, training, and research; and encourage the use of evidence-based data to promote cross-specialty uniformity for moderate sedation practices.

Procedural sedation is defined as "the technique of administering sedatives or dissociative agents with or without analgesics to an individual, in any setting, by any route, to induce an altered state of consciousness that allows the patient to tolerate painful or unpleasant procedures while preserving cardiorespiratory function." Regardless

of the medication, dose, or route of administration, when a medication is used for the purposes of altering the patient's cognitive state in order to facilitate a specific procedure, it is considered procedural sedation.

Hospitals develop specific guidelines for how and where procedural sedation may be used. The qualifications of staff participating in the procedure, the medical equipment, the supplies, and the monitoring must be the same wherever procedural sedation is provided in the hospital. Certain medications may be used in conjunction for certain populations (for example nitrous oxide used in conjunction with other analgesics for pediatric patients during moderate and deep sedation). For patients under care for procedural sedation, individuals from both the nursing and the medical staff who are trained in advanced life support and emergency medical equipment and supplies appropriate for the age and history of the patient and the type of procedure being performed are immediately available.

Measurable Elements of ASC.02.00

1. Ⓓ The hospital has established a written policy and standardized processes for procedural sedation throughout the hospital.
2. Ⓓ Policy and practice for procedural sedation are understood by all practitioners permitted to administer procedural sedation, and the policies address at least the following:
   - Areas in the hospital where procedural sedation may occur
   - Special qualifications or skills of staff involved in the procedural sedation process
   - Differences between pediatric, adult, and geriatric populations or other special considerations
   - Medications used in conjunction with certain populations
   - Immediate availability and use of specialized medical equipment, as appropriate to the patient
   - Informed consent process for both the procedure and the use of sedation
   - An individual with advanced life-support training is immediately available for patients under care for procedural sedation or anesthesia.

   (*See also* SQE.01.08, ME 2)

Standard ASC.02.01

Practitioners responsible for procedural sedation and staff responsible for monitoring patients receiving procedural sedation are qualified.

Intent of ASC.02.01

Complications related to procedural sedation primarily include cardiac or respiratory depression. Thus, certification in at least basic life support is essential. In addition, knowledge of the pharmacology of the sedation agents used, as well as reversal agents, decreases the risks of adverse outcomes. The qualifications of the physician, dentist, or other staff responsible for the patient receiving procedural sedation are important. Understanding the methods for procedural sedation as they relate to the patient and the type of procedure performed improves the patient's tolerance of an uncomfortable or painful procedure and decreases the risks of complications.

The health care practitioner performing the procedure should not be responsible for performing continuous monitoring of the patient. A separate, qualified individual, such as an anesthesiologist or a trained and competent nurse, should assume responsibility for providing uninterrupted monitoring of the patient's physiological parameters and assistance in supportive or resuscitative measures.

Measurable Elements of ASC.02.01

1. Health care practitioners responsible for providing procedural sedation show evidence of competence in at least the following:
   - Techniques and various modes of sedation
   - Pharmacology of sedation drugs and the use of reversal agents
   - Monitoring requirements
   - Response to complications
   - Airway assessment

   (*See also* SQE.01.03, ME 1)
2. The individual responsible for patient monitoring during procedural sedation is competent in at least the following:
   - Monitoring requirements from the active administration phase during the procedure through the recovery phase after the procedure
   - Response to complications
   - Use of reversal agents
   - Recovery criteria
   - Airway assessment

   (*See also* SQE.01.03, ME 1)
3. Ⓓ Procedural sedation competencies for all staff involved in sedation are documented in the personnel records.

Standard ASC.02.02

Procedural sedation is administered and monitored according to professional practice guidelines and documented in the patient's medical record.

Intent of ASC.02.02

Many factors influence the patient's response to sedation and can affect the degree to which a patient is sedated. The presedation assessment helps identify any factors that may impact the patient's response to procedural sedation and also helps to identify what findings from monitoring during and after the procedure may be significant. The degrees of sedation occur on a continuum from mild to deep sedation, and a patient may progress from one degree to another. Factors include the medications administered, the route and dosages, the age of the patient (pediatric, adult, or geriatric), and the patient's health history. For example, history of impairment of major organs, current medications that may interact with sedating medications, drug allergies, previous adverse response to anesthesia or sedation, and substance abuse may each have an impact on patient response to procedural sedation. If the patient's physical status is high risk, consideration is given to the additional clinical needs of the patient and the appropriateness of procedural sedation. These factors are included in the presedation assessment performed by a qualified individual and documented in the patient's medical record.

Patients undergoing procedural sedation require monitoring of their level of consciousness, ventilator and oxygenation status, and hemodynamic variables at a frequency based on the type and amount of medication administered, the length of the procedure, and the type and condition of the patient. Important considerations during the sedation procedure include the patient's ability to maintain protective reflexes; an independent, continuous patent airway; and the capability to respond to physical stimulation or verbal commands. A qualified individual is responsible for performing uninterrupted monitoring of the patient's physiological parameters and assistance in supportive or resuscitation measures until the patient has been safely recovered.

When the procedure has been completed, patients may continue to be at risk for complications due to delay in the full absorption of the sedating drug, respiratory depression, and/or lack of stimulation from the procedure. Patients continue to require monitoring until they have reached near their baseline level of consciousness and

hemodynamic parameters. Complications associated with moderate sedation and analgesia may be avoided if signs and symptoms of adverse drug effects such as cardiovascular decompensation or cerebral hypoxia are detected and treated in a timely manner. Patient monitoring includes strategies for the following:

- Monitoring patient level of consciousness assessed by the response of patients during procedures performed with moderate sedation/analgesia
- Monitoring patient ventilation and oxygenation, including ventilatory function, by observation of qualitative clinical signs, capnography, and pulse oximetry
- Hemodynamic monitoring, including blood pressure, heart rate, and electrocardiography
- Contemporaneous recording of monitored parameters
- Availability/presence of an individual responsible for patient monitoring

In addition to monitoring the physiological criteria, other important strategies to include are the frequency of monitoring and documentation, and general guidance and/or parameters for recovery goals. Objective established criteria help identify patients who are recovered and/or ready for discharge and are used by qualified individuals who are not qualified anesthesiologists but authorized by the individual(s) responsible for managing the anesthesia services.

Measurable Elements of ASC.02.02

1. A presedation assessment is performed that includes at least the following criteria when evaluating risk and appropriateness of procedural sedation for the patient:
   - Identify airway problems that may influence the type of sedation used.
   - Evaluate at-risk patients for appropriateness of procedural sedation.
   - Select and plan the type and level of sedation needed based on the patient assessment, identified risks, and type of procedure being performed.
   - Safely administer sedation based on the plan.
   - Interpret findings from patient monitoring during procedural sedation and recovery.
2. A qualified individual monitors the patient during the period of sedation and documents the monitoring in the medical record.
3. Established criteria are used and documented for the recovery and discharge from procedural sedation when a patient is discharged by an authorized individual other than a fully qualified anesthesiologist.
4. The presedation assessment is performed by an individual(s) qualified to do so and documented in the patient's medical record.
5. Ⓓ The following criteria are based on professional practice guidelines and defined in hospital policy:
   - Scope and content of the presedation assessment
   - Criteria for the recovery and discharge from procedural sedation, including criteria for monitoring

Standard ASC.02.03

The risks, benefits, and alternatives related to procedural sedation are discussed with the patient, their family, or those who make decisions for the patient.

Intent of ASC.02.03

Adequate information and education must be provided to the patient, their family, and/or decision-makers on the risks, benefits, and alternatives related to procedural sedation so an informed decision can be reached when obtaining consent for the procedure. The procedural sedation planning process includes this information and education. This discussion occurs as part of the process to obtain consent for procedural sedation as required in Standard PCC.03.00. A qualified individual provides this education.

Measurable Elements of ASC.02.03

1. The patient, family, and/or decision-makers are educated on the risks, benefits, and alternatives of procedural sedation. (*See also* PCC.03.00, ME 2)
2. The patient, family, and/or decision-makers are educated about postprocedural sedation recovery and pain management. (*See also* PCC.04.00, ME 1)
3. A qualified individual provides and documents the education.

Anesthesia Care

Standard ASC.03.00

A qualified individual conducts a preanesthesia assessment and preinduction assessment.

Intent of ASC.03.00

Because anesthesia carries such a high level of risk, administration is carefully planned. Therefore, an anesthesiologist or another qualified individual conducts the preanesthesia assessment. The patient's preanesthesia assessment is the basis for the anesthesia plan of care, which includes identifying what findings from the clinical assessment and from monitoring during anesthesia and recovery may be significant, and for the use of postoperative analgesia. The preanesthesia assessment may be carried out some time prior to admission or prior to the surgical procedure or shortly before the surgical procedure, as in emergency and obstetrical patients.

The preinduction assessment is separate from the preanesthesia assessment, as it focuses on the physiological stability and readiness of the patient for anesthesia and occurs immediately prior to the induction of anesthesia. When anesthesia must be provided emergently, the preanesthesia assessment and preinduction assessment may be performed immediately following one another, or simultaneously, but are documented independently.

Measurable Elements of ASC.03.00

1. A preanesthesia assessment is performed that includes at least the following elements when evaluating risk and appropriateness of anesthesia for the patient:
   - Identify airway problems that may influence the type of anesthesia used.
   - Evaluate at-risk patients for appropriateness of anesthesia.
   - Select the anesthesia and plan anesthesia care.
   - Safely administer an anesthetic based on patient assessment, identified risks, and type of procedure.
   - Interpret findings from patient monitoring during anesthesia and recovery.
   - Provide information for the use of analgesia following surgery.
2. A separate preinduction assessment is performed to reevaluate patients immediately before the induction of anesthesia.
3. The preanesthesia assessment and the preinduction assessment are performed by an individual(s) qualified to do so and documented in the patient's medical record.
4. Ⓓ The scope and content of the preanesthesia assessment and the preinduction assessment are based on professional guidelines and defined in hospital policy.

Standard ASC.03.01

Each patient's anesthesia plan of care is discussed with the patient and/or those who make decisions for the patient and documented in the patient's medical record.

Intent of ASC.03.01

The anesthesia planning process includes educating the patient, their family, and/or decision-makers on the risks, benefits, and alternatives related to the planned anesthesia. This discussion occurs as part of the process to obtain consent for anesthesia as required in Standard PCC.03.00. Anesthesia care is carefully planned. The plan includes information from other patient assessments and identifies the anesthesia to be used, the method of administration, other medications and fluids, monitoring procedures, and anticipated postanesthesia care. An anesthesiologist or a qualified individual provides this education.

When postoperative pain management is provided by anesthesia services, the postoperative pain management plan is reviewed and discussed with the patient by the anesthesiologist or other qualified individual and documented in the patient's medical record. The anesthesia agent, dose (when applicable), anesthetic technique, and qualified individual administering the anesthesia are documented in the patient's anesthesia record.

Measurable Elements of ASC.03.01

1. A qualified individual plans and documents the anesthesia care in the patient's medical record.
2. The patient, family, and/or decision-makers are educated on the risks, benefits, and alternatives of anesthesia. (*See also* PCC.04.00, ME 1)
3. When applicable, the patient, family, and/or decision-makers are educated, prior to the procedure being performed, about the options available for postoperative pain management; this education is documented.
4. The anesthesia agent, dose (when applicable), and anesthetic technique are documented in the patient's anesthesia record.
5. The anesthesiologist, or other qualified individual allowed to administer anesthesia, and the anesthesia assistants are identified in the patient's anesthesia record.
6. Ⓓ Anesthesia care is administered and monitored according to professional practice guidelines and as defined in hospital policy.

Standard ASC.03.02

Each patient's physiological status during anesthesia and surgery is monitored according to professional practice guidelines and documented in the patient's medical record.

Intent of ASC.03.02

Physiological monitoring provides reliable information about the patient's status during anesthesia (general, spinal, and regional) and the recovery period. Monitoring information guides medical and nursing care and identifies the need for diagnostic and other services. Results of monitoring trigger key intraoperative decisions as well as postoperative decisions, such as return to surgery, transfer to another level of care, or discharge. Monitoring findings are entered into the patient's medical record. Monitoring methods depend on the patient's preanesthesia status, the anesthesia choice, and the complexity of the surgical or other procedure performed during anesthesia. In all cases, however, the overall monitoring during anesthesia and surgery is consistent with professional practice and defined in hospital policy. The results of monitoring are documented in the patient's medical record.

Measurable Elements of ASC.03.02

1. The frequency and type of monitoring during anesthesia and surgery are based on the patient's preanesthesia status, the anesthesia used, and the surgical procedure performed.
2. Monitoring of the patient's physiological status is consistent with professional practice guidelines.
3. The results of monitoring are documented in the patient's medical record. (*See also* COP.01.00, ME 5)

Standard ASC.03.03

Each patient's postanesthesia status is monitored, and the patient is discharged from the recovery area by a qualified individual or by using established criteria.

Intent of ASC.03.03

The ongoing, systematic collection and analysis of data on the patient's status in recovery support decisions about moving the patient to other settings and less intensive services. Monitoring during the anesthesia period is the basis for monitoring during the postanesthesia recovery period. Monitoring consists of several elements, such as the list of physiological criteria to be monitored, frequency of monitoring and documentation, and general guidance and/or parameters for recovery goals. Monitoring during the postanesthesia recovery period must be performed according to professional practice guidelines and as defined in hospital policy. Recording of monitoring data provides the documentation to support discontinuing recovery monitoring or the discharge decisions. When the patient is transferred directly from the operating theatre to a receiving unit, monitoring and documentation are the same as would be required in the recovery room.

The time of arrival at and discharge from the recovery area (or the time recovery begins and the time of discontinuation of recovery monitoring) and monitoring findings for the postanesthesia recovery period are documented in the patient's medical record.

Measurable Elements of ASC.03.03

1. Ⓓ Patients are monitored during the postanesthesia recovery period according to professional practice guidelines and as defined in hospital policy.
2. Monitoring findings are documented in the patient's medical record.
3. Patients are discharged from the postanesthesia unit or recovery monitoring is discontinued in accordance with one of the following alternatives:
   - The patient is discharged, or recovery monitoring is discontinued, by a fully qualified anesthesiologist or other individual authorized by the individual(s) responsible for managing the anesthesia services.
   - The patient is discharged, or recovery monitoring is discontinued, by a nurse or similarly qualified individual in accordance with postanesthesia criteria developed by hospital leaders, and the patient's medical record contains evidence that criteria are met.
   - The patient is discharged to a unit that is capable of providing postanesthesia or postsedation care for selected patients, such as a cardiovascular intensive care unit or neurosurgical intensive care unit, among others.
4. The following anesthesia recovery times are recorded in the patient's medical record:
   - Time recovery starts
   - Time recovery phase is complete

Surgical Care

Standard ASC.04.00

Each patient's surgical care is planned based on the results of the preoperative assessment and documented in the patient's medical record.

Intent of ASC.04.00

The *preoperative assessment* is a clinical risk assessment to determine if it is safe for the patient to undergo surgery; therefore, it is an important deciding factor to move forward with planning the surgical procedure.

In addition, the assessment is used to select the appropriate surgical procedure and determine patient needs related to the surgery.

The preoperative assessment evaluates the patient's condition and needs prior to surgery. The assessment includes the following:

- Physical exam and test results
- Medical needs
- Psychological needs
- Social needs (for example, safe housing and support with activities of daily living)
- Economic needs (for example, ability to pay for postoperative medication or medical equipment)
- Discharge needs (for example, transfer to rehabilitation center or home nursing needs)

Results of the preoperative assessment are documented in the patient's medical record prior to surgery. The assessment provides information necessary to do the following:

- Select the appropriate surgical procedure and the optimal time to perform the surgery.
- Perform the procedure safely.
- Interpret the findings of patient monitoring during surgery.

Surgical procedure selection depends on such factors as the following:

- Patient history
- Physical status
- Diagnostic data
- Risks and benefits of the procedure for the patient

Procedure selection considers the information from the initial assessments and reassessments, diagnostic tests, and other available sources. The assessment process is carried out in a shortened time frame when an emergency patient needs surgery.

The planned surgical care is documented in the patient's medical record and includes a preoperative diagnosis. The name of the surgical procedure alone does not constitute a diagnosis.

Measurable Elements of ASC.04.00

1. A preoperative assessment is performed and documented by a qualified provider before surgery.
2. The preoperative assessment includes the following:
    - Physical exam and test results
    - Medical needs
    - Psychological needs
    - Social needs
    - Economic needs
    - Discharge needs
3. Surgical care for each patient is planned based on the preoperative assessment information.
4. A preoperative diagnosis and the planned surgical procedure are documented in the patient's medical record prior to the procedure.

Standard ASC.4.01

The risks, benefits, and alternatives are discussed with the patient and their family or those who make decisions for the patient.

Intent of ASC.04.01

Adequate information and education must be provided to the patient, their family, and/or decision-makers on the risks, benefits, and alternatives related to surgical care to participate in care decisions and to provide the informed consent required in Standard PCC.03.00. Patient education and engagement can be promoted

through improvement in the patient and family's health literacy (the ability to obtain, understand, and act on health information); for example, providing information that a reasonable patient would want and would need to know that relates to the planned surgical procedure and care to make an informed decision. In addition, when blood or blood products may be needed, information on the risks and alternatives is discussed. The patient's surgeon or other qualified individual, as defined by the hospital, provides this information.

Measurable Elements of ASC.04.01

1. The patient, family, and/or decision-makers are educated on the following elements related to the planned surgical procedure:
   - Name of test, procedure, or treatment covered by the informed consent
   - Name of responsible practitioner(s) performing the procedures(s)
   - Risks and benefits of the planned procedure
   - The likelihood of success, potential complications, the recovery process, and possible results of nontreatment
   - Surgical and nonsurgical options and/or alternatives available to treat the patient
   - The need for, risks and benefits of, and alternatives to blood and blood-product use
2. Ⓓ The patient's surgeon, or other qualified individual as defined by hospital policy, provides and documents the education.

Standard ASC.04.02

Information about the surgical procedure is documented in the patient's medical record to facilitate continuing care.

Intent of ASC.04.02

A patient's postsurgical care depends on the events and findings of the surgical procedure. Most important, all actions and results essential to the patient's condition are entered in the patient's medical record. Patient information can be presented in various formats, such as templates (either paper or electronic), an operative report such as a written operative progress note, or nursing or other treatment or care service notes. To support a continuum of postsurgical supportive care, the information about the surgery is recorded in the patient's medical record immediately after surgery, prior to the patient being transferred from the surgical or the postanesthesia recovery area. The time immediately after surgery is defined as "upon completion of surgery, before the patient is transferred to the next level of care."

Information may also be contained in other notations in the medical record. For example, amount of blood loss and transfused blood may be recorded in the anesthesia record, or information about implantable devices may be shown using a manufacturer's preprinted sticker. Defining the time immediately after surgery (for example, "upon completion of surgery, before the patient is transferred to the next level of care") ensures that pertinent information is available to the next caregiver. If the surgeon accompanies the patient from the operating theatre to the next unit or area of care, the operative note, template, or progress note can be written in that unit or area of care.

Note: Documentation of information on nonsurgical procedures and treatments, such as invasive diagnostic procedures, interventional treatments, and other diagnostics and treatments, is identified in COP.01.01.

Measurable Elements of ASC.04.02

1. Surgical reports, templates, or operative progress notes include at least the following elements:
   - Preoperative diagnosis and planned procedure
   - Postoperative diagnosis
   - Name of operative surgeon and assistants
   - Procedures performed and description of each procedure findings

- Perioperative complications
- Tubes and/or drains placed intraoperatively
- Surgical specimens sent for examination
- Amount of blood loss and amount of transfused blood
- Date, time, and signature of responsible physician

2. The hospital identifies information that may routinely be recorded in other specific areas of the medical record.
3. The surgical report, template, or operative progress note is available immediately after surgery before the patient is transferred to the next level of care.

Standard ASC.04.03

Patient care after surgery is planned and documented.

Intent of ASC.04.03

Each patient's postsurgical medical and nursing care needs differ depending on the surgical procedure performed and the health history of the patient. Postsurgical care planning can begin before surgery based on the patient's assessed needs and condition and the type of surgery being performed. Some patients may require care from other services, such as physical therapy or rehabilitation; therefore, it is necessary to plan for that care, including the level of care, care setting, follow-up monitoring or treatment, and the need for medication or other treatment and services. The postsurgical plan of care also includes the patient's immediate postoperative needs.

The postsurgical care is planned, documented in the patient's medical record within 24 hours, and verified by the responsible service to ensure continuity of services during the recovery or rehabilitative period. Postsurgical needs may change as the result of clinical improvement or new information from a routine reassessment, or they may be evident from a sudden change in the patient's condition. The plan of care is revised based on these changes and documented in the medical record as notes to the initial plan or as a revised or new plan of care.

Measurable Elements of ASC.04.03

1. All postsurgical care, treatment, and services meet the patient's immediate postsurgical needs.
2. The continuing postsurgical plan(s) is documented in the patient's medical record within 24 hours by the responsible surgeon or verified by a co-signature from the responsible surgeon on the documented plan entered by the surgeon's delegate.
3. The continuing postsurgical plan of care includes care, treatment, and services based on the patient's assessed needs.
4. When indicated by a change in the patient's needs, the postsurgical plan of care is updated or revised based on the reassessment of the patient by the health care practitioners. (*See also* COP.01.01, ME 3)

Standard ASC.04.04

Surgical care that includes the implanting of a medical device is planned with special consideration for how standard processes must be modified.

Intent of ASC.04.04

Surgical procedures involving the implantation of medical devices require that routine surgical care be modified to account for special factors. Surgical procedures that involve the implantation of a medical device are common for many medical specialties. Medical devices have become critical components of health care, not only in their effects on patient morbidity and mortality but also in their ability to extend the quality of life of the patient. An *implantable medical device* is defined as a device that is placed into a surgically or naturally

formed cavity of the body to continuously assist, restore, or replace a function or structure of the body; deliver medications; or monitor body functions throughout the useful life of the device. These special considerations may be incorporated into guidelines, protocols, operating policies, or other documents to guide the surgical team and facilitate consistent processes and outcomes.

An implantable medical device can be a prosthesis (such as a hip), a stent, a cardioverter defibrillator, a pacemaker, intraocular lenses, or an infusion pump, among other examples. The ability to track implantable medical devices is essential for tracking surgical site infections and identifying patients who may have received nonsterile implants. In addition, the tracking process allows the hospital to assess the reliability of the sterilization process. Therefore, the hospital has a process for tracking implantable medical devices.

In the event of a recall of an implantable medical device, the hospital informs and follows up with those patients who received the device. The hospital develops and implements a process for contacting and following up with the patients, including those who may be outside the country. The hospital determines the time frame for contacting patients (for example, within 24 hours of the official recall notification of a lifesaving device). This time frame may be longer for a non-lifesaving device. The patient receives information on the implantable device such as the unique device identifier, how long-term tracking of the device will be supported, the process for notification in case of a problem with the device, and education on how sharing device information supports patients' long-term health care, safety surveillance, and future research to advance practices and patient safety with the device.

Measurable Elements of ASC.04.04

1. The hospital's surgical services identify the types of implantable medical devices that are included within its scope of services.
2. Ⓓ Written policies and practices include, at least, the following:
   - Selection of devices based on current science and research
   - Verification that implants are present in the operating theatre
   - Verification of the qualifications and training of any outside technical staff required during the implant procedure (for example, the manufacturer's representative who may be required to calibrate the device)
   - Reporting process for implantable device–related adverse events
   - Reporting of implantable device malfunctions to regulatory agencies
   - Unique infection prevention and control considerations
   - Any special discharge instructions for the patient
3. The patient receives information on the implantable device that at the least includes the following:
   - Identifying information on the device, including the unique device identifier
   - How long-term tracking of the device will be supported
   - Process for notification in case of a problem with the device
   - Education on how sharing device information supports patients' long-term health care, safety surveillance, and future research
4. The hospital has a process for tracking implantable medical devices.
5. The hospital implements a process for contacting and following up with patients in a defined time frame after receiving notification of a recall of an implantable medical device.

Care of Patients (COP)

Overview

The most important responsibility of a health care organization and its staff is to provide safe and effective care and services to all patients. This requires effective communication, collaboration, and standardized processes to ensure that the planning, coordination, and implementation of care supports and responds to each patient's unique needs and goals.

Care may be preventive, palliative, curative, or rehabilitative and may include anesthesia, surgery, medication, supportive therapies, or a combination of these and is based on the assessment and reassessment of each patient. High-risk areas of care (including resuscitation, blood administration, organ and tissue transplantation) and care for high-risk or special needs populations require additional attention. Part of care delivery also includes identifying and reducing risk factors that could impact patient care such as risks associated with patients who may be suicidal, or at high risk for complications from a disease process or surgery.

Care for patients is provided by many disciplines and support staff. All individuals involved in patient care must have a clear role determined by licensure; credentials; certification; laws and regulations; an individual's particular skills, knowledge, and experience; and organization policies or job descriptions. Some care may be carried out by the patient, their family, or other trained caregivers. Additional support may also be provided by an appointed individual(s), such as a living donor advocate, who has knowledge about the care process and can independently inform patients on all considerations that could affect decision-making.

The delivery of care and services must be coordinated and integrated by all individuals caring for the patient. Working together with the patient and family, these individuals ensure that the following criteria are met:

- Based on assessment, care is planned to meet each patient's unique needs.
- The planned care is delivered to each patient.
- The patient's response to care is monitored.
- Planned care is modified when necessary, based on the patient's response.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Care Delivery for All Patients

COP.01.00 There is a uniform process for prescribing and completing treatment orders.

COP.01.01 An individualized plan of care is developed and documented for each patient.

COP.01.02 The provision of high-risk services is guided by professional practice guidelines, laws, and regulations.

Clinical Alarm System Management

COP.02.00 The hospital implements policies and procedures for safety of clinical alarm systems.

Recognition of Changes to Patient Condition

COP.03.00 Clinical staff are trained to recognize and respond to changes in a patient's condition.

Resuscitation Services

COP.04.00 Resuscitation services are available throughout the hospital.

Management of Patients at Risk of Suicide or Self-Harm

COP.05.00 The hospital has a process to identify and protect patients at risk for suicide and self-harm.

Food and Nutrition Therapy

COP.06.00 Food, nutrition products, and nutrition therapy are available to patients.

Pain Management

COP.07.00 Pain is managed effectively.

End-of-Life Care

COP.08.00 The hospital has a process to provide end-of-life care that addresses the needs of the patient and family and optimizes the patient's comfort and dignity.

Hospitals Providing Transplant Services

COP.09.00 The hospital informs patients and families about how to donate organs and other tissues.

COP.09.01 The hospital provides oversight for the process of organ and tissue procurement.

COP.09.02 The hospital's leaders provide resources to support the organ, tissue, and/or cell transplant program.

COP.09.03 The hospital identifies a qualified transplant program leader(s) and includes an interdisciplinary team that consists of clinical staff with expertise in the relevant transplant programs.

COP.09.04 There is a designated coordination mechanism for all transplant activities.

COP.09.05 The hospital complies with organ, tissue, and cell transplant responsibilities.

COP.09.06 The transplant program obtains informed consent specific to organ, tissue, and/or cell transplant from the transplant recipient candidate.

COP.09.07 The transplant program has documented protocols, clinical practice guidelines, or procedures for organ recovery and organ receipt to ensure the compatibility, safety, efficacy, and quality of human cells, tissues, and organs for transplantation.

COP.09.08 Clinical practice guidelines and clinical criteria guide the selection and care of organ, tissue, and cell transplant patients.

Transplant Programs Using Living Donor Organs

COP.10.00 Transplant programs that perform living donor transplantation adhere to local and regional laws and regulations and protect the rights of prospective or actual living donors.

COP.10.01 Transplant programs performing living donor transplants obtain informed consent specific to organ donation from the prospective living donor.

COP.10.02 Transplant programs that perform living donor transplants use clinical and psychological selection criteria to determine the suitability of potential living donors.

COP.10.03 Individualized patient care plans guide the care of living donors.

Standards, Intents, and Measurable Elements

Care Delivery for All Patients

Standard COP.01.00

There is a uniform process for prescribing and completing treatment orders.

Intent of COP.01.00

A uniform process for the prescription, completion, and documentation of patient orders contributes to the integration and coordination of patient care activities, more effective use of human and other resources, and the increased likelihood of better patient outcomes.

Each member of the health care team records observations and treatments in the patient's medical record. Many patient care activities require a qualified individual to prescribe an order for that activity. Examples of such activities include the following:

- Orders for laboratory testing
- Administration of medications
- Specific nursing care
- Nutrition therapy
- Rehabilitative therapy

These orders are documented in the patient's medical record and must be easily accessible.

Effective communication, which is timely, accurate, complete, unambiguous, and understood by the recipient, reduces errors and results in improved patient safety. Communication can be electronic, verbal, or written. Patient care circumstances that can be critically affected by poor communication include verbal and telephone patient care orders, verbal and telephone communication of critical test results, and handover communications.

Patient care orders given verbally in person and over the telephone, if permitted under local laws and regulations, are some of the most error-prone communications. Different accents, dialects, and pronunciations can make it difficult for the receiver to understand the order being given. For example, drug names and numbers that sound alike, such as erythromycin and azithromycin or fifteen and fifty, can affect the accuracy of the order. Background noise, interruptions, and unfamiliar drug names and terminology often compound the problem. When received, a verbal order must be transcribed as a written order, which adds complexity and risk to the ordering process.

Clinical and diagnostic procedures and treatments performed are documented in the patient's medical record. The outcomes or results of any treatment or procedure are documented in the patient's medical record. Information about who requested the procedure or treatment and the indication for the procedure or treatment are included in the documentation.

Orders should be in a designated section of the medical record (for example, an orders requisition form in a hard copy medical record or order entry section of an electronic health record). They should not be interspersed throughout various sections of the medical record (for example, the order requisition form and progress notes), as this increases the likelihood of a missed order. Safe practices for communicating orders and test results include the following:

- Limiting verbal communication of prescription or medication orders to urgent situations in which immediate written or electronic communication is not feasible. For example, verbal orders can be disallowed when the prescriber is present, and the patient's chart is available. Verbal orders can be restricted to situations in which it is difficult or impossible for hard-copy or electronic order transmission, such as during a sterile procedure.

- The development of guidelines for requesting and receiving test results on an emergency or stat basis, the identification and definitions of critical tests and critical values, to whom and by whom critical test results are reported, and monitoring compliance
- Writing down, or entering into a computer, the complete order or test result by the receiver of the information; using closed-loop communication with the receiver reading back the order or test result; and the sender confirming that what has been written down and read back is accurate. Permissible alternatives for when the read-back process may not always be possible may be identified, such as in the operating theatre and in emergent situations in the emergency department or intensive care unit.

Measurable Elements of COP.01.00

1. Ⓓ The hospital implements a written uniform process for prescribing patient orders that includes the following:
   - Information required in the order
   - Identifying orders that may be received verbally, via telephone, and via text (*See also* MMU.04.01, ME 6)
   - Who is qualified and permitted to prescribe patient orders (*See also* MMU.04.00, ME 1)
   - How and where orders are documented uniformly in patient medical records
   - Which staff are authorized to receive and record verbal, telephone, and text orders, in accordance with laws and regulations
   - Time frame in which verbal, telephone, and text orders must be signed by the prescriber
2. Diagnostic imaging and clinical laboratory test orders include a clinical indication/rationale when required for interpretation.
3. Complete verbal orders, including telephone orders, are documented and read back by the receiver and confirmed by the individual giving the order.
4. Procedures and treatments are carried out as ordered and are documented in the patient's medical record.
5. The results of procedures and treatments performed are documented in the patient's medical record. (*See also* ASC.03.02, ME 3)
6. Verbally reported test results are documented and read back by the receiver and confirmed by the individual giving the test result.

Standard COP.01.01

An individualized plan of care is developed and documented for each patient.

Intent of COP.01.01

The plan of care outlines care, treatment, and services to be provided to an individual patient. The overall goal of a plan of care is to achieve optimal clinical outcomes. The planning process is collaborative and uses the data from the initial assessment and reassessments performed by members of the health care team to identify and to prioritize the care, treatments, and services required to meet the patient's needs. The patient and family are involved in the planning process with the health care team.

The care plan is developed within 24 hours of admission as an inpatient and is updated as appropriate to reflect the patient's evolving condition. The plan of care is documented in the patient's medical record.

The plan of care for a patient must be related to their identified needs. Patient needs may change as the result of clinical improvement or new information from a routine reassessment (for example, abnormal laboratory or radiography results), or they may be evident from a change in the patient's condition (for example, loss of consciousness). The plan of care is revised based on these changes and is documented in the medical record as notes to the initial plan or as a new plan of care.

One method of developing care plans is to identify and establish measurable goals. Measurable goals can be chosen by the responsible practitioner with the nurse and other health care team members. Measurable goals are observable, achievable targets related to patient care and expected clinical outcomes.

Goals must be realistic, specific to the patient, and time-based to provide a means for measuring progress and outcomes related to the plan of care. Examples of measurable, realistic goals include the following:

- The patient will resume and maintain an adequate cardiac output as indicated by a heart rate, rhythm, and blood pressure that are within normal limits.
- The patient will demonstrate proper self-administration of insulin injections prior to hospital discharge.
- The patient will be able to walk from his bed to the visitor lounge with a standard walker, bearing weight as tolerated on the affected leg.

Note: A single, integrated plan of care that identifies measurable goals expected by each health care practitioner is preferable. It is good practice for the plan of care to reflect individualized, objective, and measurable goals to facilitate reassessment and revision of the plan of care.

Some departments may conduct multidisciplinary patient care conferences for patients receiving complex care from multiple services. Examples of such patients include the following:

- Patients receiving rehabilitative services
- Patients with multiple diagnoses in intensive care units
- Patients with complex discharge planning needs

Any results or conclusions from collaborative patient care team meetings or similar patient discussions are written in the patient's medical record.

Measurable Elements of COP.01.01

1. The care for each patient is planned by the responsible practitioner, nurse, and other members of the health care team within 24 hours of admission as an inpatient.
2. The plan of care is individualized based on the patient's initial assessment data and identified needs and is documented in the patient's medical record.
3. The plan of care is updated or revised based on any changes in the patient's condition and is documented in the patient's medical record. (*See also* AOP.01.05, ME 1; ASC.04.03, ME 4)
4. The results or conclusions of any patient care team meetings or other collaborative discussions are documented in the patient's medical record.

Standard COP.01.02

The provision of high-risk services is guided by professional practice guidelines, laws, and regulations.

Intent of COP.01.02

Providing high-risk services involves unique risks to patients and staff; the hospital establishes and implements guidelines and procedures to identify and decrease risks associated with these services. Some services are considered high risk because of the complex medical equipment, the nature of the treatment, the potential for harm to the patient, or toxic effects of certain high-risk medications.

High-risk care is supported by the use of such tools as the following:

- Clinical practice guidelines
- Hospital policy and procedures
- Clinical pathways

These tools are important for staff to understand and implement in a uniform manner. Hospital leaders are responsible for the following:

- Identifying services considered high risk in the hospital
- Using a collaborative process to develop written tools for guiding the uniform care
- Training staff in implementing these tools

Written tools for care must be tailored to the high-risk service to be effective in reducing risk. When providing high-risk services, the hospital establishes and implements guidelines and procedures that address the following:

- How care planning will occur, including special considerations related to the high-risk service
- The documentation required for effective communication among the care team
- Special consent considerations, if appropriate
- Patient-monitoring requirements, including the proper use of alarms
- Special qualifications or skills of staff involved in the care process
- The availability and use of specialized medical equipment

Hospital leaders identify additional risk for hospital-acquired conditions as the result of any procedures or plan of care. Examples of hospital-acquired conditions include the following:

- Deep vein thrombosis, pressure ulcers, and ventilator-associated infections in patients on life support
- Neurological and circulatory injury in restrained patients
- Bloodborne pathogen exposure in hemodialysis patients
- Central line infections
- Falls

When these risks are present, they must be prevented by educating staff and developing appropriate policies, guidelines, and procedures. The hospital uses measurement information to evaluate the services provided and integrates that information into the hospital's overall quality improvement program.

Measurable Elements of COP.01.02

1. Ⓓ Hospital leaders identify, in writing, the high-risk services, including at least the following when provided by the hospital:
   - Emergency services
   - Life support, including ventilators and extracorporeal membrane oxygenation
   - Infectious disease services
   - Dialysis
   - Restraints
   - Chemotherapy
   - Critical care services
2. Ⓓ Hospital leaders establish and implement written policies, procedures, and/or principles of care for high-risk services provided by the hospital.
3. Staff are trained to use the written tools for high-risk services.
4. Hospital leaders identify additional risks that may affect high-risk services and implement measures to reduce and/or prevent these risks.
5. Ⓓ Hospital-acquired conditions are tracked and included in the hospital's quality improvement program.

Clinical Alarm System Management

Standard COP.02.00

The hospital implements policies and procedures for safety of clinical alarm systems.

Intent of COP.02.00

Clinical alarm systems are intended to alert caregivers of potential patient problems or equipment malfunction. However, improperly managed clinical alarm systems compromise patient safety. Risk factors associated with alarm management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow or not appropriate for the patient's condition. Patient care areas have multiple alarm signals, and the noise from improperly managed alarms desensitizes staff and causes them to miss, ignore, or disable alarms. These issues vary greatly among hospitals and within different clinical areas in a single hospital. Hospital leaders must develop a systematic, coordinated approach to minimize risks associated with clinical alarm management.

Standardization contributes to safe alarm system management, but alarm management solutions may have to be designed for specific clinical units, groups of patients, or individual patients. In designing customized solutions for proper alarm management, leaders begin by identifying the most important alarm signals to manage. For example, the most common alarms to address in an adult cardiac population would be cardiac monitoring, and in labor and delivery fetal monitoring alarms may be the most common.

Consideration of the following can be helpful in determining alarm signals that may pose a risk to patient safety:

- Input from clinical staff
- Data from medical devices, including false or nonactionable alarms
- Risk to patients if the alarm signal is not attended to or if it malfunctions
- Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue
- Potential for patient harm based on internal incident history
- Published best practices and guidelines

Measurable Elements of COP.02.00

1. Ⓓ Hospital leaders implement a written management program for alarm signals that pose a risk to patient safety.
2. The program identifies the most important alarm signals to be managed based on the risk to patient safety.
3. Ⓓ Hospital leaders develop and implement strategies for managing alarms that include the following:
   - Clinically appropriate settings for alarm signals
   - Situations in which alarm signals can be disabled
   - Circumstances under which alarm parameters must be reviewed and/or be changed (for example, with significant changes in patient condition, when patients are transferred to different levels of care)
   - Identification of those who have the authority to set alarm parameters
   - Designation of those who have the authority to change alarm parameters
   - Reducing unnecessary alarm noise and improving alarm fatigue among the clinical staff
4. Clinical staff are educated on the purpose and operation of alarm systems for which they are responsible.
5. Staff responsible for the management of clinical alarms are trained and competent to do so.
6. Alarm systems, policies and procedures, and staff training procedures are reviewed as necessary and in accordance with the hospital's policy review process, at minimum every three years, to identify and implement improvements.

Recognition of Changes to Patient Condition

Standard COP.03.00

Clinical staff are trained to recognize and respond to changes in a patient's condition.

Intent of COP.03.00

Hospitals that implement a systematic approach to early recognition and response to changes in a patient's condition reduce cardiopulmonary arrests and patient mortality. It is essential to recognize the signs indicating a change or deterioration in the patient's condition. Often, a patient will exhibit early warning signs (for example, a worsening of vital signs or a subtle change in neurological status) shortly before experiencing significant clinical decline, resulting in a major event. Clinical staff use physiological criteria to assist in early detection of deteriorating patients. Most patients who experience cardiopulmonary or respiratory arrest experience clinical deterioration prior to arrest. Clinical outcomes improve when staff can identify these patients early and request additional assistance from specially trained individuals.

All clinical staff must receive education and training to recognize and intervene when a patient exhibits physiological signs that are outside of the normal range, indicating a potential for patient deterioration. Early response to changes in a patient's condition is critical to potentially preventing further deterioration.

Failure to rescue (FTR) is failure or delay in recognizing and responding to a hospitalized patient experiencing complications from a disease process or medical intervention and is a recognized cause of mortality in hospitals. Failure to rescue measures have been developed for various specialties, including the following:

- Adult and pediatric surgical services
- Adult cardiac care
- Trauma surgery
- Gastrointestinal surgery

Failure to rescue measures are selected based on the populations treated and services provided; data from these measures are used to identify opportunities for process improvement.

Early warning criteria, also known as early warning scores, are used to quickly determine patient condition or changes in patient condition. These criteria are evidence-based and age-specific. The hospital implements early warning criteria for all age groups it cares for. Examples of early warning criteria include the following:

- Early Warning Score (EWS)
- Modified Early Warning Score (MEWS)
- Pediatric Early Warning Score (PEWS)
- Neonatal Early Warning Score (NEWS)
- Revised Trauma Score (RTS)
- 10 Signs of Vitality score
- Pasero Opioid-Induced Sedation Scale (POSS)

Measurable Elements of COP.03.00

1. The hospital has a systematic process to recognize and respond to changes or deterioration of patient condition.
2. Ⓓ The hospital implements documented age-specific early warning criteria describing early signs of a change or deterioration in a patient's condition.
3. The hospital has a process for staff to seek additional assistance when they have concerns about a patient's condition based on the hospital's early warning criteria.
4. The hospital informs the patient and family how to seek assistance when they have concerns about a patient's condition.

Resuscitation Services

Standard COP.04.00

Resuscitation services are available throughout the hospital.

Intent of COP.04.00

The immediate initiation of chest compressions, respiratory support, and defibrillation when indicated impact patient outcomes, including preventing permanent injury, disability, or death. Therefore, resuscitation services must be available throughout the hospital to decrease response time and improve patient outcomes. Successful resuscitation of patients in cardiopulmonary arrest is dependent on critical interventions, such as early defibrillation and initiation of advanced life support. These services must be available to all patients, 24 hours a day, every day. Staff trained in resuscitation must have access to standardized medical equipment and medications for resuscitation.

Basic life support must be initiated immediately upon recognition of cardiac or respiratory arrest, and a process must be in place for providing advanced life support in fewer than 5 minutes. Although the requirement for COP.04.00, ME 3 is for a response under 5 minutes, the hospital should continually reevaluate its response times and make efforts to shorten the response time as much as possible. This may involve elements such as placement of emergency carts and equipment such as automated external defibrillators (AEDs) and assignment/location of staff who respond to resuscitation emergencies.

Resuscitation services, equipment, and staff training within the hospital must be based on clinical evidence and the population served (for example, if the hospital has a pediatric population, medical equipment for pediatric resuscitation must be available). The hospital performs internal reviews of previous emergency situations to evaluate response times and availability of appropriate equipment and identifies areas for improvement.

Note: *All areas of the hospital* includes all areas where treatment and services are provided, including treatment or diagnostic areas in separate buildings on the hospital campus. The hospital determines what resuscitation services, equipment, and training are provided based on its patient populations. These resources must be immediately available in all areas where specific patient populations receive services. For example, hospitals that treat children must have clinical staff trained in pediatric advanced life support, have standardized pediatric equipment and medications, and be able to appropriately select the size or dose of medication based on the child's weight or size.

Resuscitation equipment and medications are standardized throughout the hospital. Hospital leaders and clinical staff determine how to store and standardize equipment depending on the patient populations served, as in the following examples:

- Emergency departments that treat adults and children may have two separate resuscitation carts—one for adults and one for children—or one cart with designated drawers for adult and pediatric patients.
- Pediatric departments may have resuscitation carts that include weight-based equipment and medications appropriate for neonatal through young adult patients.
- Maternity wards may have resuscitation supplies for laboring patients in one resuscitation box and resuscitation supplies for newborns in a separate resuscitation box.

Advanced life support is provided in fewer than 5 minutes. Patient outcomes depend on high-quality cardiopulmonary resuscitation (CPR) and correct recognition of the causes and treatments for cardiopulmonary arrest. Therefore, at 5 minutes, an adequate amount of staff members trained in advanced life support must have arrived and initiated advanced life support protocols based on the patient's condition and clinical data. Adequate staff trained in advanced life support must remain present and available to support the resuscitation efforts until the event has concluded.

If the hospital has consistently initiated advanced life support in fewer than 5 minutes, quality data should be reviewed to determine how this time could be even shorter. An interdisciplinary committee can be formed to complete resuscitation services reviews. These reviews include resuscitation cases and data to identify and suggest practice and system improvements in resuscitation performance.

Measurable Elements of COP.04.00

1. Resuscitation services are available and provided to all patients 24 hours a day, every day, throughout all areas of the hospital.
2. Medical equipment for resuscitation and medications for basic and advanced life support are standardized and available for use based on the populations served. (*See also* MMU.03.01, ME 4)
3. In all areas of the hospital, basic life support is initiated immediately upon recognition of cardiac or respiratory arrest, and advanced life support is initiated in fewer than 5 minutes.
4. Ⓓ The hospital performs an internal review of all resuscitation events for effectiveness and makes efforts to improve identified areas for improvement, including the following at minimum:
   - How often early warning signs of clinical deterioration were present prior to in-hospital cardiac arrest in patients in unmonitored or noncritical care units
   - Timeliness of staff's response to a cardiac arrest
   - Timeliness of initiation of advanced cardiovascular life support (ACLS) to the shortest time possible
   - The quality of cardiopulmonary resuscitation (CPR)
   - Post–cardiac arrest care processes
   - Outcomes following cardiac arrest

Management of Patients at Risk of Suicide or Self-Harm

Standard COP.05.00

The hospital has a process to identify and protect patients at risk for suicide and self-harm.

Intent of COP.05.00

Suicide is considered a sentinel event. Patients being evaluated or treated for behavioral health conditions often have suicidal ideation. The hospital must implement screenings and assessments to identify patients at risk for suicide and self-harm to minimize the likelihood of a suicide or self-harm attempt.

Screening identifies those at risk or potentially in need of a further, more specialized assessment. An assessment is a systemic process done to evaluate needs that can then be fulfilled, or a plan made around them on how to meet those needs, thus the individual conducting the assessment should have an expertise or specialty in the field being assessed.

Validated screening tools are an effective way to identify individuals who require further assessment to determine risk for suicide. A validated screening tool is one that has been scientifically tested for reliability (the ability of the instrument to provide consistent results), validity (the degree to which the instrument is measuring the condition that it is designed to measure), sensitivity (the ability of the instrument to correctly identify individuals with the condition), and specificity (the ability of the instrument to correctly identify individuals without the condition). In addition, the hospital must select validated screening tools that are appropriate for the population (for example, age-appropriate).

When using validated screening tools, organizations should not change the wording of the questions because small changes can affect the accuracy of the tools.

It is important that organizations ensure that the chosen screening tool(s) is implemented and completed as directed by the creators of the tool(s). For example, the Columbia–Suicide Severity Rating Scale (C-SSRS) is a validated screening tool that contains six questions. Depending on the answer to the first two questions, additional questions apply. One or more questions may get missed if the tool is not implemented or completed as directed. Another example, the Ask Suicide-Screening Questions (ASQ) Suicide Risk Screen Tool, is a four-question validated screening tool, which also contains a fifth question to assess acuity. This question may get missed if the tool is not implemented or completed as directed. Therefore, if not completed as instructed, the validity of the tool to identify individuals who may be at risk for suicide is compromised. Ultimately, it is the responsibility of each organization to ensure that validated tools are implemented and completed accurately.

Hospitals that care for patients at risk for suicide and self-harm need to assess risks in the physical environment to identify areas and features that could be used to attempt suicide. Psychiatric hospitals and hospitals with psychiatric wards and units design, build, and maintain the environment in a manner that minimizes or eliminates risks identified in the environmental risk assessment. Nonpsychiatric units in hospitals assess clinical areas to identify objects that could be used for self-harm so they can be removed, or the risk posed by those items mitigated when needed, from the area around a patient who has been identified as high risk for suicide (for example, in psychiatric hospitals, securing windows that can be opened and removing anchor points, door hinges, and hooks that can be used for hanging; in nonpsychiatric hospitals, removing items such as blood pressure cuffs, phone cords, call light cords, and monitor wires when not needed for clinical care of the patient). In addition, the hospital should have a process to handle patient clothing and belongings to mitigate risks, such as removing and securing shoes with shoelaces and other patient items that could be used for self-harm. The hospital's environmental risk assessment process should be the starting point and should also include a plan for risk mitigation such as one-to-one observation when indicated.

Measurable Elements of COP.05.00

1. Ⓓ The hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used to attempt suicide or self-harm; the hospital takes necessary action to minimize the risk(s). (*See also* FMS.03.00, ME 1; FMS.04.00, ME 2)
2. Using a validated screening tool, the hospital screens all patients for suicidal ideation who are being evaluated or treated for behavioral conditions as their primary reason for care.
3. The hospital uses an evidence-based process to conduct a suicide assessment of patients who have screened positive for suicidal ideation. The assessment directly asks about suicidal ideation, plan, intent, suicidal or self-harm behaviors, risk factors, and protective factors.
4. Suicide screenings and assessments are documented in the patient's medical record or in accordance with laws and regulations when applicable.
5. Ⓓ The hospital follows written policies and procedures addressing the care of patients identified as at risk for suicide. At a minimum, the polices should include the following:
   - Training and competence assessment of staff who care for patients at risk for suicide
   - Guidelines for reassessment of patients who are at risk for suicide and self-harm
   - Monitoring patients who are at high risk for suicide and self-harm
6. Ⓓ The hospital follows written policies and procedures for counseling and follow-up care at discharge for patients identified as at risk for suicide and self-harm.
7. Ⓓ The hospital monitors implementation and effectiveness of policies and procedures for screening, assessment, and management of patients at risk for suicide and self-harm, and takes action as needed to improve compliance.

Food and Nutrition Therapy

Standard COP.06.00

Food, nutrition products, and nutrition therapy are available to patients.

Intent of COP.06.00

Appropriate food and nutrition contribute to improved patient outcomes, including wound healing, and management of complex diseases and disorders. Based on the patient's assessed needs, diagnoses, and plan of care, the patient's practitioner or other qualified caregiver orders food or other nutrients for the patient. The order may include special dietary requirements such as low cholesterol, diabetic diet, or clear liquids.

The patient participates in planning and selecting foods whenever possible. Patients are offered a variety of food choices consistent with their nutritional status when possible. The patient's family may participate in providing food consistent with cultural, religious, and other traditions and practices and compatible with the patient's diagnosis when appropriate. When the patient's family or others provide food to the patient, they are educated about foods that are contraindicated to the patient's care needs and plans, including information about any medications associated with food interactions. Food provided by family or others is stored under proper conditions, following current food storage guidelines, to prevent contamination.

Patients are screened to identify those who may be at nutritional risk during the initial assessment. These patients are referred to a nutritionist for further assessment. A plan for nutrition therapy is developed and carried out for patients at nutritional risk. Nutrition therapy includes the following:

- Enteral feedings
- Total parenteral nutrition
- Fortification of breast milk
- Other nutritional supplements

The patient's progress is monitored and recorded in their medical record. Physicians, nurses, the dietetics service, and, when appropriate, the patient's family collaborate to plan and to provide nutrition therapy.

Measurable Elements of COP.06.00

1. A variety of food choices or nutrition, consistent with the patient's condition, care, and needs, is regularly available.
2. There is an order for food in the patient's medical record based on the patient's nutritional status and needs prior to inpatients being fed.
3. The distribution of food is timely, and special requests are met.
4. When families provide food, they are educated about the patients' diet limitations.
5. Ⓓ Food and nutrition products, including those provided by family, are stored under proper conditions, following current food storage guidelines, to prevent contamination.
6. Patients determined to be at nutrition risk receive nutrition therapy.
7. A collaborative process is used to plan, deliver, and monitor nutrition therapy.
8. The patient's response to nutrition therapy is monitored and documented in the medical record.

Pain Management

Standard COP.07.00

Pain is managed effectively.

Intent of COP.07.00

Unrelieved pain has adverse physical and psychological effects, and patients in pain have the right to appropriate assessment and management of it. Pain may be part of the patient's experience and may be associated with the patient's condition or illness. Pain may also be an expected part of certain treatments, procedures, or examinations. Patients are informed about the likelihood of pain when it is an anticipated effect from treatments, procedures, or examinations and what options for pain management are available.

Based on the scope of services provided, the hospital has processes to manage pain appropriately, including the following:

- Identifying patients with pain during initial assessment and reassessments
- Providing information to patients about pain that may be an expected result of treatments, procedures, or examinations
- Providing management of pain, regardless of the origin of pain, according to guidelines or protocols and in alignment with patient goals for pain management
- Communicating with and educating patients and families about pain and symptom management in the context of their personal, cultural, and religious beliefs
- Educating clinical staff about pain assessment and management

Measurable Elements of COP.07.00

1. Patients are informed about the likelihood of pain and options for pain management when pain is an expected result of planned treatments, procedures, or examinations. (*See also* AOP.01.04, ME 3)
2. Patients in pain receive care according to pain management guidelines and in alignment with the patient's goals for pain management.
3. The hospital has processes to communicate with and to educate patients and families about pain. (*See also* ACC.01.04, ME 3)
4. The hospital provides education to clinical staff about pain assessment and management.

End-of-Life Care

Standard COP.08.00

The hospital has a process to provide end-of-life care that addresses the needs of the patient and family and optimizes the patient's comfort and dignity.

Intent of COP.08.00

End-of-life or dying patients have unique needs; the hospital implements processes to address these needs and to incorporate the patient's and family's preferences into the care processes. End-of-life care may be influenced by cultural and religious traditions. Concern for the patient's comfort and dignity guides all aspects of care during the final stages of life. All staff members are made aware of patients' needs at the end of life. These needs include but are not limited to the following:

- Treatment of primary and secondary symptoms
- Pain and discomfort management
- Response to the patient's and family's psychological, social, emotional, religious, and cultural concerns
- Involvement in care decisions

The patient assessment may identify symptoms that require management, such as nausea, respiratory distress, and pain; factors that alleviate or exacerbate physical symptoms; and the patient's response to symptom management. Identifying the patient's physical needs is just one aspect of determining the patient's end-of-life care. Patients and families may also have a need for spiritual, psychosocial, and support services, as appropriate to the patient's individual needs and cultural preferences.

End-of-life care provided by the hospital includes but is not limited to the following:

- Taking interventions to manage pain and discomfort
- Providing appropriate treatment for any symptoms according to the wishes of the patient and family
- Sensitively addressing such issues as autopsy and organ donation
- Respecting the patient's values, religion, and cultural preferences
- Involving the patient and family in all aspects of care
- Responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family

To accomplish these goals, all staff should be educated and trained to assess and manage the needs of patients and their families at the end of life. The hospital's goal for providing care at the end of life considers the settings in which care or service is provided (such as a hospice or palliative care unit), the type of services provided, and the patient population served. The hospital develops processes to manage end-of-life care, including the use of recognized assessment tools such as the Palliative Performance Scale, or others when appropriate. These processes include the following:

- Assessing and managing symptoms
- Defining the frequency of assessments
- Treating terminally ill patients with dignity and respect
- Planning preventive and therapeutic approaches to manage symptoms
- Educating patients, family, and staff about managing symptoms
- Providing support to the patient's family and/or caregivers
- Providing support to staff members caring for the dying patient

Measurable Elements of COP.08.00

1. The hospital has a process to assess and manage the needs of patients receiving end-of-life care.
2. Staff are educated and trained about assessing and managing needs of patients and their families at the end of life.
3. The hospital provides patient care and support services that accommodate the patient and their family with consideration of their personal, spiritual/religious, and cultural preferences.
4. End-of-life care addresses the symptoms, conditions, and health care needs of the dying patient as indicated by their assessment, including pain and comfort needs.
5. The patient and family are involved in end-of-life care decisions.
6. The hospital provides support to the patient's family, caregivers, and staff members caring for the dying patient.

Hospitals Providing Transplant Services

Note: The following standards are intended to be used in situations when patients request information about organ and tissue donation and/or when organ or tissue donation may occur. When organ or tissue donation and transplantation are performed, the standards for organ and tissue transplant programs apply. It is recognized that there are significant differences between organ and tissue transplants. The requirements apply to both, respectively, depending on the services the hospital offers. For example, if a hospital performs only tissue transplant services, the requirements then apply to the tissue transplant services offered by the hospital. The following are considered *tissue* and *cell products* for the standards below.

Examples of Tissue and Cell Products

- Amnion/amniotic membrane
- Arteries
- Autologous cells
- Autologous tissue
- Bone

- Bone marrow
- Bone paste
- Bone powder
- Bone putty
- Cancellous chips
- Cardiac (heart) valves (aortic, pulmonary)
- Cartilage
- Chondrocytes
- Cornea
- Demineralized bone matrix
- Dendritic cells
- Dermal matrix
- Dermis
- Dura mater
- Embryo
- Fascia/fascia lata
- Hematopoietic stem cells
- Leukocytes
- Ligaments
- Limbal graft
- Limbal stem cells
- Lymphocytes
- Marrow
- Membrane
- Meniscus
- Nerves
- Non-valved conduits
- Oocyte/ovarian cells
- Ovarian tissue
- Pancreatic islet cells
- Parathyroid
- Pericardium
- Peripheral blood stem cells
- Progenitor cells
- Sclera
- Semen, sperm
- Skin
- Somatic cells
- Tendons
- Testicular tissue
- Therapeutic cells (T-cell apheresis)/T-cells
- Tissue (also synthetic tissue)
- Trachea
- Umbilical cord blood stem cells
- Vascular graft
- Veins (saphenous, femoral, iliac)
- Other cellular- and tissue-based transplant or implant products whether classified by the US Food and Drug Administration (FDA) as a tissue or a medical device
- Other tissues that are classified as tissues by national or regional laws and regulations

Transplantation of organs is often a lifesaving procedure, and organ and tissue transplants are sometimes the only options for treatment of a wide range of diseases. Recent advances in transplantation have led to a greater success rate for transplanted organs and tissues. However, transplantation is not free from risk. Transmission of infections from the donor to the recipient is a well-documented safety concern. Diseases with documented transmission from infected donors after transplant include HIV, hepatitis B and C, and Creutzfeldt-Jakob disease (CJD). Recipients may also contract bacterial or fungal infections through contamination during transportation, storage, or handling.

Leaders' commitment to creating a culture conducive to organ and tissue donation can have significant impact on the overall success of the hospital's organ and tissue procurement efforts. These standards address the hospital's responsibilities for organ and tissue donation and procurement. This includes anyone determined medically suitable for donation by the organ procurement organization. If the hospital has the necessary resources to support the recovery of organs and tissues after cardiac death, non–heart-beating donors are included in the organ procurement effort.

Standard COP.09.00

The hospital informs patients and families about how to donate organs and other tissues.

Intent of COP.09.00

Patients and families receive information about the donation process and the way organ procurement is organized for the community, region, or nation (such as a national or regional organ procurement agency or network) to ensure organ donor and recipient safety. Many countries have developed procedures and systems to increase the supply of organs available for transplant. In some countries, laws determine that everyone is a donor unless specified otherwise. This is considered presumed consent. Other countries require explicit consent for organ donation.

The hospital is responsible for defining the process of obtaining and recording consent for cell, tissue, and organ donation in accordance with international ethical standards and the way organ procurement is organized in the hospital's country. The hospital has a responsibility to ensure that adequate controls are in place to prevent patients from feeling pressured to donate.

The hospital supports the choice of patients and families to donate organs and other tissues for research or transplantation. Information is provided to patients and families on the donation process and the way organ procurement is organized for the community, region, or nation.

Measurable Elements of COP.09.00

1. The hospital supports patient and family choices to donate organs and other tissues.
2. The hospital provides information to patients and families on the donation process.
3. The hospital provides information to the patient and family on the manner in which organ procurement is organized.
4. The hospital ensures that adequate controls are in place to prevent patients from feeling pressured to donate.

Standard COP.09.01

The hospital provides oversight for the process of organ and tissue procurement.

Intent of COP.09.01

Oversight for the process of organ and tissue procurement is needed to ensure that it is consistent with laws and regulations, respects the community's religious and cultural values, and is ethical. One of the primary

goals for oversight of the process for organ and tissue procurement is establishing requirements for consent. Hospital staff are trained on the donation process and support patient and family choices about the donation of organs and tissues. Staff are also trained in contemporary concerns and issues related to organ donation and availability of transplants. The hospital cooperates with other hospitals and agencies in the community responsible for all or a portion of the procurement, banking, transportation, or transplantation process.

Measurable Elements of COP.09.01

1. Ⓓ The hospital develops a written organ and tissue donation and procurement process that is consistent with the region's laws and regulations and its religious and cultural values.
2. The hospital identifies consent requirements for organ and tissue donation and procurement and develops a consent process consistent with those requirements.
3. Staff are trained on the issues and concerns related to organ donation and tissue procurement and the availability of transplants.
4. The hospital cooperates with relevant hospitals and agencies in the community to respect and to implement choices to donate.

Standard COP.09.02

The hospital's leaders provide resources to support the organ, tissue, and/or cell transplant program.

Intent of COP.09.02

The transplant program requires staff with specialized education, training, and resources to provide safe, high-quality care. Staff education and training must be specific to the responsibilities and requirements of transplants provided by the hospital. Other essential resources include supplies; patient rooms with ventilation required for the type of transplant procedure (for example, positive pressure ventilation); required pharmaceuticals for the type of transplant procedure; laboratory testing to ensure that tissues, organs, and cells are not contaminated; and other resources as identified by the program service leader. Resources related to information management systems are necessary to help collect data associated with risks, outcomes, and other information that support the transplant program's quality.

Measurable Elements of COP.09.02

1. Staff education and training are specific to the types of organs, tissues, and/or cell transplants provided by the hospital.
2. The hospital's leaders allocate resources for the transplant program.
3. Information management systems are used to support the quality of the transplant program.

Standard COP.09.03

The hospital identifies a qualified transplant program leader(s) and includes an interdisciplinary team that consists of clinical staff with expertise in the relevant transplant programs.

Intent of COP.09.03

Oversight by a qualified individual(s) and the inclusion of an interdisciplinary care team ensures the quality and safety of transplant services and improves the success of the transplant and associated patient outcomes.

A qualified individual(s) must be responsible for supporting and overseeing all transplant program activities. This individual(s) has support and oversight defined in a job description and is qualified to manage transplant services through education, training, experience, licensure, and/or certification. The required qualifications depend on the activities carried out.

Transplant recipients and living donors have specific nursing, psychological, pharmacological, and nutritional needs. As related to the type of transplant, an interdisciplinary team consists of individuals from the following:

- Medicine
- Nursing
- Nutrition
- Pharmacology
- Infection prevention and control
- Social services
- Fertility services
- Psychological services
- Rehabilitative services

This team should have the qualifications, training, and experience to provide care and services to transplant recipients and living donors. Hospitals with transplant programs consider the types of organs and/or tissues harvested and/or transplanted when creating their interdisciplinary transplant teams. These teams are formed with consideration for the specific risks, challenges, needs, laws and regulations, and professional guidelines for each type of transplant.

Measurable Elements of COP.09.03

1. Ⓓ The transplant program has an infrastructure, including systems and written policies and procedures, capable of supporting all aspects of the program.
2. A qualified individual(s) oversees and manages the transplant program.
3. The individual(s) fulfills the program's oversight responsibilities as defined by the transplant program.
4. Ⓓ The transplant program documents the composition of each transplant team(s).
5. Ⓓ The transplant program documents the team members' responsibilities.
6. Based on the services provided by the transplant team, the team includes individuals experienced in medicine, nursing, nutrition, pharmacology, infection prevention and control, social services, psychological services, rehabilitative services, and transplant coordination.
7. The transplant program evaluates team members for qualifications, training, and experience at the time each individual is being considered for the transplant team.

Standard COP.09.04

There is a designated coordination mechanism for all transplant activities.

Intent of COP.09.04

An important component in ensuring safe, high-quality care through all phases of the donor/recipient process is ensuring the coordination and continuity of the live donor's and transplant recipient's care. Transplant services carry unique and critical risks to organ, tissue, and cell recipients and, in the case of living donors, to the donor. The complex care required by the donor and recipient necessitate a coordination mechanism, typically a qualified clinical staff member. This individual ensures continuity of care for the donor and/or the recipient throughout the transplant process. This individual is also responsible for communication with the care team about the donor's and/or recipient's care. This may occur through facilitated meetings and documentation.

The individual responsible for the coordination of all transplant activities may be a physician, registered nurse, or other qualified clinical staff member—this individual may be known as a "transplant coordinator."

Measurable Elements of COP.09.04

1. The individual responsible for the coordination of the live donor's and transplant recipient's care is identified and available through all phases of transplant care.
2. The hospital ensures that continuity of care for transplant patients (candidates and recipients) is facilitated through the pre-transplant, transplant, and discharge phases of transplantation.
3. Continuity of care is facilitated for living donors during the evaluation, donation, and discharge phases of donation.
4. The coordination of all transplant activities is communicated to all staff involved in the transplant program activities.

Standard COP.09.05

The hospital complies with organ, tissue, and cell transplant responsibilities.

Intent of COP.09.05

Organs, tissues, and cells are a limited resource. The hospital ensures that organs, tissues, and cells are managed in a way that protects these resources and ensures their integrity. Organ, tissue, and cell donation, procurement, and transplantation are highly regulated. The hospital complies with all rules and regulations set by the local, regional, or national procurement and transplantation network(s). These networks often require various data regarding transplant services to monitor the quality of these services and to allocate organs, tissues, and cells only to hospitals with successful, compliant programs.

The hospital implements procedures for the handling of all organs, tissues, and cells to ensure their safe handling and to ensure that patients receive the correct organ, tissue, or cells in a condition that increases the likelihood of a successful transplantation. Organs, tissues, and cells have specific requirements for their transportation and storage until transplantation. The hospital fully implements these conditions to maintain the viability of the organ, tissue, and cells. In addition, the hospital has a process to track transplanted organs, tissues, and cells for data collection purposes, including outcomes of the transplant and ability to recall any transplants.

Measurable Elements of COP.09.05

1. The hospital performing solid organ, tissue, and/or cell transplants complies with all rules set by the local, regional, or national procurement and transplantation network.
2. The hospital performing solid organ transplants shares all data related to transplant processes required by the local, regional, or national procurement and transplantation network.
3. Ⓓ The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of organs, tissues, and/or cells.
4. Ⓓ The hospital verifies at the time of receipt of the organ that package integrity is met, and transport temperature range was controlled and acceptable for the organ(s), tissues, and/or cells. This verification is documented.
5. Ⓓ The hospital follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.
6. The hospital follows a process to track transplanted tissues.
7. Ⓓ Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store organs, tissues, and cells at a controlled temperature have functional alarms and an emergency backup plan.

Standard COP.09.06

The transplant program obtains informed consent specific to organ, tissue, and/or cell transplant from the transplant recipient candidate.

Intent of COP.09.06

Organ, tissue, and cell transplants carry unique risks; to make an informed decision about whether to proceed with a transplant, the potential recipient must be informed of these risks and challenges. To consent, a patient must be informed of those factors related to the planned care required for an informed decision. Patients are informed about factors that could affect the success of the graft or the candidate's health as a recipient.

In addition, there may be psychological, ethical, financial, and other factors that are unique to the transplant patient, such as the need for immunosuppressive medications and the projected survival rate. The patient needs to be informed of all special considerations as part of the consent process. The transplant program also follows the hospital's policy for informed consent and local and regional laws and regulations.

Measurable Elements of COP.09.06

1. Ⓓ The transplant program follows the hospital's written policy when obtaining informed consent from solid organ, tissue, and/or cell transplant candidates. (*See also* PCC.03.00, MEs 1 and 2)
2. The transplant program informs the prospective transplant candidate of organ donor risk factors that could affect the success of the graft or the candidate's health as a recipient, including but not limited to the following:
   - Donor's history, as appropriate to the laws and regulations of the country/region
   - Condition of the organ(s) used
   - Age of the organ(s)
   - Potential risk of contracting infectious disease(s) if disease(s) cannot be detected in an infected donor
   - Potential psychosocial risks
3. The transplant program informs the prospective transplant candidate of the transplant center's observed and expected one-year survival rate following solid-organ transplant; or, when the transplant program has been in operation less than 18 months, the one-year survival rate as documented in the literature.
4. The transplant program informs the prospective solid organ, tissue, and/or cell transplant candidate about potential rejection rates, immunosuppressive drugs, and possible associated costs, as applicable to the type of transplant.
5. The transplant program informs the prospective organ, tissue, and/or cell transplant candidate of alternative treatments.

Standard COP.09.07

The transplant program has documented protocols, clinical practice guidelines, or procedures for organ recovery and organ receipt to ensure the compatibility, safety, efficacy, and quality of human cells, tissues, and organs for transplantation.

Intent of COP.09.07

To reduce the risk of organ, tissue, or cell rejection, the transplant surgeon must ensure the compatibility of the donor organ(s), tissue, and/or cells to the recipient. Transmission of infectious diseases and malignancies is a potential risk for recipients of donor cells, tissues, and organs.

Therefore, the level of safety, efficacy, and quality of human cells, tissues, and organs for transplantation must be ensured. Evaluation of organ and tissue donors may identify those donors who have a higher risk for infection with a potentially harmful pathogen. Donor screening of clinical history and donor testing for communicable diseases can significantly reduce the incidence of donor transmission of disease. Donor screening should include evaluation of medical history, behavioral risk factors, and a physical examination. Donor testing should include tests for HIV, hepatitis B, hepatitis C, and other recommended tests.

The most frequently used tests for compatibility include blood typing and crossmatching and tissue typing. The transplant surgeon ensures that testing for compatibility occurs before organ recovery and organ transplantation take place. For any transplantation of human material, traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed-on means of coding to identify tissues and cells used in transplantation are essential for full traceability.

Measurable Elements of COP.09.07

1. Ⓓ The transplant team follows written organ recovery protocols, clinical practice guidelines, or procedures, which include reviewing the essential donor data and recipient data to ensure compatibility before organ, tissue, or cell recovery takes place.
2. The transplant surgeon is responsible for confirming, in writing, the medical suitability of donor organs, tissues, and cells for transplantation into the recipient.
3. When an organ or tissue arrives at the transplant center, the transplanting surgeon and at least one other health care practitioner at the transplant center verify and document that the donor's blood type and other essential data are compatible with the recipient prior to transplantation.
4. The transplant surgeon is responsible for confirming that donor evaluation and donor testing for infectious diseases and malignancy have been completed, and are documented in the medical record, before organ, tissue, or cell recovery and transplantation occur.
5. When an organ arrives at the transplant center, the transplanting surgeon and at least one other health care practitioner at the transplant center verify and document that evaluation and testing of the donor organ shows no evidence of disease and the condition of the organ is suitable for transplant.

Standard COP.09.08

Clinical practice guidelines and clinical criteria guide the selection and care of organ, tissue, and cell transplant patients.

Intent of COP.09.08

Individualized care plans are developed and guide the care of transplant patients in conjunction with clinical practice guidelines, as the care of the patient donating or receiving a cell, organ, or tissue transplant is based on the type of transplant and individual needs. The patient's health history has an impact on their recovery. In addition, the patient's psychological status may impact the transplant's success. A psychological evaluation will be conducted by a psychiatrist, psychologist, social worker, or other qualified health care professional with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness.

Measurable Elements of COP.09.08

1. Ⓓ The transplant program has documented cell-, tissue-, and/or organ-specific clinical practice guidelines for the pre-transplant, transplant, and discharge phases of transplantation.
2. Each transplant patient is under the care of a multidisciplinary patient care team coordinated by the patient's primary transplant physician throughout the pre-transplant, transplant, and discharge phases of transplantation.
3. Transplant recipient candidates are evaluated for the suitability of other medical and surgical therapies that may yield short- and long-term survival rates comparable to transplantation.
4. Transplant recipient candidates receive a psychological evaluation by a psychiatrist, psychologist, social worker, or other qualified health care professional with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness.
5. The transplant program updates clinical information in the transplant donor's and/or recipient's medical record on an ongoing basis.
6. The transplant program documents organ compatibility confirmation in the living donor's medical record.

Transplant Programs Using Living Donor Organs

Standard COP.10.00

Transplant programs that perform living donor transplantation adhere to local and regional laws and regulations and protect the rights of prospective or actual living donors.

Intent of COP.10.00

Living donors face difficult decisions and are at potential risk for lifelong complications and should not feel coerced or pressured into organ donation. The growing demand for and limited supply of organs from deceased donors have resulted in increased efforts to promote live organ donation. Living donor standards for the selection of suitable candidates for donation, informed consent, and care following the donation do not universally exist.

To help with decisions and to ensure that the living donor's rights are protected, an individual with knowledge of living organ donation, transplantation, medical ethics, and informed consent is identified and appointed to protect the patient's rights. This person is independent of the transplant team and if employed by the hospital does not report to any member of the transplant team. The goal of this person is to ensure that the living donor understands all aspects of the donation process and is autonomous in their decision-making abilities.

Measurable Elements of COP.10.00

1. Transplant programs that perform living donor transplantation adhere to local and regional laws and regulations.
2. The living organ donor has the right to make a decision about donation in a setting free of coercion and pressure.
3. An individual with knowledge of living organ donation, transplantation, medical ethics, and informed consent is identified and appointed as an advocate for the living donor.
4. The individual appointed as the living donor advocate is not involved in routine transplantation activities.
5. The individual appointed as the living donor advocate informs, supports, and respects the living donor in a culturally appropriate manner during decision-making.

Standard COP.10.01

Transplant programs performing living donor transplants obtain informed consent specific to organ donation from the prospective living donor.

Intent of COP.10.01

The prospective donor needs to thoroughly understand all aspects of the donation process, particularly to understand the risks and benefits associated with being a living donor. Many living donors give their organ to a family member or acquaintance; however, some living donors do not influence the placement of their donated organ. A very important aspect of obtaining informed consent is to ensure that the prospective donor is willing to donate and has not been coerced or promised compensation and understands that they may decline to donate at any time. The consent process includes information provided to any patient undergoing anesthesia, sedation, or surgery, and information specific to transplant.

Measurable Elements of COP.10.01

1. Ⓓ Informed consent for living donation is obtained by trained staff and is in a language the prospective living donor can understand. (*See also* PCC.03.00, MEs 1 and 2)
2. The transplant program informs the prospective living donor of potential complications, risks (including psychological risks), and future health problems associated with living organ donation.
3. The transplant program informs the prospective living donor of alternative treatments for the transplant candidate.
4. The transplant program informs the prospective living donor of the donor's right to opt out of donation at any time during the donation process.

Standard COP.10.02

Transplant programs that perform living donor transplants use clinical and psychological selection criteria to determine the suitability of potential living donors.

Intent of COP.10.02

Organ donors must be evaluated for suitability, both physical and psychological, as an organ donor. The medical evaluation determines the donor's physical ability to donate and identifies any immediate health risks and possible future health risks. The psychological evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine decision-making capacity, screen for any preexisting psychiatric illness, and evaluate any potential coercion. The donor must also be evaluated for their ability to comprehend the donation process and the potential outcomes, including possible adverse outcomes.

Measurable Elements of COP.10.02

1. Ⓓ The transplant program documents defined organ-specific living donor selection criteria.
2. The transplant program's living donor selection criteria are consistent with laws and regulations and the principles of medical ethics. (*See also* GLD.07.00, ME 1)
3. The results of a medical evaluation related to the living donor's own physical health are included in the determination of suitability for donation.
4. The results of medical tests identifying infectious diseases or malignancies are included in the determination of suitability for donation.
5. The results of a psychological evaluation conducted by a psychiatrist, psychologist, or social worker with experience in transplantation are documented in the living donor's medical record and included in the determination of suitability for donation.
6. The transplant program documents organ compatibility confirmation in the living donor's medical record.

Standard COP.10.03

Individualized patient care plans guide the care of living donors.

Intent of COP.10.03

The living donor has unique treatment and health care needs that require specific consideration. Individualized care plans are developed and implemented for all living donors. Live donor transplants are guided by living donor guidelines. However, donors have individual needs that must be addressed through careful care planning. The care of the donor is coordinated by a physician and carried out by a multidisciplinary team to ensure that the donor's needs are met prior to, during, and following donation.

Measurable Elements of COP.10.03

1. Ⓓ Transplant programs performing living donor transplants are guided by documented living donor guidelines for care in the evaluation, donation, and discharge phases of donation.
2. Transplant programs performing living donor transplants provide interdisciplinary care by a team coordinated by a physician to each donor throughout the donor evaluation, donation, and discharge phases of donation.
3. The living donor candidate receives ongoing psychological support following donation.

International Patient Safety Goals (IPSG)

Overview

This chapter addresses the International Patient Safety Goals (IPSG), required for implementation as of 1 January 2011 in all organizations accredited by Joint Commission International (JCI) under the International Accreditation Standards for Hospitals.

The purpose of the International Patient Safety Goals is to promote specific improvements in patient safety. The goals highlight problematic areas in health care and describe evidence- and expert-based consensus solutions to these problems. Recognizing that sound system design is intrinsic to the delivery of safe, high-quality health care, the goals generally focus on systemwide solutions, wherever possible.

The goals are structured in the same manner as the other standards, including a standard (goal statement), an intent statement, and measurable elements (MEs). The goals are scored similar to other standards as "met" or "not met." The accreditation decision rules include compliance with the goals as a separate decision rule.

Goals and Standards

The following is a list of all goals and standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Goals, Standards, Intents, and Measurable Elements.

Goal 1: Identify Patients Correctly

IPSG.01.00 The hospital implements a process to improve accuracy of patient identifications.

Goal 2: Improve Effective Communication

IPSG.02.00 The hospital implements a process for reporting critical results of diagnostic tests.

IPSG.02.01 The hospital implements a standardized process for handover communication.

Goal 3: Improve the Safety of Medications

IPSG.03.00 The hospital implements a process to improve the safety of high-alert medications.

IPSG.03.01 The hospital implements a process to improve the safety of look-alike/sound-alike medications.

IPSG.03.02 The hospital implements a process to manage the safe use of concentrated electrolytes.

Goal 4: Ensure Safe Surgery

IPSG.04.00 The hospital implements a process for the preoperative verification and surgical/invasive procedure site marking.

IPSG.04.01 The hospital implements a process for the time-out that is performed immediately prior to the start of the surgical/invasive procedure and the sign-out that is conducted after the procedure.

Goal 5: Reduce the Risk of Health Care–Associated Infections

IPSG.05.00 The hospital implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections.

Goals, Standards, Intents, and Measurable Elements

Goal 1: Identify Patients Correctly

Standard IPSG.01.00

The hospital implements a process to improve accuracy of patient identifications.

Intent of IPSG.01.00

Incorrect patient identification can result in wrong-person and wrong-procedure errors, treatment errors, medication errors, diagnostic errors, and more that may result in patient harm. Correctly identifying a patient and matching them with intended treatment and services must be performed in all care settings. The identification process used throughout the hospital requires two patient identifiers, such as the patient's name, identification number, birth date, a bar-coded wristband, or other ways. The patient's room number or location in the hospital, or other numbers such as incubator numbers for neonates, cannot be used for identification. The two different patient identifiers used may be different in different circumstances; however, the two identifiers used must be consistent within an area. It is a best practice that the patient be involved in the identification process to whatever extent possible. There are special circumstances in which the hospital may need to develop a specific process for patient identification. The process considers the unique needs of the patients, and staff use the process for patient identification in these special circumstances to prevent error. Two different patient identifiers are required in any circumstance involving patient interventions. Patients are identified before providing treatments, before performing procedures, and before any diagnostic procedures are performed. The hospital should include the following in its patient identification practices:

- Involve the patient in the identification process whenever possible.
- Include special circumstances in the identification process. Examples include the following:
  - Comatose or confused/disoriented patients with no identification
  - Newborn patients when the parents have not immediately chosen a name, such as using the mother's given name in addition to "baby boy" or "baby girl" and the parents' surname (for example, "Baby Girl Mariam Khan" instead of "Baby Girl Khan," or "Baby Boy Maria Silva" instead of "Baby Boy Silva" in the event more than one baby of the same gender has the same last name, and adding a third name such as the father's given name or the mother's middle name if there is the likelihood of two or more patients on the ward with the same given and surname, or multiple births
- Organizations that allow different identifiers to be used in different care areas or scenarios must ensure that the process is consistent in these circumstances, as in the following examples:
  - A patient's name and date of birth are used in verbal interactions with the patient on the ward; these same two identifiers must be used in all verbal interactions with the patient.
  - A patient's name and identification number or medical record number are used during the time-out for surgical/invasive procedures, to label specimens, or to report diagnostic tests, and the like; these same two identifiers must be used in all similar circumstances.
- Patients are identified before providing treatments, before performing procedures, before any diagnostic procedures, and before any other treatments, cares, or interventions intended for a specific patient; this includes labeling any treatments and medications intended for a specific patient. Examples include the following:
  - Blood samples and pathology samples

- Dietary trays
- Expressed mother's milk

Measurable Elements of IPSG.01.00

1. Ⓓ The hospital uses at least two patient identifiers, that do not include the use of the patient's room number or location in the hospital, to identify the patient and to label elements associated with the patient's care and treatment plan. (*See also* MMU.04.01, ME 4; MMU.05.03, ME 4; MOI.03.00, ME 1)
2. The hospital identifies patients with at least two identifiers before performing diagnostic procedures, providing treatments, and performing other procedures. (*See also* MMU.04.01, ME 4)
3. Ⓓ The hospital ensures the correct identification of patients in special circumstances, such as the comatose patient or newborn who is not immediately named.

Goal 2: Improve Effective Communication

Standard IPSG.02.00

The hospital implements a process for reporting critical results of diagnostic tests.

Intent of IPSG.02.00

Patient harm can result when critical results of diagnostic tests are not reported and acted on promptly. A *critical result* is defined as a variance from normal range that represents a pathophysiologic state that is high risk or life-threatening, is considered urgent or emergent, and in which immediate medical action is likely necessary to preserve life or prevent a catastrophic event. This is different from an *abnormal result*, defined as one outside the expected test range but not an urgent or emergent life threat. It is also important to distinguish between *critical* ***tests*** (the diagnostic tests themselves, some of which hospitals may define as being critical by nature) and *critical* ***test results*** (meaning the outcome of any diagnostic test that indicates a very serious or life-threatening condition). This standard and its measurable elements are concerned with *critical* ***test results*** (*outcomes*) from any diagnostic test, and these critical result parameters and the response to them must be established by the hospital. For example, the hospital may define a critical result for potassium levels as being below 2.5 mmol/L or above 6.0 mmol/L, indicating potentially life-threatening hypokalemia or hyperkalemia.

Hospital health care practitioners may consider a result to be very serious in some clinical situations in which the result is not in the defined critical range, such as a mildly low potassium level in the setting of digitalis toxicity. However, those clinical decisions are separate from the purposes of compliance with this standard, which requires the hospital to formally define the parameters of absolute critical ranges for tests, as in the example of critical potassium levels above, and establish a procedure for reporting and response.

Diagnostic tests include all tests, such as laboratory, imaging, and cardiac diagnostics. Critical results may also be produced from any diagnostic tests performed at the bedside, such as point-of-care blood testing, portable imaging, and 12-lead electrocardiograms. Diagnostic tests that produce defined test results that may indicate a threat to life are different from continuous electronic monitoring, such as cardiac telemetry, continuous EEG (electroencephalogram) monitoring, or fetal monitoring. Continuous electronic monitoring is a clinical assessment tool used to detect changes in the patient's condition over time that may identify a threat to life but is not designed to produce a defined critical result.

A formal reporting system is used throughout the hospital that clearly identifies how critical results of diagnostic tests are communicated to health care practitioners and how the information is documented and acted on. This should include closed-loop communication by a read-back between the reporter and the receiver. The objective is to provide the critical results within an established time frame so that the responsible licensed health care provider can evaluate its significance and act on the results within a defined time frame.

The organization must identify tests that may have critical results and educate clinical staff on what these tests are and how to recognize a critical result.

The organization implements a protocol that describes how critical results are recognized, documented, and communicated to the provider responsible for the patient's care, and the time frames for reporting and responding to critical results, including documenting of actions taken when applicable. This should include how to proceed when the individual performing the test is also the individual responsible for interpreting and responding to the test; for example, when a cardiologist performs and interprets the 12-lead electrocardiogram on the patient they are treating, or when the practitioner who performs the test is the same practitioner who is treating the patient. In these cases, the reporting of a critical result would not be necessary.

In addition to clearly identifying how results are communicated and the required time frame for doing so, the organization must implement a protocol that describes how the treating practitioner is expected to respond and in what time frame. The hospital must then monitor compliance with the above protocols and time frames for critical results and act when negative trends are observed, or adverse events occur. For example, keeping a log in the lab to document times that critical results are reported and that includes patient identifiers and names of staff who received the report is one way to simplify monitoring for compliance.

Measurable Elements of IPSG.02.00

1. Ⓓ The hospital defines, in writing, critical test results that may represent urgent or emergent life-threatening values for diagnostic tests. (*See also* AOP.03.02, ME 3)
2. Ⓓ The hospital develops a formal reporting process that identifies how critical results of diagnostic tests are reported/communicated to health care practitioners and the expected time frame for reporting the critical results.
3. The hospital identifies what critical result information is documented in the medical record.
4. Ⓓ The hospital monitors compliance with the defined time frames for reporting and acting on critical results, and documents actions taken when time frames are not met.

Standard IPSG.02.01

The hospital implements a standardized process for handover communication.

Intent of IPSG.02.01

Breakdowns in communication can occur during any handover of patient care and can result in patient safety events. *Handover* communications can also be referred to as *handoff* communications. Handovers of patient care within a hospital occur in the following ways:

- Between health care practitioners (for example, physician to physician, physician to nurse, nurse to nurse)
- Between different levels of care in the same hospital (for example, when the patient is moved from an intensive care unit to a medical unit or from an emergency department to the operating theatre)
- From inpatient units to diagnostic or other treatment departments, such as radiology or physical therapy
- Between staff and patients/families, such as at discharge

Interruptions and other distractions from unit activities can inhibit clear communication of important patient information. Standardized, critical content and processes for communication between the patient, family, caregiver, and health care team can significantly improve the outcomes related to handovers of patient care.

Standardized forms, tools, or methods support a consistent and complete handover process. The content of the handover communication and the form, tool, or method used are standardized for the type of handover. The handover process may be different for different types of handovers within the hospital. For example, handovers of patient care for the emergency department to a medical ward may require a different process or different

content than handovers from the operating theatre to the intensive care unit; however, the handovers are standardized for the type of handover occurring.

Safe practices for effective communication include the following:

- Use of standardized, critical content and processes for communication between the patient, family, health care practitioner, and others involved in the patient's care during handovers of patient care
- Use of standardized methods, forms, or tools to facilitate consistent and complete handovers of patient care
- The handover process must allow for the participants to have an opportunity to clarify information during the handover process, by providing the opportunity to ask questions, or for discussion between the giver and the receiver of information. However, it is acceptable for the discussion to take place outside of in-person interactions, such as by phone, text, or other communication format.

Handover forms or tools, if used by the hospital, are not required to be part of the medical record. In addition, the detailed information communicated during the handover is not required to be documented in the medical record; however, the hospital may want to have documentation that the handover occurred. For example, the health care practitioner would record that they completed the handover and to whom they transferred responsibility for care, and then sign, date, and time the entry.

Measurable Elements of IPSG.02.01

1. The hospital implements a standardized procedure to communicate critical information between health care practitioners during handovers of patient care.
2. The hospital uses standardized forms, tools, or methods that support a consistent and complete handover process that includes the opportunity for all staff involved to clarify information and ask questions.
3. Ⓓ The hospital collects, analyzes, tracks, and trends data for patient safety events related to handovers.

Goal 3: Improve the Safety of Medications

Standard IPSG.03.00

The hospital implements a process to improve the safety of high-alert medications.

Intent of IPSG.03.00

High-alert medication errors can lead to patient injury or death and potentially additional costs associated with caring for these patients. The Institute for Safe Medication Practices (ISMP) defines *high-alert medications* as "drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients." The most frequently cited examples of high-alert medications include the following:

- Insulin
- Opioids
- Chemotherapeutic agents
- Antithrombotic agents
- Anticoagulants
- Thrombolytics
- Medications with a narrow therapeutic range (for example, digitalis)
- Neuromuscular blocking agents
- Epidural or intrathecal medications

Examples of lists of high-alert medications are available from organizations such as ISMP and the World Health Organization (WHO). For safe management, the hospital needs to develop its own list(s) of high-alert medications based on the following:

- Its unique utilization patterns of medications
- Its own internal data about near misses (or close calls)
- Medication errors and sentinel events
- Safety issues published in professional literature

The list includes medications identified as high risk for adverse outcomes. Information from the literature and/or Ministry of Health may also help identify which medications should be included. This list is updated at least annually. The list may need to be updated more frequently if there are additions or changes to hospital services, patient populations, or new medications added to the hospital formulary that are deemed high risk.

Some high-alert medications/categories (such as neuromuscular blockade medication) have their own specific set of risks in addition to those that exist based on the high-alert category alone. Strategies to prevent harm should be based on the specific risk profile of that medication/category, in that case. Some high-alert medications may not require additional strategies in addition to the standardized strategies adopted by the hospital. The hospital must determine when a tailored strategy and standardized measures are needed. For example, neuromuscular blockade medications can be inadvertently retrieved from refrigerated storage when stored along with other refrigerated medications. An example of a strategy to mitigate this risk is to store neuromuscular blockade agents segregated from other medications, such as in lidded containers, with prominent warning labels on the container and the medications inside. Other examples are chemotherapy agents, due to the complexity of medication orders and protocols and due to the properties of some of these medications, such as those that can cause tissue necrosis when extravasation occurs. Examples of strategies for those medications include chemotherapy ordering protocols, use of central lines for administration, patient monitoring protocols during administration, and readily available extravasation kits.

A specific example of a high-alert medication best practice identified by ISMP relates to the dispensing of vincristine (and other vinca alkaloids) in a minibag of a compatible solution and not in a syringe. Significant adverse events resulting in severe neurological damage and often death have occurred from the inadvertent administration of vinca alkaloids via the intrathecal route. In organizations in which vinca alkaloids are dispensed in a minibag, there have been no reported cases of accidental administration of a vinca alkaloid by the intrathecal route. This best practice is supported by the following organizations:

- ISMP
- The Joint Commission and Joint Commission International
- World Health Organization (WHO)
- American Society of Clinical Oncology (ASCO)
- Oncology Nursing Society (ONS)
- National Comprehensive Cancer Network

However, the overall process for managing high-alert medications must still be standardized throughout the hospital, such as standard high-alert medication labeling and requiring a double-check process. The examples of additional tailored risk mitigation strategies should be *in addition* to the hospital's standardized process. Additional guidance for this is explained below. The hospital must educate clinical and technical staff handling high-risk medication on the standardized process, the risks related to each medication, and the risk mitigation strategies for each medication.

The hospital must develop a list of high-alert medications stocked and used in the hospital. The list of high-alert medications must meet the following criteria:

- Up to date
- Reviewed at least annually and when new medications are added to the formulary
- Known by clinical staff

- Accompanied by robust, well-developed risk reduction strategies that decrease the risk of errors and minimize harm

Strategies should be applicable to all hospital departments and services and sustainable over time. According to ISMP, examples of these include the following:

- Standardizing processes associated with ordering, storage, preparation, and administration of these medications
- Improving access to information about these drugs
- Limiting access to high-alert medications
- Using additional labels and automated alerts
- Building redundancies into the medication management process such as automated or independent double checks, fail-safe methods such as pumps with locking mechanisms, and reducing available options, such as limiting available concentrations of the same medication

The hospital's risk mitigation interventions must be evident in the overall medication management program and in the clinical areas where these medications are used. For example, IV heparin used in neonatal intensive care units may require different safety strategies than IV heparin in the emergency department, and this should be evident in those areas. However, general strategies such as special labels for high-alert medications and a double-check process must be standardized throughout the hospital to avoid confusion.

Measurable Elements of IPSG.03.00

1. Ⓓ The hospital identifies, in writing, its list of high-alert medications. (*See also* MMU.02.00, ME 1)
2. The hospital implements a risk mitigation strategy for reducing the risk of harm from high-alert medications that is uniform throughout the hospital and, in addition, includes tailored strategies for specific medications when necessary.
3. The hospital reviews and, as necessary, revises its list of high-alert medications annually at minimum.

Standard IPSG.03.01

The hospital implements a process to improve the safety of look-alike/sound-alike medications.

Intent of IPSG.03.01

Medications that have similar product packaging or that have names that sound similar can easily be confused by health care practitioners and may lead to potentially harmful medication errors. Look-alike/sound-alike (LASA) names are medicine names that look or sound the same as other medicine names when written or spoken. Look-alike medicine packaging refers to medicine containers or primary packaging that looks like that of another medicine. There are many medication names that sound or look like other medication names. For example, *dopamine* and *dobutamine* sound alike, and the printed names may also look alike in some languages such as English. Confusing names are a common cause of medication errors throughout the world. The following factors contribute to this confusion:

- Incomplete knowledge of drug names
- Newly available products
- Similar packaging or labeling
- Similar clinical use
- Illegible prescriptions or misunderstanding during issuing of verbal orders

Hospitals must institute risk management strategies to avoid confusion with LASA medications and enhance patient safety. The hospital must determine which medications require safeguards to prevent LASA–related confusion that can cause errors. Strategies may include but are not limited to the following:

- Including the medication's purpose on the prescriptions
- Configuring safeguards in computerized medication ordering systems to require a minimum number of letters, such as at least five letters, when health care practitioners are searching for a medication

- Changing the appearance of look-alike medication names (for example, using "**TALL**man lettering" on labels such as **DOBUT**amine and **DOP**amine or oxy**BUTY**nin and oxy**CONTIN**)

When use of the above suggested methods is not possible, the hospital must implement an alternative strategy to prevent LASA errors. The hospital should also stay updated on emerging strategies to prevent LASA errors when applicable and when available resources allow. Examples include the following:

- Configuration of computer selection screens and drop-down menus in prescription systems to prevent LASA names from appearing adjacent to each other
- Automated dispensing by means of electronic devices and serialization technology
- Use of a closed-loop system with barcode technology to enhance the readability of look-alike labels
- Consideration of potential LASA errors when reordering stock or making purchasing decisions

The hospital should keep its list of LASA medications updated regularly, as new medications are approved or trade names of drugs change. The risks for LASA–related errors are not limited to prescribing and dispensing. Other strategies to prevent LASA errors include avoiding storage of these medications close to each other, where a health care practitioner could inadvertently retrieve the wrong one for dispensing or administration. The hospital's process should also include a mechanism to evaluate whether a LASA risk exists when the hospital must substitute medications to address shortages (for example, when substituting another brand of medication that has packaging similar to a different medication in the existing formulary, or which has a different trade name from the original that is similar to another medication). The hospital should implement a *comprehensive approach* to LASA medication management, from the point of medication stock ordering where decisions are made regarding brands (trade names of medications, label appearances), throughout the continuum all the way to the frontline staff who handle and administer them. The hospital must educate clinical and technical staff handling LASA medications on the standardized process, the risks related to each medication, and the risk mitigation strategies for each medication.

Measurable Elements of IPSG.03.01

1. Ⓓ The hospital identifies, in writing, its list of look-alike/sound-alike medications. (*See also* MMU.02.00, ME 1; MMU.07.01, ME 2)
2. The hospital implements a process for managing look-alike/sound-alike medications that is comprehensive and uniform throughout the hospital. (*See also* MMU.07.01, ME 2)
3. The hospital reviews and revises, when necessary, its list of look-alike/sound-alike medications annually at minimum.

Standard IPSG.03.02

The hospital implements a process to manage the safe use of concentrated electrolytes.

Intent of IPSG.03.02

The incorrect or unintentional administration of concentrated electrolytes can be deadly errors, and the most effective means to reduce or to eliminate these occurrences is to implement a process for managing concentrated electrolytes. Concentrated electrolytes are *vials* of concentrated forms of electrolytes that *require dilution* or other preparation before IV administration. It is important to distinguish that the standard excludes concentrated forms of electrolytes such as 3%–5% saline for infusion, because it is already diluted and prepared for infusion rather than being stocked in vials that require dilution before administration. Concentrated electrolytes include but are not limited to the following:

- Potassium chloride
- Potassium phosphate
- Sodium chloride
- Magnesium sulfate

Concentrated electrolytes should not be available as unit stock on any patient care units (including in operating room/anesthesia regular stock) as much as is possible given the pharmacy capabilities. Wherever concentrated electrolytes are stored, it is critical that the hospital perform a risk assessment such as a failure mode and effects analysis (FMEA) or other recognized risk assessment methodology to identify and mitigate potential risks associated with it. In addition, concentrated electrolytes must always be segregated from other medications, and access to these restricted to only qualified and trained staff. For example, if the hospital determines it is necessary to stock concentrated electrolytes in emergency carts, they must still be segregated from the other medications in the cart with appropriate warning labels, staff must be trained on the risks and safety considerations, a risk assessment must have been conducted that includes mitigation of those risks, and this must be outlined in hospital policy.

Electrolytes should not be dispensed in their concentrated form to patient care units for individual patients. The exceptions to this recommendation are for vials contained in a cardiac surgery kit or a cardiac surgery locked storage area and available only to the operating team, magnesium sulfate contained in emergency carts or in areas where patients with preeclampsia may be treated (labor and delivery, emergency department, or intensive care unit), concentrated sodium in areas treating patients who may suffer from increased intracranial pressure (intensive care unit, emergency department, and operating room), and other special areas and circumstances defined by hospital policy and procedures.

The hospital can use labeling practices to decrease the risk of inadvertent administration of concentrated electrolytes, when it is possible for a single vial to be removed or transported from an open bin, box, or container. The individual vial must be labeled in addition to the storage container. Only qualified and trained individuals should have access to these vials.

Administration of electrolyte replacement therapy for hypokalemia, hyponatremia, and hypophosphatemia is safest when standardized guidelines and/or protocols with prediluted electrolytes (such as 20 mEq of potassium chloride in 100 cc of normal saline) are used, and the dispensing or handling of concentrated electrolyte vials on the patient care units is prohibited.

Measurable Elements of IPSG.03.02

1. Only qualified and trained individuals have access to concentrated electrolytes, and they are labeled with appropriate warnings and segregated from other medications throughout the storage and dispensing process. (*See also* MMU.04.00, ME 1; MMU.04.01, MEs 4 and 5; MMU.05.00, ME 1; MMU.05.03, ME 4)
2. The hospital only stores vials of concentrated electrolytes outside of the pharmacy for emergency situations or specific purposes, and these are clearly identified in hospital policy. (*See also* MMU.03.00, MEs 1 and 2)
3. Ⓓ The hospital performs initial and ongoing proactive risk assessments at least annually for all areas where concentrated electrolytes are stored.

Goal 4: Ensure Safe Surgery

Standard IPSG.04.00

The hospital implements a process for the preoperative verification and surgical/invasive procedure site marking.

Intent of IPSG.04.00

Wrong-patient, wrong-site, and wrong-procedure surgery present a risk for significant patient safety events that result in patient injury. Wrong-patient, wrong-site, and wrong-procedure surgery events can result from

ineffective or inadequate communication between members of the team performing the surgical or invasive procedure. The following are common risk factors for these surgery events:

- Lack of a standardized process for marking the procedure site
- Use of ambiguous site marks, such as "X" (which could be interpreted as "do not operate here" instead of marking the operative site)
- Use of materials or media that can easily be removed, such as tape, or ink that washes off during the skin preparation process
- Lack of patient involvement in the site marking
- Inadequate patient assessment
- Inadequate medical record review
- A culture that does not support open communication among team members
- Problems related to illegible handwriting
- Use of abbreviations

Surgical and invasive procedures include all procedures involving an incision or puncture, including but not limited to the following:

- Open surgical procedures
- Percutaneous aspiration
- Selected injections
- Biopsy
- Percutaneous cardiac and vascular diagnostic or interventional procedures
- Laparoscopies
- Endoscopies
- Central line insertions outside the operating theatre

Organizations need to identify all areas within the hospital where surgical and invasive procedures take place. Examples include the following:

- Cardiac catheterization lab
- Interventional radiology department
- Gastrointestinal lab
- Intensive care or critical care units

The approach the hospital takes to ensuring safe surgery applies to all areas of the hospital in which surgical and invasive procedures occur.

The (US) Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ is based in part on the principle of using multiple strategies to achieve the goal of always identifying the correct patient, correct procedure, and correct site. The essential elements of the Universal Protocol are the preoperative verification process, marking the surgical site, and the time-out that is held immediately before the start of the procedure.

Preoperative Verification Process

Preoperative verification is an ongoing process of information gathering and confirmation. The purpose of the preoperative verification process is to do the following:

- Verify the correct patient, procedure, and site.
- Ensure that all relevant documents, images, and studies are available, properly labeled, and displayed.
- Verify that any required blood products, special medical equipment, and/or implants are present.

There are various elements of the preoperative verification process that can be completed before the patient arrives at the preoperative area—such as ensuring that documents, imaging, test results, and paperwork are properly labeled and match the patient's identifiers. Waiting until the time-out to complete the preoperative verification process may unnecessarily delay surgery if paperwork or imaging are not labeled or available when surgery is about to begin. It is more likely that portions of the preoperative verification may occur more than once and in more than one place. For example, the surgical informed consent may be obtained in the surgeon's office, and then verification that it has been completed may take place in the preoperative holding area.

Marking the Site

Marking the surgical/invasive site involves the patient and is done with an instantly recognizable and unambiguous mark. Ideally, an "X" is not used as the mark, as it may be interpreted as "not here" or "wrong side" and could potentially lead to errors in patient care, nor should other ambiguous marks such as a line or a dot be used. The mark must be consistent throughout the hospital. The site is marked in all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine). When an anesthesia provider performs a procedure, such as a regional block, that involves any of the above, that provider must also mark the site in addition to the surgeon marking the surgical site. The practitioner performing the invasive procedure must be the one who marks the site.

Marking of the surgical site can be performed in the preoperative holding area, the day surgery unit (DSU), and in patient units, prior to entering the operating/procedure room by a physician who will be participating during the entire procedure. In cases of surgical procedures, the surgeon who performs the surgery should mark the site. There are different titles used for the responsible surgeon, such as attending or consulting surgeon. For nonsurgical invasive procedures, it may be a general physician who will do the procedure. The hospital should identify who is authorized to perform surgical site marking in policy and procedure, or medical staff governing documents.

There are circumstances when a trainee or other authorized designee may perform the site marking—this is when the trainee performs the entire procedure, requiring minimal or no supervision from the responsible surgeon or physician. In these circumstances, the trainee marks the surgical site. When a trainee assists the surgeon or physician responsible, only the surgeon or physician may perform the site marking.

The site marking may take place any time before the surgical/invasive procedure begins, as long as the patient is actively involved in the site marking whenever possible and the mark is visible after the patient is prepped and draped. Examples of when patient participation may not be possible include the following:

- Patients who are not competent to make health care decisions
- Children
- Patients requiring emergent surgery

The hospital has an alternative procedure for identifying the correct site in cases in which site marking may cause harm, such as premature infants, or when a patient refuses site marking, and this should be outlined in policies and procedures. The site mark must be located where it will be visible after draping of the surgical site, so that it can be verified during the final time-out.

Measurable Elements of IPSG.04.00

1. The hospital implements a preoperative verification process using a checklist or other mechanism to document verification of the following:
   - Informed consent that is appropriate to the procedure
   - Correct patient, correct procedure, and correct site
   - All required documents, blood products, medical equipment, and implantable medical devices are on hand, correct, and functional
   - Whether there is a risk of blood loss > 500 mL (7 mL/kg in children)
   - Whether the patient has a difficult airway or aspiration risk
   - Any known allergies

   (*See also* PCC.03.00, ME 2)
2. Ⓓ The hospital uses an instantly recognizable and unambiguous mark for identifying the surgical/invasive site that is consistent throughout the hospital.
3. Ⓓ The surgical/invasive site marking process includes the following:
   - Marking completed by the person performing the procedure
   - Patient involved in the marking process
   - Alternative site-marking process for cases in which marking may result in harm
   - Alternative site-identification process for patients who refuse site marking
   - Alternative site-marking techniques for situations in which routine site marking is not possible (for example, laser, stereotactic radiosurgery, dental)

Standard IPSG.04.01

The hospital implements a process for the time-out that is performed immediately prior to the start of the surgical/invasive procedure and the sign-out that is conducted after the procedure.

Intent of IPSG.04.01

The time-out allows any unanswered questions or confusion to be resolved and provides a final opportunity to identify potential errors such as wrong-site surgery, surgery on the wrong patient, or the wrong surgical procedure on the right patient. The sign-out process after surgery allows for identification of areas needing improvement and for discussion of what went well during the surgery to assist the hospital in making decisions about overall surgery processes.

The time-out process applies to all surgical and nonsurgical invasive procedures. Evidence indicates that procedures that place the patient at the most risk include those that involve general anesthesia or deep sedation, although other procedures may also affect patient safety. Hospitals can enhance safety by correctly identifying the patient, the appropriate procedure, and the correct site of the procedure.

The time-out requirement is based on the following principles:

- Wrong-person, wrong-site, and wrong-procedure surgery can and must be prevented.
- A robust approach using multiple, complementary strategies is necessary to achieve the goal of always conducting the correct procedure on the correct person, at the correct site.
- Active involvement and use of effective methods to improve communication among all members of the procedure team are important for success.
- To the extent possible, the patient and, as needed, the family are involved in the process.
- Consistent implementation of a standardized protocol is most effective in achieving safety.

The time-out is implemented most successfully in hospitals with a culture that promotes teamwork and where all individuals feel empowered to protect patient safety. A hospital should consider its culture when designing

processes to meet the time-out requirement. In some hospitals, it may be necessary to be more prescriptive on certain elements of the Universal Protocol or to create processes that are not specifically addressed within these requirements.

Hospitals should identify the timing and location of the preprocedural verification and site marking based on what works best for their own unique circumstances. The frequency and scope of the preprocedural verification will depend on the type and complexity of the procedure. The three components of the Universal Protocol are not necessarily presented in chronological order (although the preprocedural verification and site marking precede the final verification in the time-out). Preprocedural verification, site marking, and the time-out procedures should be as consistent as possible throughout the hospital.

The purpose of the time-out is to conduct a final assessment to ensure that the correct patient, site, and procedure are identified. This requirement focuses on those minimum features of the time-out. Some believe that it is important to conduct the time-out before anesthesia for several reasons, including involvement of the patient. A hospital may conduct the time-out before anesthesia or may add another time-out at that time. During a time-out, activities are suspended to the extent possible so that team members can focus on active confirmation of the patient, site, and procedure.

A designated member of the team initiates the time-out, and it includes active communication among all relevant members of the procedure team. The procedure is not started until all questions or concerns are resolved. The time-out is most effective when it is conducted consistently across the hospital.

Time-Out

The time-out is held immediately before the start of the procedure with all team members present. During the time-out, the team agrees on the following components:

- Correct patient identity (*See also* IPSG.01.00)
- Correct procedure to be done
- Correct surgical/invasive procedure site

The time-out is conducted in the location at which the procedure will be done when the patient is present and involves the active participation of the entire team. The patient does not have to participate in the time-out. Completion of the time-out is documented and includes the date and time the time-out was completed. The hospital determines the amount and type of any additional documentation. If the leading physician must leave the room (for example, in a long or multipart surgery), a complete handover to the responsible physician must occur and include components of the time-out. This activity must be documented.

Sign-Out

The WHO Surgical Safety Checklist includes a sign-out process, which is conducted in the area where the procedure was performed before the patient leaves. The following components of the sign-out are verbally confirmed by a member of the team, typically a nurse:

- Name of the surgical/invasive procedure that was recorded/written
- Completion of instrument, sponge, and needle counts (as applicable)
- Labeling of specimens (when specimens are present during the sign-out process, labels are read aloud, including patient name)
- Any equipment problems to be addressed (as applicable)
- What went well, and any problems noted, with follow-up interventions through quality improvement activities as necessary

Measurable Elements of IPSG.04.01

1. Ⓓ The full team actively participates in a time-out process, which includes the following elements in the area in which the surgical/invasive procedure will be performed, immediately before starting the procedure, and this is documented:
   - Correct patient identity
   - Correct procedure to be done
   - Correct surgical/invasive procedure site
2. Before the patient leaves the area in which the surgical/invasive procedure was performed, a sign-out process is conducted, which includes at least the following:
   - Name of the surgical/invasive procedure that was recorded/written
   - Completion of instrument, sponge, and needle counts, as applicable
   - Labeling of specimens
   - Any equipment problems to be addressed, as applicable
3. When surgical/invasive procedures are performed, including medical and dental procedures done in settings other than the operating theatre, the hospital uses uniform processes to ensure safe surgery.
4. When two or more separate procedures are being performed on the same patient by different surgeons, the team must perform another time-out before each new procedure is initiated.

Goal 5: Reduce the Risk of Health Care–Associated Infections

Standard IPSG.05.00

The hospital implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections.

Intent of IPSG.05.00

Proper hand hygiene is central to the elimination of hospital-associated and other infections. Evidence-based hand-hygiene guidelines are available from the World Health Organization (WHO), the US Centers for Disease Control and Prevention (CDC), and various other national and international organizations. The hospital must adopt and implement current evidence-based hand-hygiene guidelines. This includes efforts to standardize hand hygiene compliance data collection and ensure that the data are valid, such as trained observers. Resources from WHO and CDC include resources for training hand hygiene observers. Hand-hygiene guidelines should be posted in appropriate areas, and staff should be educated in proper handwashing and hand-disinfection procedures. Soap, running water, disinfectants, and single-use towels are in areas where handwashing and hand-disinfecting procedures are required. Air dryers are not used to dry hands in patient care areas.

Measurable Elements of IPSG.05.00

1. The hospital adopts current evidence-based hand-hygiene guidelines. (*See also* PCI.07.01, MEs 2, 5, and 6)
2. The hospital implements an evidence-based hand hygiene program throughout the hospital. (*See also* PCI.07.01, MEs 2, 5, and 6)
3. Ⓓ The hospital collects and analyzes data for compliance with handwashing and hand-disinfection procedures in accordance with evidence-based hand-hygiene guidelines throughout the hospital.

Medication Management and Use (MMU)

Overview

Medications are a critical component of the care provided to patients and are used for diagnostic, symptomatic, preventive, curative, and palliative treatment and management of diseases and conditions. According to the American Nurses Association, almost two thirds of the US population takes at least one medication per day, and more than half of the population takes at least two. Globally, medication errors and unsafe medication practices are the leading cause of injury and avoidable harm in health care systems, carrying an estimated annual cost of 42 billion dollars, excluding lost wages and productivity. Medication-related harm represents 50% of health care's reported preventable harm, with prescribing and monitoring errors leading as highest risk factors. For example, in Europe, the rate of medication errors in hospitals at the prescription stage is 0.3%–9.1%, and from 1.6% to 2.1% at the dispensing stage. A study in the United Kingdom estimated that 28% of the 237 million medication errors that happen at some point in the medication process are potentially clinically significant. But that study also found that errors can occur at all stages of the medication management process: prescribing (21.3%), transcription (1.4%), dispensing (15.9%), administration (54.4%) and monitoring (7.0%). Also, a study in Spain concluded that medication errors accounted for 37.4% of the total number of adverse events.

A medication system that supports optimal medication management must include processes that support safe and effective medication use. Safe, effective medication use involves an interdisciplinary, coordinated effort of health care practitioners applying the principles of process design, implementation, and improvement to all aspects of the medication management process, which includes the selecting, procuring, storing, ordering/prescribing, transcribing, distributing, preparing, dispensing, administering, documenting, and monitoring of medication therapies. Although health care practitioners' roles in medication management vary greatly from one country to another, sound medication management processes for patient safety are universal, and must be supported by scientific evidence and guidance for prescribers such as in the development of a program for and the use of accepted medication practice guidelines.

Note: *Medication* is defined as any prescription medications; sample medications; herbal remedies; vitamins; nutraceuticals; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, to treat, or to prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; and intravenous solutions (plain, with electrolytes and/or drugs), as well as solutions administered/used on the patient by the surgical team during surgical/invasive procedures.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Organization and Management

MMU.01.00 The hospital manages its medication management processes.

MMU.01.01 The hospital implements a program for the prudent use of antimicrobials based on the principle of antimicrobial stewardship.

MMU.01.02 The hospital has a medication recall system process.

MMU.01.03 The hospital has a process for handling expired medications.

Selection and Procurement

MMU.02.00 The hospital implements a process for the selection and procurement of medications.

Storage

MMU.03.00 Medications are properly and safely stored.

MMU.03.01 Emergency medications are available, uniformly stored, monitored, and secure when stored out of the pharmacy.

Ordering and Transcribing

MMU.04.00 The hospital identifies those qualified individuals permitted to prescribe or to order medications.

MMU.04.01 The hospital identifies safe prescribing, ordering, and transcribing practices and defines the elements of a complete order or prescription.

MMU.04.02 The hospital has a medication reconciliation process.

Preparing and Dispensing

MMU.05.00 Medications are prepared and dispensed in a safe and clean environment.

MMU.05.01 The hospital's process for radiopharmaceuticals is in accordance with laws, regulations, and guidelines.

MMU.05.02 Medication prescriptions or orders are reviewed for appropriateness.

MMU.05.03 A system is used to safely dispense medications in the right dose to the right patient at the right time.

Administration

MMU.06.00 Medication administration is safely performed by qualified individuals.

MMU.06.01 Policies and procedures govern medications brought into the hospital by the patient or family, medication prescribed for patient self-administration, and medications brought into the hospital as samples.

Monitoring

MMU.07.00 The hospital monitors and responds to actual or potential adverse drug events and adverse drug reactions.

MMU.07.01 The hospital implements a process for identifying, reporting, managing, and tracking all medication errors and near miss events (or close calls).

Standards, Intents, and Measurable Elements

Organization and Management

Standard MMU.01.00

The hospital manages its medication management processes.

Intent of MMU.01.00

Medications are an important resource in patient care, and medication management must be organized effectively and efficiently. A safe medication management system addresses an organization's medication processes and is not only the responsibility of the pharmaceutical service but also of managers and health care practitioners, nurses, and other clinicians. How this responsibility is shared depends on the hospital's structure and staffing. In hospitals where a pharmacy is not present, medications may be managed on each clinical unit according to hospital policy. In other cases when a large central pharmacy is present, the pharmacy may organize and control medications throughout the hospital. Effective medication management includes all parts of the hospital—inpatient, outpatient, specialized units, and other clinical areas where medications are used or stored.

A qualified individual must directly supervise the pharmacy or pharmaceutical service's activities, regardless of how medication management is organized within the hospital. The individual is trained and, if required, appropriately licensed and/or certified. Applicable laws and regulations are incorporated into the organizational structure and the operations of the medication management system used in the hospital. This individual, or another qualified individual, is responsible for overseeing the medication management interdisciplinary team established to develop the policies and processes for medication management practices in the hospital. Additional responsibilities of the medication management team include medication oversight, decision-making, inventory management, preparation and distribution, and medication safety and quality, including diversion, adverse events, and reporting,

To ensure efficient and effective medication management and use, the hospital conducts a systems review at least once a year. The annual review identifies how well the system is working and allows hospitals to understand the need and priority of continued system improvements in quality and safety of medication use.

Measurable Elements of MMU.01.00

1. A qualified individual oversees the medication management interdisciplinary team established to develop the policies and processes for medication management in the hospital. (*See also* GLD.06.00, ME 1; HRP.02.01, ME 2)
2. Ⓓ The medication management interdisciplinary team develops written policies and a plan for a uniform medication management system that complies with applicable laws and regulations and includes the following processes, as applicable:
   - Planning
   - Selection and procurement
   - Storage
   - Ordering
   - Preparing, dispensing, and distribution
   - Administration
   - Monitoring the effects of medication
   - Medication error and adverse event reporting
   - Evaluation
   - Formal processes for management of medication shortages and substitutions
3. Ⓓ The medication management interdisciplinary team is defined in writing and includes, at minimum, a pharmacist, a physician, a nurse, an infection prevention and control professional, and hospital leaders.
4. All settings, services, and individuals who manage medication processes are included in the organizational structure.
5. A licensed pharmacist or other qualified individual directly supervises the activities of the pharmacy or pharmaceutical service and ensures compliance with applicable laws and regulations. (*See also* GLD.06.00, ME 1)
6. Ⓓ The hospital documents at least one review annually of the medication management system.
7. Appropriate and updated sources of drug information are readily available to those involved in medication use.

Standard MMU.01.01

The hospital implements a program for the prudent use of antimicrobials based on the principle of antimicrobial stewardship.

Intent of MMU.01.01

Hospitals must implement processes to ensure optimal use of antimicrobials in order to prevent the development and spread of resistant bacteria and deliver better patient outcomes. The overuse and misuse of antimicrobials has resulted in the growth of multidrug-resistant microorganisms that are increasingly resistant to available antimicrobials. Antimicrobial resistance has been classified as an urgent public health and socioeconomic problem on a global scale. What is more, antimicrobial resistance has been estimated to have been responsible for the deaths of at least of 1.27 million people worldwide and associated with nearly 5 million deaths in 2019, and in 2022 was listed as one of the top 10 global health threats. In addition to the growth of multidrug-resistant microorganisms, there are often side effects and/or complications to antimicrobial treatment, including acquiring *Clostridioides difficile* (*C. diff*), kidney or liver damage, hearing loss, hemolytic anemia, and other such complications. The proper use of antimicrobials is important in the prevention of unnecessary complications due to improper antimicrobial use.

Health care practitioners are contributing to the development of antimicrobial resistance in several ways (for example, using antimicrobials when they are not indicated at all; continuing antimicrobials when they are no longer necessary; using a broad-spectrum antimicrobial when it is not required or continuing it unnecessarily after the sensitivity results are received; using the wrong antimicrobial, or prescribing the wrong dose, or continuing the prophylactic antimicrobial after it is no longer recommended).

To reduce the development and spread of resistant microorganisms and deliver better patient outcomes, hospitals must implement measures to ensure appropriate use of antimicrobials. Implementation of an antimicrobial stewardship program will help hospitals reach the goal of providing patients requiring antimicrobial treatment with the right antimicrobials, when indicated, at the right time, at the right dose, and for the right duration. The program includes guidelines for the optimal use of antimicrobial therapy for treatment of selected and/or high-risk infections such as sepsis, pneumonia. endocarditis, meningitis, urinary tract infections (UTIs), and multidrug-resistant organism (MDRO) infections. Guidelines would also include the proper use of antimicrobial prophylaxis.

An antimicrobial stewardship program may include the following elements: monitoring indications for all or selected antimicrobials prescribed, tracking patterns of antimicrobial prescribing practice, monitoring antimicrobial resistance trends with an antibiogram, informing staff on antimicrobial use and resistance on a regular basis, and educating staff about optimal antimicrobial use. Many antimicrobial stewardship programs also monitor *Clostridioides difficile* trends as a surrogate marker and develop a list of restricted antimicrobials that require prior authorization. It is imperative for the program to have the support of hospital leaders—which includes leaders' commitment to providing support that includes staffing, financial resources, evidence-based resources, and technology—to ensure an effective stewardship program. In addition to infection prevention and control professionals, the antimicrobial stewardship program involves physicians, nurses, pharmacists, trainees, and others.

Successful tracking of the effectiveness of the program requires a mechanism for oversight. Oversight may include an individual, a small work group, a coordinating interdisciplinary team, a task force, an antimicrobial subcommittee, or some other mechanism. Examples of strategies to optimize antimicrobial prescribing include the following:

- Preauthorization for general and specific antimicrobial use that includes an internal review and approval process prior to use
- Prospective review and feedback regarding antimicrobial prescribing practices, including the treatment of positive blood cultures, by a member of the antimicrobial stewardship program
- Tracking, trending, and analysis of multidrug-resistant organism occurrences
- Tracking, trending, and analysis of prescription patterns and amount used of the restricted antimicrobials on the hospital's list

Tracking the effectiveness of the program is an important element of the program's success. Examples of data that can help measure effectiveness include the following:

- All antimicrobial use (general and restricted)
- Evidence of a decrease in the inappropriate use of antimicrobials and a decrease in multidrug-resistant organisms
- Documentation that prescribers are following accepted clinical practice guidelines
- Appropriate optimal use of prophylactic antimicrobials
- Monitoring *Clostridioides difficile* trends as a surrogate marker
- Developing a list of restricted antimicrobials and monitoring prescription pattern and amount used

Measurable Elements of MMU.01.01

1. Ⓓ The hospital implements a written program for antimicrobial stewardship that is based on scientific evidence, accepted clinical practice guidelines, and local laws and regulations and, at minimum, includes the following:
   - Documentation indicating that the scope of the antimicrobial stewardship program includes the entire hospital and all services associated with the hospital
   - Implementation of at least two evidence-based clinical practice guidelines to improve antimicrobial use for the most common indications
   - Evaluation of adherence to at least one of the evidence-based clinical practice guidelines the hospital implements (including antimicrobial selection and duration of therapy, where applicable)
2. The hospital has an interdisciplinary team that oversees the antimicrobial stewardship program. The interdisciplinary team is defined and includes, at minimum, an infection prevention and control professional, a physician, a nurse, a pharmacist, and hospital leaders.
3. The antimicrobial stewardship program demonstrates coordination among all components of the hospital responsible for antimicrobial use and resistance, including but not limited to the infection prevention and control program, the quality and patient safety program, the medical staff, nursing services, and pharmacy services.
4. The program includes guidelines for the optimal use of antimicrobial therapy for treatment of selected and/or high-risk infections, including the proper use of prophylactic antimicrobial therapy.
5. There is a mechanism to oversee the program for antimicrobial stewardship, and the program's effectiveness is monitored according to hospital policy.
6. Ⓓ The antimicrobial stewardship program collects, analyzes, and reports data to hospital leaders, medication interdisciplinary committee, infection prevention and control department, quality improvement department, pharmacy leaders, all staff, and other stakeholders per hospital policy.
7. The antimicrobial stewardship program uses program data to improve performance of antimicrobial stewardship activities.
8. Patients and families receive education on the antimicrobial stewardship program and on the appropriate use of antimicrobials.

Standard MMU.01.02

The hospital has a medication recall system process.

Intent of MMU.01.02

Hospitals must ensure that they have a process for receiving notifications of medication recalls and for identifying, retrieving, and returning, or safely and properly destroying, medications recalled by the manufacturer or supplier when found to be either defective or potentially harmful. Product defects may be related to incorrect packaging, potential contamination, or poor manufacturing, resulting in impurities or errors in strength/potency. Sometimes, a recall is initiated by the manufacturer, who identifies a problem with a drug and voluntarily recalls it. Other times, a government agency will request that a medicine be recalled after receiving reports of problems from the public. The hospital may receive communications about medication recalls directly from the manufacturer or from regulatory authorities. The recall process includes any medications compounded within the hospital in which products that have been recalled have been used. The hospital has a process to inform health care providers about the recall and advise them on alternative treatments, if necessary, as well as notifying patients who have received recalled medication and offering appropriate guidance as needed. The time frame for notifying health care providers and patients of the recall is according to hospital policy, the manufacturer's recommendations, and local laws and regulations.

Measurable Elements of MMU.01.02

1. Ⓓ The hospital implements a written policy for receiving and acting on notifications of recalled medications, including medications compounded within the hospital in which products that have been recalled have been used.
2. Ⓓ The policy includes identifying, retrieving, and returning, or safely and properly destroying, medications recalled by the manufacturer, supplier, or regulatory agency.
3. The hospital isolates recalled medications from the rest of the medication stock to prevent accidental use or distribution and clearly labels them as "Recalled."
4. The hospital notifies patients who received recalled medication and provides them with appropriate guidance.
5. The hospital has a process to inform health care providers about the recall and advise them on alternative treatments if necessary.
6. The process includes documentation of all actions taken related to the recall of a medication, including details such as the recall notice, affected lot numbers, actions taken, communications sent, and any responses received.

Standard MMU.01.03

The hospital has a process for handling expired medications.

Intent of MMU.01.03

Hospitals must ensure that they have a process for identifying, retrieving, and returning, or safely and properly discarding, expired medications. There is a policy or procedure that addresses any use of or the destruction of medications known to be expired or outdated. An expired medication is one that is past the expiration date listed on the original packaging from the manufacturer. A "beyond use date" (BUD) is the date and/or time after which the product should not be used. A "beyond use date" medication is defined as a medication that is opened, or used not in original form or conditions that the manufacturer provides, and is typically safe and effective to use for a short period of time after opening (shelf life). This would apply to a refrigerated medication that has a usable time outside of the refrigerator or an insulin vial that is opened and used for 28 days, or a sterile admixture that is compounded using other components. These "beyond use date" medications should be marked with a date of expiration based on when they were opened so that staff know the end date of use.

Measurable Elements of MMU.01.03

1. Ⓓ The hospital establishes and implements a written process for the following:
   - Identifying, retrieving, and returning opened and unopened, expired medications and outdated medications
   - Using unopened, expired medications and outdated medications
   - Destroying medications known to be expired or outdated
2. The hospital isolates expired medications from the rest of the medication stock to prevent accidental use or distribution and clearly labels them as "Expired."
3. The process includes documentation of all actions taken related to the expired medication.

Selection and Procurement

Standard MMU.02.00

The hospital implements a process for the selection and procurement of medications.

Intent of MMU.02.00

The hospital has a method for overseeing the hospital's medication list, including how listed medications are used; a method for ensuring that medications for prescribing or ordering are stocked; and a process for procuring medications not stocked or normally available to the hospital or for times when the pharmacy is closed. These methods and processes exist to support the hospital's mission, patient needs, and types of services provided.

Every hospital must decide which medications to make available for prescribing and ordering by the health care practitioners. The hospital develops a list (often referred to as a formulary) of all the medications it stocks or that are readily available from contracted services. In some cases, laws and regulations may determine the medications on the list or the source of those medications. Medication selection is a collaborative process that includes patient need and safety as well as economics. Medications are occasionally out of stock due to delayed delivery, national shortages, or other reasons not anticipated through normal inventory control.

The hospital has a method, such as designating an interdisciplinary team, to maintain and to monitor the medication list and to monitor the use of medications in the hospital; for example, monitoring the use of antimicrobials. Those involved in the oversight of the list include health care practitioners involved in the ordering, dispensing, administering, and monitoring processes for medications. The interdisciplinary team reports its findings, recommendations, and program status to hospital leaders. Criteria for selecting medications include, at a minimum, the following:

- Indications for use
- Effectiveness
- Drug interactions
- Potential for errors and abuse
- Adverse drug events
- Sentinel event advisories
- Population(s) served (for example, pediatrics, geriatrics)
- Other risks
- Costs

There is a process or mechanism to monitor patient response to newly added medications. For example, when the decision is made to add a new type of medication or a new class of drugs to the list, there is a process to collect, aggregate, and monitor data related to appropriateness of indication, how the drug is prescribed (dosage or route, for example), and any unanticipated adverse events or conditions associated with the new drug during the introductory period. The list is reviewed at least annually based on emerging safety and efficacy information and information on usage and adverse events.

On occasion, medications not stocked or readily available to the hospital are needed, and there is a process to approve and procure such medications. For example, patients who are on home infusions who become inpatients may not have enough medication to continue the infusion while in the hospital. Such specialty medications may include lifesaving infusions for pulmonary hypertension and those used in insulin pumps. There is a process to approve and procure such medications. Also, there are occasions when medications are needed during the night or when the pharmacy is closed. Each hospital needs to plan for these occurrences and educate staff on procedures to follow in the event they occur.

Measurable Elements of MMU.02.00

1. The interdisciplinary team collaborates with hospital leaders to develop criteria for determining how decisions are made for which medications are available for dispensing or administering. (*See also* IPSG.03.00, ME 1; IPSG.03.01, ME 1)
2. Ⓓ The list of medications by both brand name and generic name, stocked in the hospital or readily available from contracted services is reviewed annually.
3. The process used to develop and monitor the list (unless determined by regulation or an authority outside the hospital) is developed by the interdisciplinary team in collaboration with hospital leaders.
4. There is a process for procuring medications during the following:
   - At night or when the pharmacy is closed
   - When a medication is not on the formulary, stocked, or readily available in the hospital

Storage

Standard MMU.03.00

Medications are properly and safely stored.

Intent of MMU.03.00

The oversight of medication storage includes all locations where medications are stored to ensure consistency with product stability and protection from loss or theft. Medications may be stored within a storage area, in a pharmacy or pharmaceutical service, on the patient care units, in unit pharmacies, or the nursing station in the clinical unit.

There are some types of medications that require special handling, as with the following examples:

- Radioactive medications pose a safety risk.
- Antineoplastic and other hazardous medications carry a risk to health care workers who handle, prepare, dispense, administer, or dispose of these drugs.
- Investigational medications may require special storage and/or consent.

Measurable Elements of MMU.03.00

1. Medications are stored under conditions suitable for product stability, including medications stored on individual patient care units and ambulances, as applicable. (*See also* IPSG.03.02, ME 2)
2. The hospital stores all medications, including biologicals and controlled (scheduled) medications, in a secured area to prevent diversion, and locked, as applicable, in accordance with laws and regulations. These medications are accurately accounted for according to applicable laws and regulations. (*See also* IPSG.03.02, ME 2; FMS.05.00, ME 2)
3. Ⓓ There is a written process for managing medications or products requiring special handling, such as hazardous medications, radioactive medications, and investigational medications. (*See also* MMU.06.00, ME 6)
4. Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and applicable warnings.
5. All medication storage areas, including medication storage areas on patient care units and ambulances (as applicable), are periodically inspected to ensure that medications are stored properly.
6. Medications are protected from loss or theft throughout the hospital. (*See also* FMS.04.00, ME 2)

Standard MMU.03.01

Emergency medications are available, uniformly stored, monitored, and secure when stored out of the pharmacy.

Intent of MMU.03.01

Quick access to appropriate emergency medications is critical when patient emergencies occur. Each hospital plans the uniform location of emergency medications, which facilitates quick access to the correct medications in emergencies. Emergency resuscitation is a highly stressful, time-sensitive situation. As a result, the risk of medication errors occurring during emergency resuscitation may be higher. The Institute for Safe Medication Practices (ISMP) identifies that commonly reported contributing factors to this higher risk of errors include the following:

- Look-alike product packaging or drug names
- Disorganized and nonstandardized emergency carts
- Excessive stock in emergency carts
- Distractions caused by the hectic environment
- Poorly communicated verbal orders
- Inexperienced staff
- Alternative drugs in emergency carts
- Confusing or missing information about drugs
- Multiple concentrations of a drug in emergency cart drawers

Therefore, when patient emergencies occur, quick access to appropriate emergency medications is critical.

Each hospital plans the location of emergency medications and the medications to be supplied based on the populations served. For example, agents to reverse anesthesia are found in the operating theatres. Emergency cabinets, carts, bags, or boxes can be used for this purpose. Emergency medications are stored uniformly to facilitate quick access to the correct medications. For example, in each emergency cart in the hospital, the emergency medications are in the same drawer, and the medications are laid out in the same manner within the drawer of each cart. This is particularly important for staff who may need to access an emergency medication from a cart they do not typically use. Storage of medications in pediatric emergency carts is different from adult emergency carts; however, the medications are stored uniformly within each type of cart. Although common emergency medications used in pediatric resuscitation are not different than those used in adult resuscitation, the dosage is often different and weight-based, or it requires a different concentration, whereas adult dosages are generally (but not always) given by dose. For example, a common dose of epinephrine used for adult cardiac arrest is 1 mg and for the pediatric population it is weight-based and recommended at 0.01 mg/kg by the American Heart Association's Pediatric Advanced Life Support (AHA PALS) protocol. The hospital must ensure that emergency carts also have the necessary tools and drug concentrations to facilitate dosing of pediatric medications in an emergency.

The hospital establishes a procedure or process to prevent abuse, theft, or loss of the medications to ensure access to emergency medications when needed, as well as ensuring that medications are replaced when used, damaged, or out of date. For example, incorporating emergency cart checks into the daily work of the unit staff can help to ensure the integrity of the cart and its contents. The hospital must understand the balance between ready access and security for locations where emergency medications are stored, but also keep in mind that access to emergency medications must not require a specific individual(s) on the unit to unlock the emergency cart. In instances such as these, if the individual(s) is unavailable, the medications are no longer readily accessible, even though they may be secure.

Consistency and uniformity in the approach to emergency resuscitation may significantly reduce the risks and improve patient outcomes. One example of a strategy a hospital can take is a risk-based approach to increase safety and improve patient outcomes by looking at internal data from previous emergency situations to review

the availability of emergency medications or reviewing public literature on the subject. Examples of strategies identified in the literature include the following:

- Use a strategy to differentiate between adult and pediatric medications; for example, using separate adult and pediatric carts or, when using a universal cart, storing the medications and equipment in separate adult and pediatric drawers.
- Keep a designated medication box for neonates in areas that care for neonates.
- Standardize cart and drawer layout throughout the hospital.

Measurable Elements of MMU.03.01

1. Emergency medications are immediately available in the patient care areas or are readily accessible within the hospital to meet emergency needs.
2. Ⓓ The hospital establishes and implements a consistent and uniform written process for how emergency medications are stored; maintained; replaced when used, damaged, or out of date; and protected from loss or theft. (*See also* FMS.04.00, ME 2)
3. Access to emergency medications shall not require a specific individual or keys to unlock the emergency cart.
4. The hospital uses a risk-based approach to identify and implement strategies to improve the efficiency and accuracy of medication administration during emergency resuscitation. This approach at minimum includes the following:
   - Review of internal data from previous emergency situations to assess the availability of emergency medications (*See also* COP.04.00, ME 2)
   - Review of literature on the subject

Ordering and Transcribing

Standard MMU.04.00

The hospital identifies those qualified individuals permitted to prescribe or to order medications.

Intent of MMU.04.00

Each hospital is responsible for identifying those individuals with the requisite knowledge and experience and who are also permitted by licensure, certification, laws, or regulations to prescribe or to order medications. Selecting a medication to treat a patient requires specific knowledge and experience. A hospital may place limits on prescribing or ordering by an individual, such as for controlled substances, chemotherapy agents, or radioactive and investigational medications. Individuals permitted to prescribe and to order medications are known to the pharmaceutical service or others who dispense medications. In emergency situations, the hospital identifies any additional individuals permitted to prescribe or to order medications.

Measurable Elements of MMU.04.00

1. Only those permitted by the hospital and by relevant licensure, laws, and regulations prescribe or order medications. (*See also* COP.01.00, ME 1; IPSG.03.02, ME 1)
2. Individuals permitted to prescribe and to order medications are known to the pharmaceutical service or others who dispense medications.

Standard MMU.04.01

The hospital identifies safe prescribing, ordering, and transcribing practices and defines the elements of a complete order or prescription.

Intent of MMU.04.01

A common cause of adverse events in the hospital setting is medication errors. Strategies to reduce the variation in writing orders, such as defining required elements of a complete order or prescription, help reduce the risk of medication errors and improve patient safety. One recent study reported that "medication errors are most common at the ordering or prescribing stage. Typical errors include the health care practitioner writing the wrong medication, wrong route or dose, or the wrong frequency. These ordering errors account for almost 50% of medication errors." In paper records, illegible medication prescriptions or orders are one cause of medication errors that jeopardize patient safety and may delay treatment. Strategies to reduce illegibility of written orders are important in reducing the risk of medication errors. Safe prescribing, ordering, and transcribing are guided by hospital policies and procedures. Medical, nursing, pharmacy, and administrative staff collaborate to develop and to monitor the policies and procedures. Relevant staff are trained in correct prescribing, ordering, and transcribing practices.

All orders and prescriptions contain the name of the drug, the dose and/or strength, and the frequency and route of administration. For example, it might be part of the medical history. Also, the following are examples of additional information that the prescription order should contain when appropriate:

- PRN (pro re nata, or "as needed") orders: indications for use, detailed directions for overlapping orders (for example, more than one medication for pain)
- Weight-based or otherwise adjusted orders: for example, children, frail elderly, those with compromised renal function, oncology patients
- Adjusted for therapeutic range: for example, dosages may need to be updated based on laboratory values for specific medications, such as heparin infusions or phenytoin.

There are processes in place to manage medication orders. Thus, this standard sets hospitalwide expectations for medication orders. The processes are reflected in complete orders entered in the medical record, the pharmacy or dispensing unit receiving the information needed for dispensing, and the administration of the medication based on a complete order.

A diagnosis, condition, or indication for use must be present for each medication ordered. This information can be anywhere in the medical record and need not be on the order itself.

When managing titrated medication, the following information must be present in the titration orders: the medication name, medication route, initial rate of infusion (dose/unit of time), incremental units to which the rate or dose can be increased or decreased, how often the rate or dose can be changed, the maximum rate or dose of infusion, and the objective clinical measure to be used to guide changes. Examples of objective clinical measures to be used to guide titration changes include blood pressure measurement, weight-based heparin protocols, the Richmond Agitation–Sedation Scale (RASS) and the Critical-Care Pain Observation Tool (CPOT).

The hospital implements a policy that includes certain types of medication orders. The types are identified and listed as follows:

- As needed (PRN) orders: Orders acted on based on the occurrence of a specific indication or symptom
- Standing orders: A prewritten medication order with specific instructions from the physician or other licensed practitioner to administer a medication to a person in clearly defined circumstances
- Automatic stop orders: Orders that include a date or time to discontinue a medication
- Titrating orders: Orders in which the dose is either progressively increased or decreased in response to the patient's status
- Taper orders: Orders in which the dose is decreased by a particular amount with each dosing interval
- Range orders: Orders in which the dose or dosing interval varies over a prescribed range, depending on the situation or patient's status

- Signed and held orders: New prewritten (held) medication orders and specific instructions from a physician or other licensed practitioner to administer medication(s) to a patient in clearly defined circumstances that become active upon the release of the orders on a specific date(s) and time(s)
- Orders for compounded drugs or drug mixtures not commercially available
- Orders for medication-related devices (for example, nebulizers, catheters)
- Orders for medications at discharge or transfer
- Orders for contrast medications

If applicable with the care, treatment, and services the hospital offers, these additional orders are included in the policy:

- Orders for investigational medications
- Orders for herbal products
- Orders for radiopharmaceuticals

Measurable Elements of MMU.04.01

1. Ⓓ The hospital establishes, implements, and trains staff on a written process for the safe prescribing, ordering, and transcribing of medications in the hospital.
2. A diagnosis, condition, or indication for use exists for each medication ordered.
3. Ⓓ All orders and prescriptions contain the following elements:
   - Name of the drug
   - Dose
   - Frequency
   - Route of administration

   (*See also* IPSG.03.02, ME 1)
4. Ⓓ Additional elements of complete medication orders or prescriptions include, at minimum, the following as appropriate to the order:
   - Data necessary to accurately identify the patient
   - When generic or brand names are acceptable or required
   - Specific guidelines for the use of PRN orders
   - Weight-based orders
   - Rates of administration for intravenous infusions
   - Special orders such as titrating, tapering, or range orders
   - Titration orders include the medication name, medication route, initial rate of infusion (dose/unit of time), incremental units to which the rate or dose can be increased or decreased, how often the rate or dose can be changed, the maximum rate or dose of infusion, and the objective clinical measure to be used to guide changes.

   (*See also* IPSG.01.00, MEs 1 and 2; IPSG.03.02, ME 1)
5. Ⓓ The hospital implements a written policy that includes the following types of medication orders:
   - As needed (PRN) orders
   - Standing orders
   - Automatic stop orders
   - Titrating orders
   - Taper orders
   - Range orders
   - Signed and held orders
   - Orders for compounded drugs or drug mixtures not commercially available
   - Orders for medication-related devices (for example, nebulizers, catheters)
   - Orders for investigational medications, if applicable
   - Orders for herbal products, if applicable
   - Orders for medications at discharge or transfer
6. Ⓓ The hospital implements a written process to manage the following medication orders:
   - Incomplete, illegible, or unclear; including measures to prevent continued occurrence
   - Special types of orders, such as emergency, standing, or automatic stop, and any elements unique to such orders
   - Verbal, telephone, and text medication orders and the process to verify such orders (*See also* COP.01.00, ME 1)
7. Medications prescribed or ordered are documented in the patient's medical record or inserted into the patient's medical record at discharge or transfer.

Standard MMU.04.02

The hospital has a medication reconciliation process.

Intent of MMU.04.02

Medication ordering and transcribing is an important process of safe medication management for the patient and for reducing the risks for adverse events. Patients entering a hospital are often taking multiple medications at home. Obtaining an accurate list of those medications and documenting them in the patient's medical record helps reduce the risk of an adverse event.

Medication discrepancies can affect patient outcomes. It can be difficult to obtain a complete list from every patient in an encounter, and accuracy is dependent on the patient's ability and willingness to provide this information. A credible effort to collect this information is recognized as meeting the intent of the requirement. Examples of a credible effort may include contacting the patient's pharmacy and/or family members or consulting with the patient's primary physician.

Medication reconciliation is defined as the process of identifying the medications currently being taken by an individual. These medications are compared to newly ordered medications, and discrepancies are identified and reconciled. The types of information that clinicians use to reconcile medications include but are not limited to medication name, dose, frequency, route, and purpose. Hospitals should identify the information that needs to be collected to reconcile current and newly ordered medications and to safely prescribe medications in the future. Height and weight information may not be collected for every patient. However, the hospital must have a process to ensure that all required information for safe prescribing is collected and documented in the patient's medical record (*see also* MMU.04.01). This can be accomplished by collecting height, weight, age, and other information from every patient; by identifying categories of patients (for example, pediatric renal impairment, oncology, burn injuries, cardiology); and by identifying types of medications (for example, chemotherapy or other medications calculated by body surface area [BSA]) for which specific information must be collected, such as height and weight.

Good medication management practices include a review of a proposed new medication against the list of medications the patient is currently taking to improve the quality and safety of adding a new medication to the patient's treatment plan and reduce the risk of an adverse medication event. A listing of all current medications is recorded in the patient's medical record and is available to the pharmacy, nurses, and physicians. The hospital establishes a process to compare the patient's list of medications taken prior to admission against the initial orders.

Measurable Elements of MMU.04.02

1. Ⓓ The hospital identifies, in writing, the information needed to reconcile current and newly ordered medications.
2. The patient's medical record contains a list of current medications taken prior to admission or registration as an outpatient, and this information is made available to the patient's health care practitioners and the pharmacy as needed. (*See also* ACC.03.00, ME 5)
3. Medication reconciliation includes comparing the initial medication orders with the list of medications taken prior to admission, according to the hospital's established process.
4. A medication review is conducted when there are changes to the patient's level of care, unit, or health care practitioner service, including the discharge planning process for medication management

Preparing and Dispensing

Standard MMU.05.00

Medications are prepared and dispensed in a safe and clean environment.

Intent of MMU.05.00

Some medications and solutions require preparation under very specific guidelines to prevent contamination and risk of infection to the patient. The pharmacy or pharmaceutical service and others with proper training and experience prepare and dispense medications in a clean and safe environment that complies with laws, regulations, and professional practice standards. The hospital identifies the standards of practice for a safe and clean preparation and dispensing environment.

For example, standards of practice can include how medication preparation areas are to be cleaned and when a mask should be worn, or a laminar airflow hood should be used in the preparation of a medication. Staff compounding and preparing these medications are trained in the principles of medication preparation and aseptic technique. Similarly, positive or negative pressure rooms and laminar airflow hoods are available and used when indicated by professional practices; for example, in the preparation of sterile compounding, total parenteral nutrition (TPN) admixtures, chemotherapy, and epidurals. Due to the need for positive and negative pressure capabilities and laminar airflow hoods to prepare these medications, it is recommended that they be exclusively prepared in the pharmacy unless the patient care unit is specialized with the needed safety equipment and staffed with trained individuals (for example, a specialized oncology unit). A common situation in medication preparation that carries a risk of transmitting contagious diseases is the use of single-use and multidose vials on more than one patient. The misuse of these vials has caused harm to individual patients through occurrences and outbreaks of bloodborne pathogens and associated infections in both inpatients and outpatients—including hepatitis B and C virus, meningitis, and epidural abscesses.

Sterile compounding is defined as the combining, admixing, mixing, diluting, pooling, reconstituting, repackaging, or altering of a drug or bulk drug substance to create a sterile medication. Ensuring a safe compounding environment takes organization and diligence. Facility requirements are intended to establish a safe environment for compounded sterile preparations (CSPs). The International Organization for Standardization (ISO) air cleanliness classification of the compounding environment is a critical measure that can be affected by facility design; therefore, facility architecture is taken into account when establishing a sterile compounding area. Environmental monitoring and related documentation must be completed on a routine basis to ensure that adequate environmental and personnel controls are in place to prevent contamination of CSPs.

Hazardous medication compounding is the compounding of hazardous drugs that pose a risk of exposure to patients and health care workers (for example, drugs that are carcinogenic, are teratogenic, or have developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or structure and toxicity profiles of new drugs that mimic existing hazardous drugs). Hospitals must follow all applicable requirements based on laws and regulations, professional standards of practice, and hospital policy, including education, training, and responsibilities of staff handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating, and cleaning; spill control; and documentation of the above. These standards apply to all health care personnel who receive, prepare, administer, transport, or otherwise come in contact with hazardous drugs and all the environments in which they are handled.

Literature identifies standards and safe practices for the use of single-dose and multidose vials; for example, ensuring that all needles and syringes are single patient use only and never reentering a vial with a used needle or used syringe. Medications that do not require pharmacy-specific safety measures such as sterile compounding rooms or laminar flow hoods and that are stored in and dispensed from areas outside the pharmacy (for example, patient care units) comply with the same cleanliness measures required in the pharmacy. In addition, medication dispensing areas located on patient care units should be free from clutter and distraction.

Measurable Elements of MMU.05.00

1. Medication preparation and dispensing adhere to laws, regulations, and professional standards of practice. (*See also* IPSG.03.02, ME 1)
2. Medications are prepared and dispensed in clean, uncluttered, safe, and functionally separate areas with appropriate medical equipment and supplies. (*See also* PCI.04.00, MEs 1 and 2)
3. Staff preparing/compounding sterile products/medications are trained and competent in the principles of medication preparation and aseptic techniques and are provided resources to support the medication preparation process.
4. During preparation, staff visually inspect the medication for particulates, discoloration, or other loss of integrity.
5. Guidelines for use of single-use and multidose vials are identified and implemented in the medication processes.
6. Medications stored, prepared, and dispensed from areas outside the pharmacy (for example, patient care units) comply with the same cleanliness measures required in the pharmacy.

Standard MMU.05.01

The hospital's process for radiopharmaceuticals is in accordance with laws, regulations, and guidelines.

Intent of MMU.05.01

A process to prepare and dispense radiopharmaceuticals in accordance with laws and regulations and guidelines helps monitor the safety and efficacy of the radioactive drugs intended for patient care and treatment in the hospital. The United States Pharmacopeia and the National Formulary (USP-NF) defines a *radiopharmaceutical* as a "finished dosage form that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms 'radiopharmaceutical' and 'radioactive drug' are commonly used interchangeably." As applicable, radiopharmaceuticals must arrive at the hospital in the appropriate shielding equipment. Furthermore, when handling, preparing, and dispensing radiopharmaceuticals, compliance with local radiation laws and regulations for staff and environmental safety is critical.

Measurable Elements of MMU.05.01

1. Ⓓ The hospital has a written process to prepare and dispense radiopharmaceuticals in accordance with laws and regulations and clinical practice guidelines.
2. Radiopharmaceuticals are prepared by, or under the supervision of, an appropriately trained and qualified individual (for example, a nuclear technologist, registered pharmacist, doctor of medicine or osteopathy, chemist, biologist, or qualified nurse).
3. Sterile radiopharmaceutical facilities are designed and controlled to minimize airborne contamination, and provide an appropriately lighted and comfortable working environment.
4. Radiopharmaceuticals are transported and stored in accordance with laws and regulations and guidelines to maintain their stability and radioactivity until they are administered.
5. Radiopharmaceuticals are packaged in appropriate containers, and labeled to provide the following essential information:
   - Name of the radiopharmaceutical
   - Dosage
   - Expiration date
   - Radiation warning symbol(s)

Standard MMU.05.02

Medication prescriptions or orders are reviewed for appropriateness.

Intent of MMU.05.02

Good medication management includes two reviews of each prescription or order:

- The appropriateness of the medication for the patient and their clinical needs performed at the time the medication is prescribed or ordered
- The verification at the time of administration that the medication is exactly as ordered or prescribed

Each newly prescribed or ordered medication is reviewed for appropriateness, including when the dosage or other appropriateness factors noted below changes; for example, when new drugs are prescribed, and therapeutic duplication may be an issue, or when a potential medication interaction may occur. The hospital defines what patient-specific information is required for the appropriateness review of the order or prescription. For example, if a newly prescribed medication can affect the kidneys or liver, the appropriateness review includes specific clinical information about the patient's renal and liver function, as well as when these organ functions change.

The process to conduct an appropriateness review for an order or prescription prior to dispensing includes evaluation of appropriateness of the drug, dose, frequency, and route of administration; therapeutic duplication; allergies, or sensitivities, and interactions between the medication and other medications or food; variation from hospital criteria for use; patient's weight and other physiological information; current or potential impact as indicated by laboratory values; and other contraindications.

The hospital determines the manner in which the appropriateness review is conducted. For example, the appropriateness review may be conducted by individuals competent to do so by virtue of education and training, such as licensed pharmacists, or as specified by privileging specific to performing appropriateness reviews for independent health care practitioners with training and competency in performing an appropriateness review process; or for nurses or other professionals with training and demonstrated competency in the review process.

The hospital may choose to use clinical decision support programs associated with medication management to enhance the process or to conduct the appropriateness review process in conjunction with a designated licensed professional or trained individual; nonetheless, clinical decision support alone does not suffice for a full appropriateness review and is therefore not accepted as an alternative in terms of meeting the requirement for conducting an appropriateness review. For example, many electronic medication ordering systems are designed to review the order for the complete elements of an appropriateness review, including patient-specific clinical information, and provide an alert to the ordering individual of a contraindication to prescribing the medication. When the ordering individual overrides the alert, the hospital develops a process for a full review of the order by a health care practitioner who is trained and demonstrates competence in a full appropriateness review.

Appropriateness reviews must be conducted even when circumstances are not ideal. For example, if the central pharmacy or a unit pharmacy is not open, or the drug will be dispensed from stock on the ward or clinic, the appropriateness review may be conducted in conjunction with the verification review when the ordering individual will administer the medication and monitor the patient.

When the ordering individual is not available to administer the medication and monitor the patient, critical elements of the appropriateness review may be performed by other trained and competent individuals for administration of the first dose of the medication. However, the entire appropriateness review must be performed by a licensed pharmacist, or other licensed professional, such as a nurse or physician, competent in the knowledge required for a full appropriateness review, within 24 hours.

The critical elements of the appropriateness review may be conducted by other licensed trained individuals during times when the pharmacy is not available. These individuals require documented training in conducting the critical elements of the appropriateness review and will be supported by reference materials, computer programs, and other resources. Thus, when a physician calls in a new medication order during the night for a patient, the trained individual will write down and read back the order and then conduct an appropriateness review for the identified critical elements. A second review will be required by a licensed pharmacist or other licensed professional, such as a nurse or physician competent in the knowledge required for a full appropriateness review, within 24 hours.

There may be circumstances in which the full appropriateness review is not practical, such as in an emergency or when the ordering physician is present for ordering, administering, and monitoring of the patient (for example, in the operating theatre or the emergency department), or with oral, rectal, or injectable contrast in interventional radiology or diagnostic imaging where the medication is part of the procedure.

To facilitate the appropriateness review, those performing the review require access to the patient's medication record as well as to the clinical information that is pertinent to the review process; for example, information related to the patient's renal or liver function when a medication can affect or be affected by those organs. This information is essential to the appropriateness review. When computer programs are used to cross-check drug-drug interactions and drug allergies, the programs are current and updated according to recommendations of the program manufacturers. In addition, when print reference materials are used, the most current versions of the materials are used.

Measurable Elements of MMU.05.02

1. Ⓓ The hospital defines, in writing, the patient-specific information required for an effective review process, and the source or availability of this information is available at all times when the pharmacy is open or closed.
2. Each prescription or order is reviewed for appropriateness in a manner, identified by the hospital, that ensures a full appropriateness review prior to dispensing and administration, except in an emergency or when the ordering physician is present for ordering, administering, and monitoring of the patient, in accordance with laws and regulations. (*See also* MMU.06.00, ME 2)
3. The process to conduct an appropriateness review for an order or prescription prior to dispensing includes evaluation of the following:
   - Appropriateness of the drug, dose, frequency, and route of administration
   - Therapeutic duplication
   - Real or potential allergies or sensitivities
   - Real or potential interactions between the medication and other medications or food
   - Variation from hospital criteria for use
   - Patient's weight and other physiological information
   - Current or potential impact as indicated by laboratory values
   - Other contraindications
4. Individuals permitted to conduct appropriateness reviews meet the following criteria:
   - Are assessed competent to do so by a qualified individual(s).
   - Are permitted to do so by privileges or job descriptions.
   - Are provided resources to support the review process.
5. When the designated licensed professional is not available to perform the full appropriateness review, a trained individual conducts and documents a review of the following critical elements for the first dose, prior to the full appropriateness review that must be conducted within 24 hours:
   - Allergies
   - Lethal drug-drug interactions
   - Weight-based dosing
   - Potential organ toxicity
6. Clinical decision support programs used in conjunction with a designated licensed professional or trained individual for the full appropriateness review, as well as other computer programs and print reference materials used to cross-check the critical elements of an appropriateness review, are current and updated.
7. Ⓓ After the medication order has been reviewed, concerns, issues, or questions are clarified with the individual prescriber before dispensing according to hospital policy.

Standard MMU.05.03

A system is used to safely dispense medications in the right dose to the right patient at the right time.

Intent of MMU.05.03

Medication use has become increasingly complex, and medication errors are a major cause of preventable patient harm. A uniform system for dispensing and distributing medications in the most ready-to-administer form can help reduce the risk of medication errors.

The hospital dispenses medications in the most ready-to-administer form possible to minimize opportunities for error during distribution and administration. The issue of the most ready-to-administer form becomes crucial during emergent situations in which immediate administration of the medication is lifesaving (for example, during resuscitation). The central pharmacy and other medication-distribution points throughout the hospital use the same system. The system supports accurate dispensing of medications in a timely manner.

Dispensing practices and recordkeeping must include antidiversion strategies. When medications are prepared by someone different from the person administering the medication (for example, when medications are prepared by the surgical nurse to be administered to a patient during a surgical procedure in the operating theatre by the surgeon), the risk of a medication error is increased. Thus, when a medication is removed from its original packaging or prepared and dispensed in a different form/container—and not immediately administered (for example, insulin, medications prepared for use during a surgical procedure in the operating theatre, intravenous continuous drip medication, total parental nutrition [TPN])—the medication must be labeled with the name of the medication, the dosage/concentration of the medication, the date of preparation, the date of expiration, and two patient identifiers. When medications are prepared for use during a surgical procedure in the operating theatre and unused portions are discarded immediately following the surgical procedure, the patient's name and expiration date may not be necessary.

Measurable Elements of MMU.05.03

1. The hospital dispenses medications and maintains records in accordance with laws and regulations, licensure, and professional standards of practice.
2. Medications are dispensed in the most ready-to-administer form available.
3. The system supports accurate and timely dispensing and documentation of dispensing practices that meet patient needs.
4. Ⓓ The hospital has a written policy for medication labeling practices that at minimum includes the following:
   - Information on medication labels
   - Medications not immediately administered
   - Preparing individualized medications for multiple patients (*See also* IPSG.01.00, ME 1)
   - When a patient medication(s) is prepared by someone other than the person administering the medication

   (*See also* IPSG.03.02, ME 1)
5. All medications prepared in the hospital are correctly labeled with the following:
   - Medication name, strength, and amount (if not apparent from the container)
   - Expiration date when not used within 24 hours
   - Expiration date and time when expiration occurs in less than 24 hours
   - The date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas

Administration

Standard MMU.06.00

Medication administration is safely performed by qualified individuals.

Intent of MMU.06.00

Each hospital is responsible for identifying those individuals with the requisite knowledge and experience and who are also permitted by licensure, certification, laws, or regulations to administer medications. Administering a medication to treat a patient requires specific knowledge and experience. A hospital may place limits on medication administration by an individual, such as for controlled substances or radioactive and investigational medications. In emergency situations, the hospital identifies any additional individuals permitted to administer medications.

The medical record of each patient who receives medication contains a list of the medications prescribed or ordered for the patient and the dosage and times the medication was administered. Included are medications

administered "as needed." If this information is recorded on a separate medication form, the form is inserted in the patient's medical record at discharge or transfer.

The hospital defines the verification process to be used in administering medications. When the medication is prepared and dispensed on the patient care unit, the process of appropriateness review described in MMU.05.02 must also be carried out by a qualified individual.

In support of the patient's engagement in all aspects of their medical care and treatment, patients are informed about the medication they are being given and provided with an opportunity to ask questions about the medications. Medications are administered to the patient on a timely basis and noted in the patient's medical record.

Measurable Elements of MMU.06.00

1. Only authorized clinical staff administer medications. The hospital defines those who are authorized to administer medication, with or without supervision, in accordance with laws and regulations. The hospital may place limits, when appropriate, on the medication administration of individuals.
2. The hospital implements a process for medication administration to verify that the medication is correctly administered in accordance with the medication prescription or order. (*See also* MMU.05.02, ME 2)
3. Prior to administration, the individual administering the medication must do the following:
   - Verify the identity of the patient.
   - Verify that the medication selected matches the medication order or prescription and product label, including time, frequency, dose, and route.
   - Visually inspect the medication for particulates, discoloration, or other loss of integrity.
   - Verify that the medication has not expired.
   - Verify that no known contraindications exist.
   - Verify that the medication is being administered at the proper time, in the prescribed dose, and by the correct route.
   - Discuss unresolved concerns about the medication with the patient's physician or health care practitioner (if different from the physician or health care practitioner) and/or staff involved with the patient's care, treatment, and services according to hospital policy.
4. Medications are administered as prescribed on a timely basis, and each dose is recorded in the patient's medical record.
5. As appropriate, prior to administering a new medication, the patient or family is informed about any potential clinically significant adverse drug reactions or other concerns regarding administration of a new medication and have an opportunity to ask questions. This education is documented in the patient's medical record.
6. Before administering a radioactive pharmaceutical for diagnostic purposes, staff verify that the dose to be administered is within 20% of the prescribed dose, or, if the dose is prescribed as a range, staff verify that the dose to be administered is within the prescribed range. (*See also* MMU.03.00, ME 3)

Standard MMU.06.01

Policies and procedures govern medications brought into the hospital by the patient or family, medication prescribed for patient self-administration, and medication samples.

Intent of MMU.06.01

Medications that are not dispensed from the hospital pharmacy, such as medications brought in by the patient or family or medication samples, require special processes for labeling, storage, and control of use. The hospital has a process for determining the identity, safety, and any other relative contraindications to use patient-supplied or sample medications. The hospital must be aware of current regional trends related to the prevalence

of counterfeit medications and active recalls for medications and the associated active pharmaceutical ingredients.

Medications brought into the hospital by the patient or their family or prescribed within the hospital for self-administration are known to the patient's physician and noted in the patient's medical record.

The hospital implements a process for patient self-administration of medications, administration of medications by a family, and the management, use, and documentation of medication or medication samples.

Measurable Elements of MMU.06.01

1. Ⓓ The hospital defines, in writing, when medications brought into the hospital by patients or their families or brought into the hospital as samples can be administered.
2. Ⓓ If self-administration of medications is allowed, the hospital follows the written processes that guide the safe and accurate self-administration of medications or the administration of medications by a family member. The processes address training, supervision, and documentation.
3. The hospital educates patients and families involved in self-administration and documents in the patient's medical record about the following:
   - Medication name, type, and reason for use
   - How to administer the medication, including process, time, frequency, route, and dose
   - Anticipated actions and potential side effects of the medication administered
   - Monitoring the effects of the medication
   - Proper storage of the medication
4. The hospital determines that the patient or the family member who administers the medication is competent at medication administration before allowing them to administer medications.

Monitoring

Standard MMU.07.00

The hospital monitors and responds to actual or potential adverse drug events and adverse drug reactions.

Intent of MMU.07.00

The purposes of monitoring are to evaluate the medication's effect on the patient's symptoms or illness, as well as blood count, renal function, liver function, and other medication-related physical and biological effects with medications; to evaluate the patient for adverse effects; and to respond to the noted effects accordingly. Definitions of *adverse drug events* and *adverse drug reactions* are referenced in the JCI policy for sentinel events and as follows:

> *Adverse drug event:* an injury resulting from a medical intervention related to a medication, including harm from an adverse drug reaction or a medication error.
>
> *Adverse drug reaction:* a response to a medicinal product that is noxious and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis, or treatment of disease or for the restoration, correction, or modification of physiological or psychological function.

Patients, their physicians, nurses, and other health care practitioners work together to monitor patients on medications. Based on monitoring, the dosage or type of medication can be adjusted when needed. It is appropriate to closely monitor the patient's response to the first dose(s) of a medication new to the patient. Such monitoring is intended to identify the anticipated therapeutic response as well as allergic responses, unanticipated drug-drug interactions, or a change in the patient's equilibrium raising the risk of falls, among others.

Monitoring medication effects includes observing, timely responding to, and documenting any adverse effects. The hospital has a policy that identifies all adverse effects that are to be recorded and those that must be reported. The hospital establishes a mechanism for reporting adverse events when required and the time frame for reporting.

Measurable Elements of MMU.07.00

1. Ⓓ The hospital follows a written process to monitor, respond to, and document actual or potential adverse drug events, and adverse drug reactions. (*See also* PCC.02.00, ME 3)
2. Ⓓ The hospital follows a written process addressing prescriber notification in the event of adverse drug events and adverse drug reactions.
3. The hospital complies with internal and external reporting requirements for actual or potential adverse drug events and adverse drug reactions.
4. The hospital uses a standardized process for reporting adverse drug events as part of the hospital quality and patient safety program.
5. Adverse drug events are reported as identified by the process in the time frame required.
6. The hospital conducts a root cause analysis of data when adverse drug event patterns or undesirable trends occur.
7. The hospital uses the analysis of adverse drug-related events to improve medication use processes.

Standard MMU.07.01

The hospital implements a process for identifying, reporting, managing, and tracking all medication errors and near miss events (or close calls).

Intent of MMU.07.01

JCI defines a *medication error* as "a preventable event that may cause or lead to inappropriate medication use or patient or resident harm while the medication is in the control of the health care professional, patient, resident, or consumer. Such events may be related to professional practice; health care products; procedures and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

Processes are developed and implemented for the purposes of identifying, tracking, trending, analyzing, and reporting errors and adverse events, near misses, and complications. In addition, to proactively learn where systems may be vulnerable to adverse events, the program collects data and information on "near miss" events and complications—a process variation that did not affect the outcome—and evaluates them to prevent the actual occurrence of adverse events. Routine measurement data, as well as data from intensive assessments, contribute to this understanding of where improvement should be planned and what priority should be given to the improvement.

The hospital is responsible for planning and implementing changes for improvement based on the analysis of errors or adverse events, near misses, and complications. The process includes defining a medication error and a near miss, using a standardized format for reporting, and educating staff on the process and importance of reporting. The hospital establishes a definition of a near miss and what types of events are to be reported, as well as potential complications related to the care, treatment, and services provided.

Health care organizations that foster a culture of safety focus on safe medication management practices, which include promoting the reporting of errors without fear of retribution. The documentation and reporting of errors are the first steps in learning from them and avoiding repeat occurrences. The information must be documented and reported, and the data must be analyzed to identify opportunities for improvement. Without implementing a process that includes utilization of the data for improving safety practices, hospitals face challenging barriers in their safety improvement efforts. For example, a survey in Europe showed the following results:

- Eight percent of hospitals do not record medication errors in a database, and only 13% of hospitals make medication errors data available to the public. However, 33% of hospitals do not have medication errors databases for sharing continual improvements.
- Fourteen percent of hospitals do not routinely track medication errors, and 71% of hospitals track medication errors centrally (with most using the error data monitoring as a root cause analysis to resolve incidents as well as being investigated at regular quality meetings). Nevertheless, 23% of hospitals do not use that system regularly.

The reporting process is part of the hospital's quality and patient safety program. The reports are directed to one or more individuals who are accountable to take action. The program focuses on preventing medication errors through understanding the types of errors that occur in the hospital and in other organizations and why near misses occur. Improvements in medication processes and staff training are used to prevent errors in the future. The pharmacy participates in such staff training. In addition, strategies to improve communication among the professionals involved in prescribing, validating, preparing, administering, and dispensing medication are key to reduce medication errors.

Measurable Elements of MMU.07.01

1. Ⓓ The hospital adopts definitions of a medication error and a near miss from established and updated guidelines.
2. Ⓓ The hospital establishes and implements written processes for the following:
   - Identifying medication errors and near misses
   - Timely reporting of medication errors and near misses
   - Managing medication errors and near misses, including investigating, developing an action plan(s), and following up on the actions over time as applicable
   - Tracking medication errors and near misses

   (*See also* IPSG.03.01, MEs 1 and 2; QPS.03.04, ME 3)
3. Those accountable for acting and following up on the reports are identified.
4. Ⓓ The hospital conducts a root cause analysis of the data when medication error and near miss patterns or undesirable trends occur.
5. The hospital uses the analysis of medication errors and near miss events to improve medication use processes.

Patient-Centered Care (PCC)

Overview

Each patient and their family have their own unique needs, strengths, values, and beliefs. Patient and family education helps patients better understand and participate in their care and make well-informed care decisions. Health care organizations work to establish trust and open communication with patients and to understand and protect each patient's cultural, psychosocial, and spiritual values.

Patient care outcomes can be improved when patients and, as appropriate, their families and/or those who make decisions on their behalf are well informed and involved in care decisions and processes in a way that matches their cultural expectations.

To promote patient rights and patient-centered care, organizations begin by defining those rights and involving patients and their families in making decisions about the patient's care. Patients need to be well informed of their rights and how to act on them. Multidisciplinary team members are taught to understand and to respect patients' beliefs and values and to provide considerate and respectful care that promotes and protects patients' dignity and self-worth.

This chapter addresses processes to do the following:

- Identify, protect, and promote patient rights.
- Inform patients of their rights.
- Include the patient's family, when appropriate, in decisions about the patient's care.
- Incorporate patient satisfaction and experience in the quality of care.
- Obtain informed consent.
- Educate staff about patient and family rights.
- Inform patients and families about the hospital's oversight process of organ and tissue procurement.

How these processes are carried out in an organization depends on its country's local laws and regulations and any international conventions, treaties, or agreements on human rights endorsed by the country.

These processes are related to how an organization provides health care in an equitable manner, given the structure of the health care delivery system and the health care financing mechanisms of the country.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Patient and Family Rights

PCC.01.00 The hospital implements processes that support patient and family rights during care.

PCC.01.01 The hospital respects, protects, and promotes patient rights.

PCC.01.02 The hospital protects patient privacy, confidentiality, and access to health information.

PCC.01.03 The hospital provides patients with information regarding the safety and security of personal possessions.

PCC.01.04 The hospital identifies its vulnerable populations and the risks to those populations.

Patient Experience

PCC.02.00 Patients and families are engaged in all aspects of their care, treatment, and services.

PCC.02.01 The hospital informs patients and families about their rights and responsibilities to refuse or discontinue treatment, withhold resuscitative services, and forgo or withdraw life-sustaining treatments.

PCC.02.02 The hospital evaluates patient experience data and makes improvements to enhance the quality of patient care.

PCC.02.03 The hospital informs patients and families about their right to report complaints and to be notified of errors related to their care and the hospital's process for acting on them.

Patient Consent Process

PCC.03.00 Informed consent is obtained through a process defined by the hospital and carried out by trained staff in a manner and language the patient or their surrogate can understand.

Patient and Family Education

PCC.04.00 The hospital provides an education program that is based on the care, treatment, and services it provides and meets the needs of the patient population it serves.

PCC.04.01 Each patient's educational needs and learning ability are assessed and documented in their medical record.

Standards, Intents, and Measurable Elements

Patient and Family Rights

Standard PCC.01.00

The hospital implements processes that support patient and family rights during care.

Intent of PCC.01.00

The hospital is responsible for understanding and protecting patient and family rights during care. Hospital leaders are responsible for how patients are treated. Hospital leaders must know and understand patient and family rights and what the hospital's responsibilities are regarding patient rights as required by laws and regulations. Leaders then provide direction to department/service leaders who ensure that staff throughout the hospital assume responsibility for protecting these rights.

Patients may wish to have family members participate in their care decisions. Patients have the right to identify whom they consider to be their family and be allowed to have them involved in their care, even when the patient's family does not meet the traditional or cultural definition of family. Patients have the prerogative to decide who should be allowed to be present to participate in the patient's care.

Patients are given the opportunity to decide the following:

- If and to what extent they wish family to be involved
- What information may be provided to family or others
- Under what circumstances may family members or others be involved in care or receive patient information

The hospital implements processes to ensure that all staff members are aware of their responsibilities regarding patient and family rights and to respond to any concerns related to these rights.

The hospital uses a collaborative and inclusive process to develop patient care policies and procedures and includes patients and families in the process. The hospital has a process to allow patients to identify whom they consider to be family. This includes families who may not meet the traditional or cultural definition of family. Examples include the following:

- Common-law marriages or partnerships
- Unrelated caregivers
- Adopted or foster children
- Blended families

The hospital has a process to allow patients or their legal guardian or surrogate decision-maker to decide the following:

- If and to what extent family may be involved in care
- What information may be provided to the patient's family; for example, a patient may not want to share a diagnosis with their siblings or children, or a parent of a minor patient may not want to inform the minor patient of a terminal illness.
- Under what circumstances family or others may be involved in care or receive patient information; for example, a patient may want family involved from admission to discharge, or a patient may want family involved only if the patient requires surgery or other invasive diagnostic and therapeutic procedures.

Measurable Elements of PCC.01.00

1. Hospital leaders work collaboratively to protect and to advance patient and family rights.
2. Ⓓ Hospital leaders implement patient and family rights as identified in laws and regulations.
3. Ⓓ Hospital leaders protect patient and family rights in relation to the cultural practices of the community or individual patients served.
4. Hospital leaders protect the patient's right to identify whom the patient wishes to participate in care decisions.
5. The hospital has a process to determine the patient's or family's preferences regarding what and when information is provided to the patient, family, or others.
6. All clinical staff are trained on how to support patient and family rights and their participation in care.

Standard PCC.01.01

The hospital respects, protects, and promotes patient rights.

Intent of PCC.01.01

Patients must understand their rights and responsibilities related to their care. The hospital has a responsibility to provide care that respects patient dignity, values, beliefs, and religious or spiritual preferences. The hospital prepares a written statement of patient and family rights and responsibilities, according to laws and regulations, that is available to patients when they are admitted as inpatients or registered as outpatients.

Patients deserve to be treated with respect and dignity. Patients may perceive a loss of respect or dignity due to increased need for assistance with various tasks, including feeding, toileting, movement, and personal hygiene.

The patient has the right to respectful and considerate care. Hospital staff members have a responsibility to recognize and respect the patient's dignity and personal worth. Each patient brings their own values and beliefs to the care process. Strongly held values and beliefs can shape the care process and responses to care. Some values and beliefs are common and may be cultural and religious in origin. Other values and beliefs are those of

the patient alone. All patients are encouraged to express their beliefs in ways that respect the beliefs of others. Staff seek to understand how the patient's values and beliefs impact care and services.

When a patient or family wishes to speak with someone about religious or spiritual needs or observe a spiritual or religious custom, the hospital has a process to respond to the request. The hospital prepares a written statement of patient and family rights and responsibilities, and it is available to patients and their families.

This written statement must be easily accessible to all patients and their families. Examples of this written statement include the following:

- An informational document given to patients during admission or registration
- A brochure given to patients during admission or registration
- A poster in admitting, registration, or patient waiting areas

The hospital must provide information about patient and family rights in a language that patients understand. To do this, hospitals may do the following:

- Have written documents available in commonly used languages for the location.
- Display posters with commonly used languages.
- Offer translation services to explain rights and responsibilities for patients who do not speak commonly used languages for the location.

The hospital has a process to inform patients who cannot read their rights and responsibilities.

The hospital has a process to ask if patients have cultural, religious, or spiritual preferences that could impact their care and makes accommodations when safe to do so. Examples of these preferences include the following:

- Fasting or other dietary restrictions
- Restrictions related to blood transfusion or organ transplantation
- Prayer or worship times

Responses to patient requests related to religion or spirituality may be carried out by the following:

- On-site religious or spiritual staff
- Local or community resources
- Family-referred sources

Measurable Elements of PCC.01.01

1. Information about patient rights and responsibilities is provided to each patient in a language the patient understands. (*See also* MOI.02.02, ME 3)
2. Ⓓ The hospital's written policy on patient rights is available to staff. (*See also* SQE.01.06, ME 2)
3. The hospital treats the patient in a respectful manner that supports the patient's dignity.
4. The patient's spiritual and cultural beliefs, values, and preferences are respected.
5. The hospital responds to requests related to religious or spiritual support.

Standard PCC.01.02

The hospital protects patient privacy, confidentiality, and access to health information.

Intent of PCC.01.02

Patients have a right to personal privacy and confidentiality. Breaches in privacy and confidentiality negatively impact the trust patients have in their care teams and create risks for patients. Patients and/or their surrogate have a right to access their own health information to understand the care and services they have received. Staff members providing care and services to patients should inquire about the patient's privacy needs and expectations related to the care or service. Although there are some common approaches to providing privacy for all patients, individual patients may have different or additional privacy expectations and needs. These

expectations and needs may change over time. Patient privacy must be respected during all aspects of care, including during the following:

- Clinical interviews
- Examinations
- Procedures
- Treatments
- Transport

Patients may desire privacy from others, including the following:

- Hospital staff
- Other patients
- Family members or others identified by the patient
- Other individuals (for example, accreditation or certification surveyors or other auditors)

In addition, patients may not wish to be photographed or recorded.

Clear communication between hospital staff and patients builds trust. Communication related to privacy expectations may be documented in the patient's plan of care as needed. Documentation of privacy expectation ensures continuity and consistency among the health care team members.

Health information is important for understanding patients and their needs and for providing care and services. The hospital respects such information as confidential and has implemented policies and procedures that protect such information from loss or misuse. The policies outline what and how information may be released and are consistent with laws and regulations.

Patient information may be shared for various reasons, including the following:

- Continuity of care
- Contagious diseases
- Billing or insurance purposes
- Medical research

Patient permission is obtained before sharing information, as required by laws and regulations.

Patients also have the right to access their own health information. When they have access to their health information, patients can make better decisions about their health care. Access to health information has benefits for patients, including the following:

- Allowing patients to review and monitor compliance with their treatment plans
- Fixing any errors that may be in their medical record
- Monitoring their progress in managing their disease(s)

Measurable Elements of PCC.01.02

1. Patient privacy is respected for all clinical interviews, examinations, procedures/treatments, and transport. (*See also* GLD.09.00, ME 3; HCT.01.03, ME 2; MOI.01.01, ME 1; MOI.01.02, ME 3)
2. Confidentiality of patient information is maintained according to laws and regulations.
3. The hospital has a process for patients to give permission for the release of information consistent with laws and regulations.
4. The hospital has a process for providing patients with access to their health information consistent with laws, regulations, and culture.
5. The hospital provides patients with access to health information, regardless of their ability to pay.

Standard PCC.01.03

The hospital provides patients with information regarding the safety and security of personal possessions.

Intent of PCC.01.03

The hospital communicates its responsibility, if any, for the patient's possessions to patients and families as part of its efforts to ensure the safety and security of personal possessions. The hospital determines its level of responsibility for any or all of the patient's personal possessions brought into the hospital and implements a process to account for the possessions and to protect them from theft or loss. The hospital informs patients and their families about the hospital's level of responsibility for personal possessions and its process for protecting them. Examples of levels of responsibility include the following:

- Only being responsible for items locked in safes in patient rooms
- Only being responsible for patient possessions held by hospital security

The hospital has a process to store patient possessions across the organization and in various conditions. Examples include the following:

- Emergency patients
- Same-day surgery patients
- Inpatients
- Patients unable to make alternative safekeeping arrangements
- Patients incapable of making decisions regarding their possessions

Measurable Elements of PCC.01.03

1. The hospital has determined its level of responsibility for patients' possessions. (*See also* FMS.04.00, ME 2)
2. Patients receive information about the hospital's responsibility for protecting personal possessions.
3. Patients' possessions are safeguarded when the hospital assumes responsibility or when the patient is unable to assume responsibility.

Standard PCC.01.04

The hospital identifies its vulnerable populations and the risks to those populations.

Intent of PCC.01.04

Identification of a hospital's vulnerable populations and their risk factors helps to develop, implement, and evaluate population-based interventions to address the health disparities for those populations. Vulnerable populations are individuals at greater risk due to disparities in physical, economic, and social health status and often have health conditions exacerbated by inadequate health care. The hospital's predetermined list includes vulnerable populations that are applicable to the hospital's scope of services, determined by evaluation of the annual risk assessment performed, and in accordance with local laws and regulations. Vulnerable populations must include identification of the applicable vulnerable subpopulations. Examples of subpopulations under the populations in the predetermined list in ME 2 include but are not limited to the following:

- Persons with disabilities or chronic illnesses
  - People living with HIV/AIDS
- Socioeconomically disadvantage (low-income, homeless, uninsured/underinsured)
  - Certain geographical communities
  - Internally displaced persons (IDPs)
  - Stateless persons
  - National minorities
  - Poor migrants, refugees, asylum-seekers
  - Prisoners
- Aged/elderly
- Children/youth
  - Child abduction ("code pink")
  - Child corporal punishment

- Racial/ethnic minorities
  - Women
  - Indigenous people
  - Scheduled Castes (SC), scheduled Tribes (ST)
- Sexual minorities

Hospitals can add or remove populations from the list as applicable to their scope of services and must speak to the list during survey. Unless the local environment is unstable and in constant turmoil, the hospital's vulnerable populations may not drastically change every year. Nonetheless, an annual risk assessment must be completed, as there are several factors that influence the vulnerability of populations, and in order to accurately determine the present state of vulnerability of populations, the risk assessment must be performed.

Measurable Elements of PCC.01.04

1. The hospital includes the following sources, at minimum, when defining its vulnerable populations:
   - Predetermined list of widespread populations as applicable to the hospital's scope of services
   - Determined by results of the annual risk assessment
   - In accordance with laws and regulations
2. Ⓓ The hospital's predetermined list includes the following vulnerable populations, as applicable to the hospital's scope of services:
   - Disabled and chronically ill
   - Socioeconomically disadvantaged
   - Elderly/frail
   - Children/adolescents
   - Racial/ethnic minorities
   - Sexual minorities
3. Ⓓ The hospital performs a vulnerable population risk assessment, annually, at minimum, to identify the following:
   - Vulnerable populations the hospital serves
   - Risks associated with each vulnerable population
   - Specific resources needed to support the care, treatment, and services of these vulnerable populations, including community resources for continuity of care postdischarge
   - Staff education for select vulnerable populations, as determined by the hospital
4. Ⓓ The hospital establishes a written policy and implements a process to identify how risks are managed for each vulnerable population. (*See also* PCI.07.00, ME 2; HRP.02.02, ME 3)

Patient Experience

Standard PCC.02.00

Patients and families are engaged in all aspects of their care, treatment, and services.

Intent of PCC.02.00

Patients engaged in their health care can make better, collaborative decisions with their providers. This leads to improved patient outcomes. Effective patient activation and engagement permits the patient to actively participate in their health care by collaborating with their health care providers. Examples of patient engagement include the following:

- Participating in decisions about care (accepting and refusing treatments)
- Asking questions and seeking information about care
- Requesting a second opinion

Patients and families need information about their medical condition to participate in making decisions about their care and to care for themselves after discharge. Health care providers inform patients about assessment and diagnostic findings, diagnoses, and the proposed care and treatment.

Patients have a right to be informed of the expected outcomes of the planned care and treatment. Patients must also be informed when an unanticipated event or outcome has occurred during their care or treatment. Examples of unanticipated events include the following:

- Hospital-acquired infections
- Medication errors
- Pressure ulcers
- Postoperative infections

It is clear who will provide patients with the information about their care, including the following:

- Medical condition
- Planned care and treatment
- Expected outcomes
- Unanticipated events

Patients and families understand the decisions made about their care and how to participate in those decisions. Not all patients may want to know a confirmed diagnosis and prognosis or to participate in the decisions regarding their care. These patients are offered the option to include others in decision-making about their care.

The hospital has a policy about the process of seeking a second opinion. The hospital must not prohibit, prevent, or obstruct the patient's effort to seek a second opinion. The hospital participates in obtaining a second opinion by providing the patient or other health care provider with information about the patient's condition. The hospital must not withhold any information requested for a second opinion. The hospital is not expected to pay for a second opinion when requested by the patient.

A patient may designate another person(s) to receive information with them or instead of them in accordance with laws and regulations. The patient may also allow this person to make decisions about and provide consent for their care on their behalf. Examples include the following:

- Family member
- Spouse or partner
- Caregiver
- Friend
- Surrogate decision-maker

Information in the policy about seeking a second opinion may include the following:

- The process for obtaining and sharing patient information needed for the second opinion
- Whether an additional consent for release of patient information is required to share information for the second opinion
- Who is responsible for facilitating the request and any communication related to obtaining a second opinion
- Any information about additional payments related to obtaining a second opinion

Measurable Elements of PCC.02.00

1. The hospital supports and promotes patient and family engagement in care processes and in decision-making.
2. The health care team informs patients and their family about medical conditions, any confirmed diagnosis, a prognosis, and the planned care and treatment(s) to encourage patient engagement and collaboration. (*See also* PCC.03.00, ME 1)
3. Patients are informed of any unanticipated outcomes that occurred during the course of their care and treatment. (*See also* MMU.07.00, ME 1)
4. The hospital permits a patient to seek a second opinion without compromising the patient's care.

Standard PCC.02.01

The hospital informs patients and families about their rights and responsibilities to refuse or discontinue treatment, withhold resuscitative services, and forgo or withdraw life-sustaining treatments.

Intent of PCC.02.01

The hospital respects a patient's rights to make decisions about discontinuing, refusing, withholding, or forgoing life-sustaining treatments. There are processes to educate patients and their families about the potential outcomes of these decisions and the hospital's responsibilities related to these decisions. Patients, or those making decisions on their behalf, may decide not to continue with the planned care or treatment or to discontinue treatment after it has started. (Care should never be discontinued, nor should physicians suggest that it would.) Some of the most difficult decisions involve withholding resuscitative services or withdrawing life-sustaining services.

Because these sorts of decisions are complex, the hospital develops a framework for guiding this decision-making process. The framework does the following:

- Helps the hospital identify its position on these issues.
- Ensures that the hospital's position aligns with its community's religious and cultural norms and to any legal or regulatory requirements, particularly when legal requirements for resuscitation are not consistent with the patient's wishes.
- Addresses situations in which these decisions are modified during care.
- Guides health care practitioners through the ethical and legal issues in carrying out patient wishes.

The hospital develops policies and procedures to ensure consistency of the decision-making process related to the patient's wishes. The development of these policies and procedures involves many professionals and viewpoints. The policies and procedures identify lines of accountability and responsibility and how the process is documented in the patient's medical record.

The hospital informs patients and families about their rights to make these decisions, the potential outcomes of these decisions, and the hospital's responsibilities related to such decisions. Patients and families are informed about any care and treatment alternatives.

Measurable Elements of PCC.02.01

1. The hospital identifies its position on withholding resuscitative services and forgoing or withdrawing life-sustaining treatments.
2. The hospital's position aligns with its community's religious and cultural norms and any legal or regulatory requirements.
3. The hospital informs patients and families about their rights to refuse or to discontinue treatment and the hospital's responsibilities related to these decisions.
4. The hospital informs patients about the consequences of their decisions.
5. The hospital informs patients about available care and treatment alternatives.
6. The hospital provides health care practitioners with resources related to the ethical and legal considerations in carrying out patient wishes.

Standard PCC.02.02

The hospital evaluates patient experience data and makes improvements to enhance the quality of patient care.

Intent of PCC.02.02

Evaluating the patient's experience and other elements of patient care provides more complete information about their quality. This information can be used to determine if patients are satisfied with the care they are

receiving and can be used to guide improvements throughout the hospital. The patient experience is made up of a wide range of interactions that occur with all types of staff—including physicians, nurses, other professionals, and ancillary staff—as well as the care, treatment, and services they receive during their health care encounters. An important component of patient-centered care is understanding the patient experience.

Gathering and analyzing information about the patient experience can be used to help determine if the care patients are receiving is responsive to the individual patient preferences, needs, and values. The hospital has established a process for collecting and analyzing the patient experience as part of measuring the quality of patient care and potentially improving patient outcomes.

The patient experience is an objective measure, which includes several aspects of health care delivery. Patients consider this information when making decisions about where to obtain health care. Patient satisfaction is a subjective measure of the patient's perception of a service compared to their expectations. Both are important in understanding a patient's perspective of their care.

Examples of objective patient experience measures include the following:

- Whether patients have access to their health care data
- Time spent on hold when attempting to schedule an appointment
- Whether patients agree that their health care team answered all of their questions about their care

Examples of subjective patient satisfaction measures include the following:

- Whether patients were pleased with the room layout
- Whether patients found that staff members responded to their needs in a timely manner
- Whether patients felt safe in the hospital

Patient satisfaction measures that impact patient care can be used to obtain initial patient experience data and meet the expectations of this standard. However, hospital leaders should update the data collection measures to eventually identify patient experience information for meaningful improvement.

Measurable Elements of PCC.02.02

1. Hospital leaders implement a process for collecting and assessing the patient experience.
2. Ⓓ Data from the patient experience are collected, aggregated, analyzed, and transformed into information to identify and implement strategies for improving the patient experience. (*See also* QPS.03.00, ME 2)
3. Hospital leaders determine priority areas for improving the patient experience that will positively impact patient care.
4. Ⓓ Data are collected and analyzed following improvements to the patient experience to evaluate their impact on quality of patient care.

Standard PCC.02.03

The hospital informs patients and families about their right to report complaints and to be notified of errors related to their care and the hospital's process for acting on them.

Intent of PCC.02.03

Patients have a right to report complaints about their care and to have those complaints reviewed and, when possible, resolved. Patients also have the right to be notified of errors in their care. Effective processes to address these issues can improve the quality of care provided. Decisions about patient care sometimes lead to questions, conflicts, or other dilemmas for the hospital and the patient, family, or other decision-makers. These dilemmas may arise from decisions related to access, treatment, or discharge. They can be particularly difficult to resolve when decisions are complex or involve ethical considerations. For example, withholding resuscitative services, forgoing or withdrawing life-sustaining treatment, or determining where to discharge a patient with complex care needs.

The hospital has processes for investigating and resolving complaints within a defined time frame. The hospital develops policies that specify who needs to be involved in the processes and how the patient and family participate.

The hospital has a process for disclosing errors to the patient and their family, and a policy describes this process. The hospital is responsible for disclosing and resolving errors while caring for the patient. Timely disclosure of errors encourages rapid investigation to minimize the likelihood of similar errors, decreases the likelihood of litigation, and helps preserve trust between the patient and their care team. Examples of errors include the following:

- Wrong medication administered to a patient
- Wrong diagnostic test completed on a patient
- Wrong-site surgery performed on a patient
- Providing care or treatment without informed consent when one is required

The process for disclosing errors to patients is in accordance with local laws and regulations. The process to report complaints may include the following:

- A dedicated phone number to report complaints
- A webform or paper form that can be submitted to the hospital
- A designated person to review patient complaints
- A defined time frame to resolve the complaint
- Guidance on how to include patients and their family in the complaint resolution process

The hospital develops a policy that addresses the disclosure of clinical errors to patients, and the process of disclosing errors is developed in accordance with local laws and regulations. This process includes the following:

- Prompt disclosure of the error
- Apologizing for the error
- Describing how the error occurred
- Describing how the patient's care and length of stay may be impacted by the error
- Discussing how the hospital is preventing the error from happening again

Measurable Elements of PCC.02.03

1. Patients and families are informed about the process for reporting complaints. (*See also* APR.09.00, MEs 1 and 2)
2. The hospital investigates and, when possible, resolves complaints within a time frame as defined in hospital policy. If the complaint cannot be resolved immediately, the hospital acknowledges receipt of the complaint and notifies the patient of follow-up to the complaint.
3. Ⓓ The hospital develops a written policy that addresses disclosure of clinical errors to patients that includes, at minimum, the following:
   - How the hospital defines clinical error
   - The circumstances under which disclosure of a clinical error is recommended
   - Who is responsible for notifying a patient of a clinical error
   - Other individuals or entities that must be notified when applicable
4. The hospital implements and follows its policy on disclosure of clinical errors.
5. The hospital follows its internal process to analyze clinical errors and to prevent the error from occurring again.

Patient Consent Process

Standard PCC.03.00

Informed consent is obtained through a process defined by the hospital and carried out by trained staff in a manner and language the patient or their surrogate can understand.

Intent of PCC.03.00

Informed consent is crucial to high-quality patient care, as it ensures that patients understand the potential risks and benefits, and alternatives. The informed consent process respects patient autonomy and decision-making abilities. One of the main ways that patients are involved in their care decisions is by granting informed consent. To consent, a patient must be informed of those factors required to make an informed decision.

The consent process is clearly defined by the hospital in policies and procedures and includes documentation requirements. Relevant laws and regulations are incorporated into the policies and procedures. Informed consent may be required multiple times throughout the care process. Patients and families are informed as to which tests, procedures, and treatments require consent and how they can give consent; for example, verbal agreement or consent or signing a consent form.

Patients understand who can provide informed consent in addition to the patient, if applicable through laws, regulations, or culture. Designated staff members are trained on the informed consent process. Education is provided to patients and families as part of the process of obtaining informed consent for treatment and is provided in a language and manner the patient understands.

The hospital identifies situations in which a surrogate decision-maker may be involved in decisions about the patient's care. This is particularly true when the patient does not have the mental or physical ability to make decisions, when culture or custom requires that others make decisions, or when the patient is a child. When the patient cannot make decisions about their care, a surrogate decision-maker is identified.

Informed consent is a process. This process must align with local laws and regulations and professional norms. The process may occur over multiple conversations. A summary of these conversations must be documented according to hospital policy.

The hospital defines what information must be documented as part of the consent process in its policy; common elements in documentation requirements include the following:

- Name of the hospital
- Name of the test, procedure, or treatment covered by the informed consent
- Name of the responsible practitioner(s) performing the procedures(s)
- Signature of the patient or designee if the hospital or laws and regulations require a signed consent form
- Date and time consent is granted by the patient
- Statement that the procedure was explained to the patient or designee, including benefits, risks, and alternatives
- The likelihood of success, potential complications, the recovery process, and possible results of nontreatment
- Name, signature, and role of the person who explained the procedure to the patient or surrogate
- Name, signature, and role of the clinical staff member witnessing the consent if required

The hospital defines requirements and a process for granting emergency consent or when bypassing the informed consent process is acceptable. This may include the following:

- What situations would merit an emergency consent or bypassing the informed consent process (for example, to provide lifesaving treatment to an unconscious patient with no identification or contact information, when unable to reach a surrogate or guardian of a minor)

- Who is allowed to grant emergency consent or to determine when to bypass the informed consent process
- How to notify the patient or designee of the decision to grant emergency consent or bypass the informed consent process

When informed consent is required, informed consent must be obtained and documented prior to starting the treatment or procedure except in emergency situations.

The hospital clearly defines documentation requirements in its informed consent policy. Except in emergencies, the hospital will require an informed consent form signed by the patient or surrogate in accordance with local laws and regulations. However, all hospitals must clearly define what information is required and how documentation occurs; documentation is consistent with hospital policy. Documentation requirements may include the following:

- Where and how the informed consent process is documented in the patient medical record (for example, on a consent form or in a progress note)
- Date and time of documentation
- The information discussed with the patient or their designee as part of the informed consent process (for example, the name of the procedure or treatment, alternative treatments, risks and benefits of the proposed procedure or treatment, expected outcomes and common complications of the procedure or treatment)
- The name, signature, and role of the clinical staff member providing information to and receiving consent from the patient or their designee
- The name and signature of the patient or designee granting consent

Measurable Elements of PCC.03.00

1. Ⓓ The hospital develops a written policy and implements an informed consent process that includes at least the following:
   - Defining what information must be discussed and documented as part of the consent process
   - Identifying situations in which a surrogate decision-maker is necessary or allowed and who in addition to the patient can provide consent, in accordance with laws and regulations
   - Stipulating that the date and time must be documented as part of the consent process
   - Identifying and training staff who are permitted to obtain informed consent
   - Describing the process and requirements for obtaining emergency consent or bypassing the informed consent process
   - Documenting requirements for obtaining informed consent over the phone if permitted

   (*See also* ACC.02.01, ME 5; COP.09.06, ME 1; COP.10.01, ME 1; PCC.02.00, ME 2)
2. Ⓓ Hospital policy identifies what tests, procedures, and treatments require consent, including, at minimum, the following:
   - Surgery
   - Anesthesia and sedation
   - Use of blood and blood products
   - Other high-risk procedures and treatments identified by the hospital

   (*See also* ASC.02.03, ME 1; COP.09.06, ME 1; COP.10.01, ME 1; IPSG.04.00, ME 1)
3. The informed consent process and related education is provided in a manner and language the patient or surrogate decision-maker understands. (*See also* ACC.02.01, ME 4)
4. Informed consent is obtained in a manner consistent with the process outlined in hospital policy.

Patient and Family Education

Standard PCC.04.00

The hospital provides an education program that is based on the care, treatment, and services it provides and meets the needs of the patient population it serves.

Intent of PCC.04.00

Patient education promotes patient engagement and leads to improved outcomes, including improved adherence to medications and treatments. The hospital creates its education program based on services provided and the needs of its patient population. The hospital chooses how the program is organized and how resources are allocated.

Clinical staff collaborate to develop patient education materials. This collaboration results in more comprehensive, consistent, and effective patient education. Those responsible for providing patient education have the knowledge, resources, and communication skills to do so. The hospital decides how to oversee the education program. Examples of oversight include an education coordinator, committee, or service.

The hospital ensures that those providing education have resources to do so. This may include the following:

- Providing training on how to provide effective patient education
- Assigning clinical staff with the appropriate clinical or educational background in the subject matter
- Providing patient resources (for example, on-demand education videos, written materials, hands-on exercises, materials to teach how to use new technology or equipment following discharge)
- Ensuring access to translator services

Measurable Elements of PCC.04.00

1. The hospital plans education based on the care, treatment, and services provided and the needs of its patient population. (*See also* ASC.02.03, ME 2; ASC.03.01, ME 2; HCT.01.01, ME 4)
2. The hospital has a program to educate patients throughout the hospital that includes the following:
   - Oversight by a qualified member(s) of the clinical staff
   - Access to educational resources based on the care, treatment, and services provided and the needs of the patient population
3. Patient and family education is developed and delivered collaboratively by interdisciplinary staff members.
4. Clinical staff who provide the education have the subject knowledge and communication skills to do so.

Standard PCC.04.01

Each patient's educational needs and learning ability are assessed and documented in their medical record.

Intent of PCC.04.01

Clinical staff must understand each patient's unique educational needs and learning ability to deliver effective education. Education focuses on the specific knowledge and skills the patient will need to make care decisions, participate in their care, and continue care at home or the next level of care.

A patient's individualized educational needs are based on the patient's care and treatments. Educational needs are documented in the patient's medical record throughout the care continuum as needs are identified or changed. Documentation of these needs makes it easier for the patient's care team to participate in the education process. Education needs include the following:

- A patient's preferred language for spoken or written information
- A patient's preferred way of receiving information (for example, a video, demonstration, written materials)
- The participation of an additional learner (for example, a parent, a home care nurse)

There are many patient variables that determine if the patient and family are willing and able to learn. Qualified clinical staff assess patients and their family for any learning needs or barriers and readiness to learn. Patients and families may be affected by learning barriers. Examples of barriers include the following:

- Literacy level
- Language
- Motivation
- Visual or hearing impairments
- Learning disorders

Education is provided to patients and families throughout the care process and documented in the patient's medical record. Examples of when education occurs and documented include the following:

- As part of the process of obtaining informed consent for treatment
- When patients are expected to be discharged home with a medical device or dressings for a wound
- At the start of a new home feeding or medication regimen

Each hospital decides documentation requirements for the educational assessment, planning, and delivery of patient education.

Patients and their families are encouraged to participate in the care process and to ask questions. The hospital has a process to verify that patients and their families understand the education they have received, such as use of the "teach back" method.

Measurable Elements of PCC.04.01

1. Each patient's and, when appropriate, family's educational needs and preferences are assessed and recorded in the patient's medical record. This must include, at a minimum, the following:
   - The language the patient prefers for education
   - The form(s) the patient prefers for education
   - Who should receive education in addition to the patient (for example, a spouse or caregiver)
   - Any known barriers to learning
2. Education provided to patients and families is documented in the patient's medical record. (*See also* ACC.04.01, ME 5)
3. The hospital has a process to verify that patients and families acknowledge receipt and understanding of the education provided. (*See also* ACC.04.01, ME 5)

Section III: Health Care Organization Management Standards

Facility Management and Safety (FMS)

Overview

Health care organizations work to provide safe, functional, and supportive facilities for patients, families, staff, and visitors. To reach this goal, the physical facility, medical and other equipment, and people must be effectively managed. In particular, management must strive to do the following:

- Identify, reduce, and control hazards and risks.
- Prevent accidents and injuries.
- Maintain safe conditions.

Effective management includes interdisciplinary planning, education, and monitoring as follows:

- The leaders plan the space, equipment, and resources needed to safely and effectively support the clinical services provided.
- All staff are educated about the facility, how to reduce risks, and how to monitor and to report situations that pose risk.
- Performance criteria are used to evaluate important systems and to identify needed improvements.
- Comprehensive, facilitywide risk assessments are developed and monitored on each of the facility management and safety programs when needed.

Written programs are developed and include the following eight areas, when appropriate to the facility and activities of the organization:

1. Safety—The degree to which the organization's buildings, construction areas, grounds, and equipment do not pose a hazard or risk to patients, staff, or visitors
2. Security—Conducting ongoing assessment of risk to enhance protection from loss, destruction, tampering, or unauthorized access or use
3. Hazardous materials and waste—Handling, storage, and use of radioactive and other materials are controlled, and hazardous waste is safely disposed of.
4. Fire safety—Conducting ongoing assessment of risks to enhance protection of property and occupants from fire and smoke.
5. Medical equipment—Equipment is selected, maintained, and used in a manner to reduce risks.
6. Utility systems—Electrical, water, and other utility systems are maintained to minimize the risks of operating failures.
7. Emergency management—Risks are identified and response to epidemics, disasters, and emergencies is planned and effective, including the evaluation of the structural and nonstructural integrity of patient care environments.
8. Construction and renovation—Risks to patients, staff, and visitors are identified and assessed during the construction, renovation, demolition, and other maintenance activities.

When the organization has nonhospital entities within the patient care facilities to be surveyed (such as an independently owned coffee shop or gift shop), the organization has an obligation to ensure that these independent entities comply with the following facility management and safety programs:

- Safety and security programs
- Hazardous materials and waste management programs

- Fire safety programs
- Construction and renovation

Laws, regulations, and inspections by local authorities largely determine how a facility is designed, used, and maintained. All organizations, regardless of size and resources, must comply with these requirements as part of their responsibilities to their patients, families, staff, and visitors.

Organizations are required to comply with laws and regulations, including building and fire codes. They are knowledgeable about the details of the physical facilities they occupy by performing regular facility inspections. They proactively gather data and carry out strategies to reduce risks and to enhance the patient care environment.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Leadership and Planning

FMS.01.00 The hospital complies with relevant laws, regulations, building and fire safety codes, and facility inspection requirements.

FMS.01.01 A qualified individual(s) oversees the facility management and safety structure.

Risk Assessment and Monitoring

FMS.02.00 The hospital develops and documents a risk assessment based on facility management and safety risks identified throughout the organization, prioritizes the risks, establishes goals, and implements improvements to reduce and eliminate risks.

Safety

FMS.03.00 The hospital implements a program to provide a safe physical facility.

Security

FMS.04.00 The hospital implements a program to provide a secure environment for patients, families, staff, and visitors.

Hazardous Materials and Waste

FMS.05.00 The hospital implements a program for the management of hazardous materials and waste.

Fire Safety

FMS.06.00 The hospital establishes and implements a program for fire safety that complies with national and local codes, laws, and regulations.

FMS.06.01 The hospital maintains fire safety equipment and fire safety building features.

FMS.06.02 All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, evaluated, and maintained.

FMS.06.03 The hospital conducts regular exercises with staff to evaluate the fire safety program.

FMS.06.04 The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility.

Medical Equipment

FMS.07.00 The hospital develops and implements a program for the management of medical equipment throughout the organization.

FMS.07.01 The hospital has a process for monitoring and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures.

Utility Systems

FMS.08.00 The hospital implements a program for the management of utility systems throughout the organization.

FMS.08.01 The hospital utility systems program ensures that essential utilities, including power, water, and medical gases, are always available, and alternative sources for essential utilities are tested and evaluated.

FMS.08.02 Designated individuals or authorities monitor water quality regularly.

FMS.08.03 Quality of water used in hemodialysis is tested and evaluated for chemical, bacterial, and endotoxin contaminants, and processes for hemodialysis services follow professional standards for water quality and for infection prevention and control.

FMS.08.04 The hospital reduces the risk of infection in the facility through the use of mechanical and engineering controls.

Emergency and Disaster Management

FMS.09.00 The hospital develops, maintains, and evaluates an emergency management program to respond to internal and external emergencies and disasters that have the potential of occurring within the hospital and community.

FMS.09.01 The hospital implements and evaluates an emergency management program to respond to the presentation of global communicable diseases.

Construction and Renovation

FMS.10.00 When planning for construction, renovation, and demolition projects, or maintenance activities that affect patient care, the organization conducts a preconstruction risk assessment.

Standards, Intents, and Measurable Elements

Leadership and Planning

Standard FMS.01.00

The hospital complies with relevant laws, regulations, building and fire safety codes, and facility inspection requirements.

Intent of FMS.01.00

Laws, regulations, and inspections by national and local authorities determine in large part how a facility is designed, used, and maintained. All hospitals, regardless of size and resources, must comply with these requirements as part of their responsibilities to their patients, families, staff, and visitors.

Requirements may differ depending on when the facility is built and approved. For example, many building construction codes and fire safety codes, such as for sprinkler systems, apply only to new construction. Hospitals begin by complying with laws and regulations.

Some hospitals are located inside larger, multiuse buildings, such as high-rise office buildings and shopping malls, and may lease or rent the space in which they provide care, treatment, and services. In these circumstances, it is necessary for hospital leaders to communicate with the property owner to ensure that the building complies with relevant laws, regulations, codes, and other requirements. In addition, hospital leaders communicate and collaborate with the property owner regarding shared building systems and building-related issues not under the hospital's control. It is important to understand expectations and who is responsible for maintaining these systems. Shared systems and building issues may include security and fire safety. Examples include video surveillance systems, entry and fire alarms, fire suppression systems, emergency exits, maintenance of utilities, power, ventilation, water quality, and other building issues. It is important for hospital leaders to have access to documents managed by the property owner, such as maintenance records and inspection reports relevant to the hospital's facilities. Hospital leaders evaluate compliance of the property to determine that the utilities and facilities belonging to the owner are managed accordingly to meet patient needs.

Hospital leaders and the hospital's facility management and safety structure are responsible for the following:

- Knowing what national and local laws, regulations, building and fire safety codes, and other requirements, such as licenses and permits, apply to the hospital's facilities
- Implementing the applicable requirements or approved alternative requirements
- Maintaining and documenting compliance with local and national laws, regulations, building and fire safety codes, inspection reports, and other facility requirements
- Planning and budgeting for the necessary replacement or upgrading of facilities, systems, and equipment to meet applicable requirements or as identified by monitoring data and providing evidence of progress toward implementing the improvements

When the hospital has been cited for not meeting requirements, hospital leaders take responsibility for planning and meeting the requirements in the prescribed time frame.

The hospital documents its building and fire safety laws, regulations, and codes and any corrective actions taken to address citations from external facility inspections and reports. When the hospital is located inside a multiuse building, hospitals must comply with relevant laws, regulations, and facility inspection reports, utility maintenance requirements, and other requirements related to shared systems and building issues. When hospital leaders are not able to receive the reports of inspections and documentation, a credible effort should be available (for example, documentation of communication efforts with the building ownership).

Measurable Elements of FMS.01.00

1. Hospital leaders implement the national and local laws, regulations, building and fire safety codes, and other requirements applicable to the hospital's facilities.
2. Ⓓ Corrective actions taken to meet the conditions of external facility reports and inspections by national and local authorities are documented.
3. Hospital leaders plan and budget for replacing or upgrading facilities, systems, and equipment needed to meet requirements and for the continued operation of a safe, secure, and effective facility.
4. When the hospital is located inside a multiuse building, hospital leaders obtain evidence of compliance with relevant laws, regulations, codes, facility inspection reports, utility maintenance requirements, and other requirements related to shared systems and building issues.

Standard FMS.01.01

A qualified individual(s) oversees the facility management and safety structure.

Intent of FMS.01.01

Hospitals work to provide safe, functional, and supportive facilities for patients, families, staff, and visitors. The hospital must strive to do the following:

- Reduce and control hazards and risks.
- Prevent accidents and injuries.
- Maintain safe conditions.

Effective management includes multidisciplinary planning, education, and monitoring as follows:

- Hospital leaders plan the space, technology, and resources needed to safely and effectively support the clinical and nonclinical services provided.
- Relevant staff are educated about the facility, how to reduce risks, and how to monitor and to report situations that pose risk.
- Performance criteria are used to evaluate important systems and to identify needed improvements.

Hospital leaders identify an individual qualified by training and experience to oversee the facility management and safety structure. Training and experience may include but is not limited to risk management, facility management, and hospital operations. The individual who oversees the structure may be a member of the leadership team, a leader in charge of one or more of the facility management and safety programs, or another designated individual. All facility management and safety programs report to this individual, who is responsible for integrating and coordinating the activities and functions of the overall facility management and safety structure. In a small hospital, one individual may be assigned part-time to oversee the structure. In a larger hospital, several engineers or other specially trained individuals may be assigned to manage one or more facility management and safety programs under the direction of the individual who is responsible for the overall structure.

The facility management and safety structure must be managed effectively and in a consistent and continuous manner.

Depending on the hospital's size and complexity, a facility safety/environmental risk committee or some other mechanism may be formed to support the individual responsible for the facility management and safety structure. For example, this committee could coordinate activities of the facility management and safety programs, such as completing risk assessment activities, analyzing monitoring data, and implementing facility improvements. The mechanism chosen by the hospital to support the individual responsible for the facility management and safety structure must consider a multidisciplinary team and include representatives from the various facility management and safety programs, leadership, infection prevention and control, laboratory and radiation safety programs, laser safety, housekeeping services, and the quality and patient safety program, among others.

When independent business entities are present within the organization, the hospital has an obligation to ensure that these entities comply with relevant facility management and safety programs. Independent business entities are independently owned businesses occupying space within the hospital (for example, coffee shops, gift shops, banks).

Measurable Elements of FMS.01.01

1. Ⓓ Oversight and direction of the facility management and safety structure is assigned to an individual(s) qualified by experience and training, and evidence of the experience and training is documented. (*See also* GLD.06.00, ME 1)
2. The qualified individual(s) is responsible for ensuring the following:
   - Recommendations for space, technology, and other resources to support the facility management and safety structure are provided to hospital leaders.
   - The facility management and safety programs are current and fully implemented.
   - Staff and others are trained on the programs.
   - The programs are coordinated, evaluated, and monitored.
   - The programs are reviewed and revised at least annually, or more frequently if needed (for example, when there are changes to requirements in the country's laws and regulations, or changes to the hospital's facilities, systems, or equipment).
3. When independent business entities are present within the organization, the entities comply with the applicable facility management and safety programs.

Risk Assessment and Monitoring

Standard FMS.02.00

The hospital develops and documents a risk assessment based on facility management and safety risks identified throughout the organization, prioritizes the risks, establishes goals, and implements improvements to reduce and eliminate risks.

Intent of FMS.02.00

Risk assessment identifies and evaluates potential failures and sources of errors in a process and includes prioritizing areas for improvement based on the actual or potential impact of care, treatment, or services provided.

The hospital develops and documents a facilitywide risk assessment, at least annually, that integrates all eight facility management and safety programs to maximize safety to patients, patients' families, staff, and visitors. For example, risks including but not limited to safety/security risks related to infant abduction or active shooter; risks from hazardous waste such as materials contaminated with blood or body fluids, or handling of hazardous chemicals such as high-level disinfectants and chemical sterilants; specific fire risks such as surgical fires (where alcohol-based skin prep is in use with electrocautery devices), or electrical or grease fires in the kitchen; utility system risks such as loss of external electrical power supply, or water management risks from waterborne pathogens such as *Legionella*; risks from plumbing or roofing water leaks in the building leading to hazardous mold growth; risks from medical gas or vacuum systems such as risks of explosion; or construction risks related to dust and dissemination of fungal spores near vulnerable patients, or hazardous materials such as asbestos. The hospital prioritizes the specific risks identified in the risk assessment. Goals are established and improvements are implemented to reduce and eliminate the risks. The goals and improvements are monitored for effectiveness, including progressing and sustained improvement. Changes may be required to goals and improvements based on successes and challenges identified in monitoring data.

Measurable Elements of FMS.02.00

1. Ⓓ The hospital develops and implements an annual risk assessment that includes eight facility management and safety programs:
   - Safety (*See also* FMS.03.00, ME 2)
   - Security
   - Hazardous materials and waste
   - Fire safety (*See also* FMS.06.00, ME 3)
   - Medical equipment
   - Utility systems
   - Emergency and disaster management (*See also* GHI.05.00, ME 4)
   - Construction and renovation (*See also* FMS.10.00, ME 1)
2. Ⓓ The hospital prioritizes the risks, identifies goals and key performance improvements, and implements improvements to reduce and eliminate risks. (*See also* GLD.06.01, ME 1)
3. Ⓓ The hospital evaluates the effectiveness of the improvements, and, based on the results, the hospital updates the applicable facility management and safety programs. (*See also* GLD.06.01, ME 2)
4. Ⓓ Hospital leaders provide the annual risk assessment report and the effectiveness of the facility management and safety programs to the governing entity, and the governing entity takes actions based on the report. (*See also* GLD.04.01, ME 1)

Safety

Standard FMS.03.00

The hospital implements a program to provide a safe physical facility.

Intent of FMS.03.00

Safety refers to ensuring that the building, property, medical and information technology, equipment, and systems do not pose a physical safety risk to patients, families, staff, and visitors. Prevention and planning are essential to creating a safe and supportive patient care facility.

Effective planning requires the hospital to be aware of all the risks present in the facility. The goals are to prevent accidents and injuries and to maintain safe and secure conditions for patients, staff, and others, such as families, contractors, vendors, volunteers, visitors, trainees, and students. The hospital develops and implements a written safety program. As part of the safety program, the hospital conducts and documents an ongoing inspection of its physical facilities. The results of the inspection are reviewed and addressed in a documented comprehensive, facilitywide risk assessment, at least annually, to identify areas in which safety risks and potential for harm exist.

A worksite analysis, conducted annually to assess the safety of the hospital's workplace violence prevention program, includes a proactive analysis of the worksite, an investigation of the hospital's workplace violence incidents, and an analysis of how the program's policies and procedures, training, education, and environmental design reflect best practices and conform to applicable laws and regulations. All safety incidents and issues may be reported to staff in quality assessment, improvement, or other functions as well as to the designated leader of the workplace violence reduction effort. A summary of such incidents may also be shared with the person designated to coordinate safety management activities. Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve care, treatment, or services, or to prevent similar incidents, are not lost as a result of following the legal process.

The risk assessment also considers a review of processes and an evaluation of new and planned services that may pose safety risks. It is important to involve a multidisciplinary team when conducting safety inspections in the hospital. Examples of safety risks that pose a potential for injury or harm include sharp and broken furniture, broken windows, water leaks in the ceiling, ergonomic risks (for example, risks to staff when moving patients or heavy objects), and fall risks (for example, due to uneven or slippery floors or missing handrails).

Conducting regular rounds to inspect for safety risks, and the annual safety risk assessment, helps the hospital identify, prioritize, plan for, and carry out improvements. Prioritizing and planning also includes budgeting for longer-term facility, system, and equipment upgrading or replacement.

Measurable Elements of FMS.03.00

1. Ⓓ The hospital develops and implements a written program to provide a safe physical facility. (*See also* COP.05.00, ME 1; GLD.07.02, ME 2; HCT.02.00, ME 1; PCI.01.01, ME 2)
2. Ⓓ The hospital has a documented, current, accurate safety inspection of its physical facilities. Results of facility inspection are reviewed and addressed in a comprehensive, facilitywide risk assessment. (*See also* FMS.02.00, ME 1)
3. Ⓓ The hospital identifies goals, implements improvements, and monitors data to ensure that safety risks related to workplace violence are reduced or eliminated. (*See also* GLD.07.02, ME 3)
4. Based on its process(es), the hospital reports and investigates safety incidents involving patients, staff, or others within its facilities.
5. Based on its process(es), the hospital reports and investigates safety incidents related to workplace violence involving patients, staff, or others within its facilities. (*See also* GLD.07.02, ME 3)

Security

Standard FMS.04.00

The hospital implements a program to provide a secure environment for patients, families, staff, and visitors.

Intent of FMS.04.00

Security refers to protecting the organization's property and the patients, families, visitors, and staff from harm or loss. Examples of vulnerabilities and threats related to security risks include workplace violence, infant abduction, theft, and unlocked/unsecured access to restricted areas in the hospital. Security incidents can be caused by individuals from either outside or inside the hospital.

The hospital develops and implements a written security program to ensure that everyone in the hospital is protected from personal harm and loss or damage to property. This may include coordination with local law enforcement. As part of the security program, the hospital conducts and documents a risk assessment, at least annually, to identify areas in which security risks exist. The risk assessment also considers a review of processes and an evaluation of new and planned services that may pose security risks.

Staff, students, trainees, contract workers, volunteers, vendors, individuals associated with independent business entities, and others, as determined by the hospital, are identified by badges (temporary or permanent) or another form of identification. Others, such as families and visitors in the hospital, may be identified depending on hospital policy, laws, and regulations.

Restricted areas such as the pharmacy, newborn nursery, and operating theatres must be secure and monitored. Children, elderly adults, and vulnerable patients not able to protect themselves or signal for help must be protected from harm. In addition, remote or isolated areas of the facility and grounds may require the use of security cameras.

Measurable Elements of FMS.04.00

1. Ⓓ The hospital develops and implements a written program to provide a secure environment.
2. Ⓓ The security program identifies all security risk areas and restricted areas and ensures that they are monitored and kept secure. (*See also* COP.05.00, ME 1; MMU.03.00, ME 6; MMU.03.01, ME 2; PCC.01.03, ME 1)
3. The security program ensures that relevant patients, as well as staff, students, trainees, contract workers, volunteers, vendors, and individuals associated with independent business entities, are identified.
4. All security equipment and systems, including devices related to detection, alarm notification, and timely response, are inspected, evaluated, and maintained.
5. The security program includes education of relevant staff on roles and responsibilities during a security-related event.
6. The hospital conducts regular exercises with staff to evaluate the security program and integration with local responders.
7. The hospital conducts an annual worksite analysis related to its workplace violence prevention program and takes actions to mitigate or resolve the identified workplace violence security risks. (*See also* GLD.07.02, ME 2)
8. Based on its process(es), the hospital reports and investigates security incidents involving patients, staff, or others within its facilities.
9. Based on its process(es), the hospital reports and investigates security incidents related to workplace violence involving patients, staff, or others within its facilities. (*See also* GLD.07.02, ME 3)

Hazardous Materials and Waste

Standard FMS.05.00

The hospital implements a program for the management of hazardous materials and waste.

Intent of FMS.05.00

The hospital uses a variety of hazardous materials and waste. When staff are educated about safe handling, storage, and disposal of hazardous materials and waste, they are more likely to follow the process that will maintain a safe environment for patients, staff, and visitors. Therefore, it is critical for a hospital to develop and implement a written program for the management of hazardous materials and waste that includes identifying and safely controlling these materials and waste throughout the facility.

The hospital identifies and develops an inventory of its hazardous materials. The hospital starts by doing a thorough search for all areas within the organization where hazardous materials may be located. Documentation from this search should include information about the type of each hazardous material being stored, the quantities of the material(s), and the location(s) in the organization. This documentation should also address the maximum quantities allowed for storing the hazardous material in one location/area. For example, if the material is highly flammable or toxic, there are limits on the quantities of the material that can be stored in one location. An inventory of hazardous materials is created and updated, at least annually, to reflect changes in the hazardous materials used and stored in the organization.

Hazardous materials can be categorized by the following:

- Chemicals (for example, chemicals used for cleaning, disinfection, sterilization, water treatment, pathology, pharmacy, hand hygiene)
- Cytotoxic and hazardous drugs
- Radioactive material
- Hazardous gases and vapors

The hospital also establishes the types of hazardous waste generated by the organization and how they are identified (for example, color-coded and labeled waste bags/bins). The following are categories of hazardous waste:

- Infectious
- Sharps
- Pathological and anatomical
- Pharmaceutical
- Chemicals/heavy metals/pressurized containers
- Genotoxic/cytotoxic
- Radioactive material

The hospital's hazardous materials and waste program complies with all applicable laws and regulations and national standards, and addresses hazardous materials and hazardous waste to include processes for the following:

- Taking inventory of hazardous materials and waste, including the type, the location(s), and the quantities (for example, approximate or average in each location)
- Updating the maximum allowed quantity for each location at least annually
- Safely handling, storing, and using hazardous materials
- Properly and clearly labeling hazardous materials, consistent with information from the safety data sheets (SDS)
- Establishing and identifying categories of hazardous waste
- Safely handling and storing hazardous waste

- Tracking the quantity of and proper disposal of hazardous waste in accordance with local laws and regulations
- Employing proper protective equipment and procedures for spills and exposures
- Reporting and investigating spills, exposures, and other incidents
- Documenting permits, licenses, or other regulatory requirements

Information regarding procedures for handling or working with hazardous materials and waste in a safe manner must be immediately available at all times and includes information about the physical data of the material (such as its boiling point, flashpoint, and the like), its toxicity, what effects using the hazardous material may have on health, identification of proper storage and disposal after use, the type of protective equipment required during use, and spill-handling procedures, which include the required first aid for any type of exposure. Many manufacturers provide this information in the form of SDS.

In the event of a hazardous materials spill, the hospital has procedures for responding to and managing spills and exposures. Procedures include having spill kits available where needed with the appropriate personal protective equipment and spill control materials for the potential type and size of spill. Procedures also address how to report spills and exposures.

Hospitals implement procedures for responding to a hazardous material exposure, including initial first aid, obtaining appropriate medical care, reporting incidents, and so on. Exposure to a hazardous material requires immediate access to the appropriate first aid. In some cases, such as with an exposure to a corrosive or caustic chemical, access to an eyewash or shower station may be necessary for immediate and continuous flushing to prevent or minimize injury. An eyewash station is designed to flush both eyes simultaneously for 15 continuous minutes at a flow rate of 1.5 liters per minute (0.4 gallons per minute). However, an eyewash station may not be needed in all cases of hazardous material exposures. Hospitals should conduct a risk assessment to identify where in the organization eyewash stations are required, taking into account the physical properties of the hazardous chemicals used, how these chemicals are used by staff to perform their work activities, and staff's use of personal protective equipment. Alternatives to an eyewash station may be appropriate depending on the types of risks and potential for exposures. For example, personal eyewash bottles may be appropriate in areas where exposure to a mild irritant is a risk, or where individuals could use the bottles for immediate flushing as they make their way to a proper eyewash station or get to an area for medical attention. Hospitals that have eyewash or shower stations installed must ensure proper maintenance, including a weekly flush and annual preventive maintenance.

Measurable Elements of FMS.05.00

1. Ⓓ The hospital develops and implements a written program for the management of hazardous materials and waste. (*See also* HRP.02.01, ME 2)
2. Ⓓ The hazardous materials and waste program identifies the type, quantities, and locations of hazardous materials and waste, and has a complete inventory, which is updated at least annually, to reflect changes in the hazardous materials used and stored in the organization. (*See also* AOP.03.05, MEs 1 and 5; MMU.03.00, ME 2; PCI.05.00, ME 1)
3. The hazardous materials and waste program establishes and implements procedures for clear labeling, safe handling, storage, and use of hazardous materials that is consistent with safety data sheets.
4. The hazardous materials and waste program establishes and implements the proper protective equipment required during handling and use of hazardous materials.
5. The hazardous materials and waste program establishes and implements procedures for the management of spills and exposures, including the use of proper protective equipment and reporting of spills and exposures.
6. Information about the hazardous materials related to safe handling, spill-handling procedures, and procedures for managing exposures are up to date and available at all times.
7. Staff can describe and/or demonstrate precautions and procedures for handling and managing hazardous materials and waste, as applicable to the staff member's role and responsibilities.

Fire Safety

Standard FMS.06.00

The hospital establishes and implements a program for fire safety that complies with national and local codes, laws, and regulations.

Intent of FMS.06.00

Hospitals must be vigilant about fire safety, as fire is an ever-present risk in the health care environment. To protect all occupants of the hospital's facilities from fire and smoke, the hospital develops and implements a written program for fire safety.

An ongoing assessment of compliance with the country's codes, laws, and regulations related to fire safety is important for identifying and minimizing risks.

An interim measure(s) may be necessary when the planned improvement to address the fire safety risk cannot be implemented right away. The purpose of implementing interim measures is to ensure the safety of the building's occupants during times when features and systems for fire safety are defective, compromised, or inoperable due to construction, maintenance, or a breakdown or repair. The type of and need for an interim measure(s) will depend on the type and scope of the fire safety risk and the amount of time until the planned improvement to fully address the risk will be implemented.

The fire safety program includes criteria for evaluating when and to what extent interim measures should be implemented.

Examples of interim measures include posting signs to identify alternative exits; inspecting exits/exit routes on a daily basis in the affected area; providing temporary but equivalent fire alarm and detection systems when a system is impaired; providing additional firefighting equipment; increasing fire safety surveillance of buildings, grounds, and equipment; and providing additional training of staff on the use of firefighting equipment; among other interim measures.

The hospital considers the risk posed to patients, staff, and others when determining the plan and time frame for implementing improvements and/or interim measures. The ongoing risk assessment and time frame for implementing interim measures and improvements are documented.

Note: A list of additional interim measures can be found in the "Interim Measures" appendix in this manual.

Measurable Elements of FMS.06.00

1. Ⓓ The hospital develops and implements a written program for fire safety to protect all occupants of the hospital's facilities from fire and smoke emergencies.
2. Ⓓ The fire safety program includes implementing interim measures, when necessary, to ensure that the safety of the hospital's patients, staff, and visitors is maintained when fire safety risks cannot be immediately addressed.
3. Ⓓ The hospital's comprehensive, facilitywide risk assessment as required by FMS.02.00, ME 1 includes evaluation of the following fire-related risks:
   - Fire separations
   - Smoke separations/compartments
   - Hazardous areas (and spaces above the ceilings in those areas) such as soiled linen rooms, trash collection rooms, and medical gas storage rooms
   - Fire exits
   - Kitchen and kitchen grease-producing cooking devices
   - Laundry and trash chutes
   - Emergency power systems and equipment
   - Medical gas and vacuum system components
   - Storage and handling of potentially flammable materials (for example, flammable liquids, combustible gases, oxidizing medical gases such as oxygen and nitrous oxide)
   - Procedures and precautions to prevent and manage surgical fires
   - Fire hazards related to construction, renovation, or demolition projects

Standard FMS.06.01

The hospital maintains fire safety equipment and fire safety building features.

Intent of FMS.06.01

Every hospital needs to plan how it will keep its occupants safe in case of fire and smoke emergencies. Health care facility structure and design can help prevent, detect, and suppress fires and provide safe exit from the facility. Hospitals are better prepared for fire emergencies when the fire safety program includes the early detection, suppression, and containment of fire and smoke and measures to ensure safe exit from the facility when fire and smoke emergencies occur.

The hospital's program for fire safety addresses the following:

- Early warning, early detection, and notification systems, such as smoke detectors, fire alarms, and fire patrols
- Suppression mechanisms that are appropriate for the area (for example, information technology rooms, electrical rooms) and type of fire to be expected, such as water hoses, fire extinguishers, chemical suppression systems, and sprinkler systems
- Containment of fire and smoke, including fire separations and smoke compartments, when required by local laws and regulations; features for containment of fire and smoke are maintained to ensure their effectiveness.
- Safe and unobstructed access to exits in the event of a fire or smoke emergency, including clear exit signage that is understandable to the hospital's occupants (for example, with a pictogram and/or language[s] that the majority of occupants understand) and emergency lighting

Features such as these give patients, staff, and visitors adequate time to safely exit the facility or reach a safe location within the facility in the event of fire or smoke emergencies. These features are effective no matter what the age, size, or construction of the facility.

Measurable Elements of FMS.06.01

1. The fire safety program includes equipment/systems for the early detection and alarm notification of fire and smoke.
2. The fire safety program includes equipment/systems for the suppression of fire.
3. The fire safety program includes the safe exit from the facility through free and unobstructed access to exits.
4. The fire safety program includes clearly visible exit signage that is understandable to the hospital's occupants.
5. The fire safety program includes lighting for emergency exit corridors and stairs.
6. When required by local laws and regulations, the fire safety program includes containment of fire and smoke, and these features are maintained to ensure effectiveness and safety.

Standard FMS.06.02

All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, evaluated, and maintained.

Intent of FMS.06.02

The hospital's fire safety program identifies the frequency of inspecting, testing, and maintaining fire protection and safety systems, consistent with requirements. Fire safety equipment and systems in hospitals include but are not limited to the following:

- Heat and smoke detectors
- Fire alarms
- Fire pumps
- Standpipe systems
- Sprinklers
- Fire suppression systems
- Fire hoses
- Portable fire extinguishers
- Fire doors and assemblies (including sliding and roll-down doors)
- Automatic shutdown devices for air handling systems
- Automatic smoke management systems

The hospital inspects, evaluates, and maintains all fire safety equipment and systems within its building(s), including equipment for early detection and suppression of fire and smoke. Activities and frequencies for inspection, testing, and maintenance are consistent with manufacturers' recommendations. When local codes, laws, and regulations include requirements for inspection, testing, and maintenance of fire safety equipment and systems, the hospital follows the more stringent requirements, whether those are the manufacturers' recommendations or the local codes, laws, and regulations.

Any deficiencies identified, such as impaired or nonfunctioning systems and equipment, are immediately corrected. When corrections cannot be immediately carried out, interim measures are implemented to reduce fire risk and ensure safety of patients, staff, and visitors until deficiencies can be fully corrected. The results of all inspections, testing, and maintenance are documented, including corrections and interim measures that are implemented.

Measurable Elements of FMS.06.02

1. All fire safety equipment and systems, including those for smoke and fire detection and suppression, are inspected, evaluated, and maintained according to manufacturers' recommendations or as required by local codes, laws, and regulations, whichever sets the more stringent requirement.
2. Ⓓ Inspection, testing, and maintenance of all fire safety equipment and systems are documented, including results and corrective actions.
3. Any deficiencies identified in fire safety equipment and systems are immediately corrected, or interim measures are implemented to reduce fire risk until deficiencies can be fully corrected.

Standard FMS.06.03

The hospital conducts regular exercises with staff to evaluate the fire safety program.

Intent of FMS.06.03

The hospital's fire safety program includes but is not limited to the following:

- Plan for reporting and responding to a fire emergency
- Plan for safely evacuating the facility in the event of fire or smoke emergencies
- Process for evaluating all portions of the fire safety program during each 12-month period
- Responsibilities of different staff members during a fire emergency
- Necessary education of staff to effectively protect and evacuate patients when an emergency occurs
- Participation of staff members in at least one fire safety exercise per year, or more frequently when required by laws and regulations, national fire protection standards, or other authorities

Exercises to evaluate the fire safety program can be accomplished in multiple ways but should always include a physical component in which staff must respond to an alarm and take appropriate actions during a fire alarm exercise. Staff are trained in what to do, how to exit, and where to assemble (the "assembly points"). The hospital may choose to conduct evacuation exercises during various shifts, including nights and weekends. (Simulated evacuation exercises in areas such as the intensive care unit, operating theatre, or on high floors of the building may provide additional insights but are not mandatory.) **Note:** Evacuation exercises to evaluate the fire safety program should not directly involve patients or visitors; however, it must address how staff would protect patients and visitors in a fire emergency. It is also important to note that high-risk areas of hospitals that are identified in its risk assessment, such as operating theatres and hyperbaric treatment areas and equipment, may have unique risks that require additional elements of its fire safety exercises. In this case, the hospital should conduct exercises based on these risks, as well as laws and regulations, Ministry of Health requirements, or other authorities.

Another example of an exercise to evaluate the fire safety program is assigning a "fire marshal" to each unit and having them randomly quiz the staff about what they would do if a fire occurred on their unit. The staff can be asked specific questions, such as, "Where is the oxygen shutoff valve? If you have to shut off the oxygen valve, how do you take care of patients who need oxygen? Where are the fire extinguishers on your unit located and how/in what circumstances would you use one? How do you report a fire? How do you protect the patients during a fire? If you need to evacuate patients horizontally or vertically, what is your process?" Staff should be able to respond correctly to these questions. The fire marshal should keep a record of those who participated. Other examples of exercises include computer-based teaching and testing or a written test for staff to take relating to the fire safety program.

Whatever the exercise chosen to evaluate the fire safety program, staff should be knowledgeable of the program and be able to describe how to bring patients to safety. Staff who do not pass are reeducated and retested.

Measurable Elements of FMS.06.03

1. All hospital personnel, including the night shift and weekends, are trained in the fire safety program and participate in drills to evaluate the fire safety program at least annually, or more frequently when required by laws and regulations or other authorities.
2. Staff who provide patient care can describe and demonstrate how to bring patients to safety.
3. Ⓓ Results of exercises to evaluate the fire safety program are documented, and staff who do not pass are reeducated and retested on the fire safety program.

Standard FMS.06.04

The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility.

Intent of FMS.06.04

The fire safety program addresses limiting smoking and meets the following criteria:

- Applies to all patients, families, staff, and visitors.
- Eliminates smoking in the hospital's facilities or minimally limits smoking to designated non–patient care areas that are ventilated to the outside.
- Prohibits smoking in all areas under construction or renovation.

Smoking includes but is not limited to the use of cigarettes, cigars, pipes, hookahs, electronic cigarettes (including e-cigarettes and vaping devices), and other ignition sources for smoking.

The fire safety program that addresses limiting smoking identifies any exceptions related to patients, such as the medical or psychiatric reasons a patient may be permitted to smoke, and those individuals permitted to grant such an exception. When an exception is made, the patient smokes in a designated, nontreatment area, away from other patients.

Measurable Elements of FMS.06.04

1. The fire safety program addresses eliminating or limiting smoking within the hospital facility.
2. The program applies to patients, families, visitors, and staff.
3. The program identifies who may grant patient exceptions for smoking and when those exceptions apply.

Medical Equipment

Standard FMS.07.00

The hospital develops and implements a program for the management of medical equipment throughout the organization.

Intent of FMS.07.00

Management of medical equipment is performed to ensure that all equipment is functioning properly and available for use.

The medical equipment management program includes the following:

- An inventory of all medical equipment
- Regular inspections
- Testing according to use and manufacturers' requirements
- Documentation of results

- Performance of preventive maintenance, significant repairs, and disposal when necessary
- Completed documentation of all repair work

As part of the medical equipment program, the hospital conducts and documents a risk assessment, at least annually, to identify areas in which medical equipment risks exist.

Medical equipment management is performed by a qualified individual(s) based on background experience, education, and training. Medical equipment is used by departments throughout the hospital (for example, facilities team, bioengineering team, environmental services) and should have unified management processes to maintain an integrated system. Testing and inspection are performed when equipment is new and then on an ongoing basis according to age, use, and manufacturers' instructions. Inspections, testing results, any maintenance, and repairs are documented to ensure continuity of processes and guide capital planning for replacements, upgrades, and other changes.

Measurable Elements of FMS.07.00

1. Ⓓ The hospital develops and implements a written program for the management of medical equipment that is hospital owned and non-hospital owned (leased, rented, patient owned). (*See also* GLD.05.02, ME 1; HRP.02.01, ME 2)
2. Ⓓ The equipment program includes the following:
   - An inventory of all medical equipment
   - Regular inspections when equipment is new and as required by manufacturers' guidelines
   - Testing according to use and manufacturers' requirements
   - Documentation of results
   - Performance of preventive maintenance and calibration as applicable
   - Adherence to local laws and regulations

   (*See also* AOP.03.04, ME 2; AOP.05.04, ME 2)
3. Ⓓ The hospital identifies goals, implements improvements, and monitors data to ensure that medical equipment risks are reduced or eliminated.

Standard FMS.07.01

The hospital has a process for monitoring and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures.

Intent of FMS.07.01

Medical equipment malfunctions pose risks to patients, providers, and other staff members, and having processes in place ensures awareness of issues and allows for action to prevent harm.

The hospital has a system in place for monitoring and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures sent by the manufacturer, supplier, or regulatory agency. Some countries require reporting of any medical equipment that has been involved in a death, serious injury, or illness. Hospitals must identify and comply with the laws and regulations pertaining to the reporting of medical equipment incidents. The hospital conducts a root cause analysis in response to any sentinel events.

Measurable Elements of FMS.07.01

1. The hospital has a process for monitoring and acting on medical equipment and implantable device hazard notices, recalls, reportable incidents, problems, and failures. (*See also* AOP.03.04, ME 5; AOP.05.04, ME 5)
2. The hospital reports any deaths, serious injuries, or illness that are a result of medical equipment through the hospital's incident and adverse event reporting process. (*See also* GLD.04.00, ME 7)
3. The medical equipment management program addresses the use of any medical equipment with a reported problem or failure, or that is the subject of a hazard notice or is under recall.

Utility Systems

Standard FMS.08.00

The hospital implements a program for the management of utility systems throughout the organization.

Intent of FMS.08.00

Utilities can be defined as the systems and equipment that support essential services that provide safe health care. Such systems include electrical distribution; power; plumbing; boiler/steam; heating, ventilating, and air-conditioning (HVAC); medical gas; medical/surgical vacuum; waste management; and communication and data systems. The safe, effective, and efficient operation of utility and other key systems in the hospital is necessary for patient, staff, and visitor safety and for meeting patient care needs. Patient care, both routine and urgent, is provided on a 24-hour basis, every day of the week in a hospital. Thus, an uninterrupted source of essential utilities is critical to meeting patient care needs.

The hospital develops and implements a written program for the management of utility systems throughout the hospital. The utility systems program includes inspection, testing, and maintenance to ensure that utilities operate effectively and efficiently to meet the needs of patients, staff, and visitors.

A good utilities management program ensures the reliability of the utility systems and minimizes the potential risks. For example, water contamination, ineffective ventilation in critical care areas, oxygen cylinders that are not secured when stored, leaking oxygen lines, and frayed electrical lines all pose hazards. To avoid these and other risks, the hospital has a process for regularly inspecting such systems and performing preventive and routine maintenance. During testing, attention is paid to the critical components (for example, switches and relays) of systems.

Hospitals should have a complete inventory of all utility systems components and identify which components have the greatest impact on life support, infection prevention and control, environmental support, and communication. The utilities management program includes strategies for utility maintenance that ensure that these key systems components, such as electricity, water, waste, ventilation, and medical gas, are regularly inspected, evaluated, maintained, and, when necessary, improved, to reduce and eliminate risks.

Measurable Elements of FMS.08.00

1. Ⓓ The hospital develops and implements a written program for the management of utility systems throughout the hospital. (*See also* HCT.01.04, ME 1)
2. Ⓓ The hospital identifies goals, implements improvements, and monitors data to ensure that the utility systems risks are reduced or eliminated.
3. Ⓓ The hospital inventories its utility systems components and maps their current distribution.
4. Ⓓ The hospital identifies, in writing, the activities and intervals for inspecting, evaluating, and conducting preventive and routine maintenance on all operating components of the utility systems on the inventory, based on criteria such as manufacturers' recommendations, risk levels, and hospital experience.
5. The hospital labels utility system controls to facilitate partial or complete emergency shutdowns.

Standard FMS.08.01

The hospital utility systems program ensures that essential utilities, including power, water, and medical gases, are available at all times, and alternative sources for essential utilities are tested and evaluated.

Intent of FMS.08.01

Patient care, both routine and urgent, is provided on a 24-hour basis, every day of the week in a hospital. Hospitals have different utility system needs based on their mission, patient needs, and resources. However, an uninterrupted source of essential utilities, including water, power, and medical gas, is critical for meeting patient care needs.

An emergency power system is required for all hospitals that intend to provide continuous service under emergency conditions. Such a system provides sufficient power to maintain essential functions during power failures. It also reduces the risks associated with such failures. Emergency and backup power sources are tested under planned circumstances that simulate actual load requirements. For example, for quarterly testing, requirements are that the test run for 30 minutes and should achieve 30% of the nameplate load. The 30-minute time frame does not include the time it takes for the warm-up or cool-down period. Hospitals may choose other methods for testing that meet industry standards.

Water quality can change suddenly from many causes, some of which occur outside of the hospital, such as a break in the supply line to the hospital. When there is a disruption in the usual source of water supplied to the organization, emergency potable water supplies must be immediately available.

Regardless of the type of system and level of its resources, a hospital needs to protect patients and staff in emergencies, such as when essential utilities fail, are interrupted, or become contaminated. To prepare for such emergencies, the hospital does the following:

- Identifies its essential utilities based on the systems, equipment, and locations that pose the highest risks to patients and staff if the utilities were interrupted, failed, or otherwise became unavailable (for example, key systems, equipment, and locations that require illumination, refrigeration, life support, water for cleaning and sterilization of supplies).
- Assesses and minimizes the risks of utility system failures in these areas.
- Plans emergency power and clean water sources for these areas and needs.
- Tests the availability and reliability of emergency sources of power and water.
- Documents the results of tests.
- Ensures that the testing and evaluation of alternative sources of water occurs at least annually or more frequently if required by local laws, regulations, or conditions of the sources for water (examples of conditions of the sources for water that may increase the frequency of testing include repeated repair of the water system and frequent contamination of the water source).
- Ensures that the testing and evaluation of power occurs at least quarterly or more frequently if required by local laws, regulations, manufacturers' recommendations, or conditions of the sources for power (examples of conditions of the sources for power that may increase the frequency of testing include unreliable electrical grids and recurrent, unpredictable power outages).

When the emergency power system requires a fuel source, determining how much fuel to store on-site should include consideration of past outages and any anticipated delivery problems caused by shortages, weather, and geographic conditions and locations. The hospital may determine the amount of fuel stored unless laws and regulations/local authority specifies the amount.

Measurable Elements of FMS.08.01

1. The hospital ensures backup availability/continuity of essential utilities (including power, water, and medical gas) 24 hours a day, 7 days a week. (*See also* FMS.09.00, ME 1)
2. Ⓓ The hospital tests and evaluates the availability and quality of the alternative source(s) of water at least annually or more frequently if required by local laws and regulations or conditions of the source of water. The hospital documents the results of the tests.
3. Ⓓ The hospital tests and evaluates alternative sources of power at least quarterly or more frequently if required by local laws and regulations, manufacturers' recommendations, or conditions of the source of power. The hospital documents the results of the tests.

Standard FMS.08.02

Designated individuals or authorities monitor water quality regularly.

Intent of FMS.08.02

Water quality is prone to sudden change, including changes outside the control of the hospital. It is imperative for hospitals to maintain water quality, as it is a crucial factor in clinical care processes, including dental procedures and hemodialysis. Thus, the hospital establishes a process to monitor and maintain water quality and implements actions when water quality is found to be unsafe.

The number of sites tested for water quality is determined by the hospital based on its own risk assessment. Testing of potable and/or non-potable water is conducted regularly. The frequency of testing can be based on any or all of the following:

- Local laws and regulations
- Conditions of the sources for water
- Previous experience with water quality problems

The testing can be carried out by individuals designated by the hospital, such as staff from the clinical laboratory, or by public health or water control authorities outside the hospital, or others judged competent to perform such tests. Whether performed by qualified hospital staff or by authorities outside the hospital, or other qualified individuals, it is the responsibility of the hospital to ensure that the testing is completed and documented.

In addition to testing water quality, to prevent and reduce the risks of contamination and growth of bacteria such as *Escherichia coli*, *Legionella*, and many others, guidance is sought from the hospital's infection prevention and control program as well as data from water quality–related patient adverse events. These sources help inform whether actions should be taken, such as preventive measures, to reduce the risk of contamination and growth of bacteria.

Water is an integral part of dental care. Hospitals that provide dental services take measures to ensure that the water used in dental treatments and procedures is safe. This includes following manufacturer's guidelines for treating and testing dental unit waterlines. The hospital ensures that dental staff are trained and understand the dental unit waterline treating and testing requirements and procedures.

Measurable Elements of FMS.08.02

1. Ⓓ Quality of potable water is tested and evaluated at least quarterly or more frequently in accordance with laws and regulations, conditions of the sources for water, and previous experience with water quality problems. The testing results are documented.
2. Ⓓ Quality of non-potable water is tested and evaluated at least every six (6) months or more frequently based on local laws and regulations, conditions of the sources for water, and previous experience with water quality problems. The testing results are documented.
3. Preventive measures and strategies are implemented to reduce the risks of contamination and growth of bacteria in water.
4. Ⓓ Dental unit waterlines are treated, tested, and evaluated according to manufacturer's guidelines, and treatments and testing are documented.

Standard FMS.08.03

Quality of water used in hemodialysis is tested and evaluated for chemical, bacterial, and endotoxin contaminants, and processes for hemodialysis services follow professional standards for water quality and for infection prevention and control.

Intent of FMS.08.03

Water quality is essential for the safe and effective delivery of hemodialysis, as those patients may be more vulnerable to infection risk and adverse outcomes.

It is necessary that the processes and procedures used in hemodialysis strictly follow industry standards and professional guidelines for water quality and infection prevention and control measures, such as the Association for the Advancement of Medical Instrumentation (AAMI). This includes but is not limited to testing water used for hemodialysis prior to and during dialysis treatments in accordance with evidence-based guidelines and other authorities, monthly at minimum for bacterial growth and endotoxins, and testing annually at minimum for chemical and other contaminants such as arsenic and heavy metals. It is also important to sample water for testing from both pre- and post-dialysis machine/reverse osmosis treatment unit/filter when required by industry standards and professional guidelines, to ensure that incoming water supply is not contaminated and meets water quality standards and that the machines and reverse osmosis units are performing as expected.

Other actions to ensure appropriate water quality and reduce infection risk in the hemodialysis services include routine disinfection of the water distribution system and testing hemodialysis machines. Frequency for disinfecting the water distribution system depends on such factors as the design of the system and the degree of prevention needed to control bacterial biofilm from forming on the interior of the water pipes.

Water quality treatments and testing results are documented.

When applicable to its services, the hospital establishes and implements procedures for reprocessing dialyzers, such as processes for cleaning, testing, and storing the dialyzers and the frequency for reusing/replacing them.

When problems with water quality are encountered in the hospital, actions are taken to address the problems while maintaining patient safety in the organization. For example, water quality problems may require the hospital to limit certain services or use alternative water sources until the problem is addressed. After the issue is resolved and water quality monitoring demonstrates that the water is safe, the hospital returns to its regular patient care services.

Measurable Elements of FMS.08.03

1. Hemodialysis services in the hospital follow industry standards and professional guidelines for maintaining water quality and implementing infection prevention and control measures.
2. Ⓓ Water used in hemodialysis is tested in accordance with evidence-based guidelines prior to and during treatments and evaluated monthly for bacterial growth and endotoxins and evaluated annually for chemical contaminants. The testing results are documented.
3. Ⓓ The hospital performs routine disinfection of the hemodialysis water distribution system.
4. Ⓓ The hospital conducts testing and evaluation on all hemodialysis machines annually, including machines not in use, and testing results are documented.
5. Ⓓ The hospital establishes and implements procedures for reprocessing dialyzers, including, as applicable, frequency for reusing/replacing dialyzers and processes for cleaning and testing dialyzers.

Standard FMS.08.04

The hospital reduces the risk of infection in the facility through the use of mechanical and engineering controls.

Intent of FMS.08.04

Engineering controls, such as positive and negative pressure ventilation systems, biological hoods in laboratories, and thermostats on refrigeration units and on water heaters used to sterilize dishes and kitchen equipment, are examples of how environmental standards and controls contribute to good sanitation and the reduction of infection risks in the hospital.

Positive pressure ventilation systems are used in protective areas of the hospital that require the highest level of cleanliness; for example, operating theatres, sterile storage areas, and rooms for immunocompromised patients. Positive pressure ventilation ensures that air is directed out of the area, minimizing the likelihood that microorganisms are introduced into the environment.

Hospitals identify and follow local and national laws and regulations and professional standards regarding the use and maintenance of positive pressure ventilation systems.

Proper water and steam temperatures are required to prevent the growth of microorganisms and to successfully carry out cleaning, disinfection, and sterilization procedures. Hospital leaders consult local and national laws and regulations, as well as professional guidelines, to determine appropriate water and steam temperatures to minimize the likelihood of infection transmission through water. In addition, hospital leaders ensure that water and steam reach the necessary temperatures for the proper duration to effectively carry out any cleaning, disinfection, or sterilization process; for example, proper water temperature for dishwashing and steam temperatures for autoclaving.

The hospital operates and maintains airflow, ventilation systems, and humidity controls to maintain indoor air quality. This includes maintaining heating, ventilating, and air-conditioning (HVAC) systems in a manner that minimizes infection risks to patients, staff, and visitors. Airborne contaminants can be spread through exhaust, through general ventilation, and during cleaning. Maintenance of airflow and ventilation systems can minimize this risk. Operation and maintenance are completed in accordance with local and national laws and regulations and professional guidelines and include proper maintenance of inlets, outlets, fans, filters, diffusers, ductwork, humidifiers, and so on.

Measurable Elements of FMS.08.04

1. The hospital operates and maintains negative and positive pressure ventilation systems in accordance with local and national laws and regulations and professional standards.
2. The hospital operates and maintains temperature controls for water, steam, and others in accordance with local and national laws and regulations and professional standards.
3. The hospital operates and maintains airflow, ventilation systems, and humidity controls in a manner that minimizes infection risk in the hospital in accordance with local and national laws and regulations and professional guidelines.

Emergency and Disaster Management

Standard FMS.09.00

The hospital develops, maintains, and evaluates an emergency management program to respond to internal and external emergencies and disasters that have the potential of occurring within the hospital and community.

Intent of FMS.09.00

Community emergencies and disasters may directly involve the hospital, such as damage to patient care areas as a result of an earthquake, tsunami, or terrorist attack that keeps staff from coming to work. To plan, prepare, and respond effectively to emergencies and disasters, the hospital develops and implements an emergency and disaster management program.

The development of the program begins by identifying the types of emergencies and disasters that are likely to occur in the hospital's region (for example, earthquakes, typhoons, floods, landslides, explosions) and the impact these emergencies and disasters would have on the hospital. For example, a hurricane or tsunami is more likely to occur in areas where the ocean is near; however, facility damage or mass casualties as a result

of war or a terrorist attack could potentially occur in any hospital. The program should address all six critical elements:

- Communication
- Resources and assets
- Safety and security
- Staff responsibilities
- Utilities management
- Patient clinical and support activities

Hospitals play a significant role in the community during emergencies and disasters. In order for hospitals to maintain operations during and after emergencies and disasters, it is important to evaluate and identify the structural and nonstructural limitations of the hospital's buildings. Determining how buildings will respond to the emergencies and disasters that are likely to occur in the region is an important aspect in developing evacuation plans and identifying priority areas for building improvements.

An evaluation of structural elements includes the type of building design and materials as well as components of the building's load-bearing system, including the foundation, columns, beams, walls, floor slabs, and so on. The building's location is also considered part of the structural elements (for example, risks related to proximity to other buildings, location in a hazard zone such as a floodplain, and other issues). An evaluation of nonstructural elements includes architectural elements that are not load-bearing (such as the roof, ceilings, windows, and doors); emergency access and exit routes to and from the hospital; critical systems (such as electricity, plumbing, waste management, and fire protection); medical and laboratory equipment; and other nonstructural elements that are crucial for the safe operation of the hospital. An evaluation of structural and nonstructural elements allows the hospital to identify vulnerabilities and develop plans for addressing these vulnerabilities and improving hospital safety and preparedness.

It is just as important to identify the probable effects of an emergency or disaster as it is to identify the types of emergencies and disasters likely to occur. This helps in planning the strategies that are needed in the event that the hospital experiences an emergency or disaster. For example, what is the likelihood that a natural disaster, such as an earthquake, will affect water and power? Could an earthquake prevent staff from responding to the disaster, either because roads are blocked or because they or their family members are also victims of the event? In such situations, staff responsibilities for their families and/or personal safety may make it difficult or impossible to be at the hospital responding to an emergency or disaster. Hospitals need to identify and plan for other resources when staff may not be able to come to the hospital to provide and support patient care during an emergency or disaster.

In addition, hospitals need to identify their role within the community. For example, what resources will the hospital be expected to provide to the community in the event that an emergency or disaster occurs, and what communication methods will be used within the community?

The emergency and disaster management program is evaluated by an annual test of the full program internally or as part of a communitywide test or testing of critical elements of the program during the year.

If the hospital experiences an actual emergency or disaster, activates its program, and debriefs properly afterward, this situation represents the equivalent to an annual test.

Measurable Elements of FMS.09.00

1. Ⓓ The hospital develops, evaluates, and maintains a written emergency and disaster management program that provides processes for the following:
   - Determining the type, likelihood, and consequences of hazards, threats, and events (*See also* GHI.05.00, ME 2)
   - Identifying the structural and nonstructural vulnerabilities of the hospital's patient care environments and how the hospital will perform in the event of an emergency or disaster
   - Planning for alternative sources of power and water in emergencies and disasters
   - Determining the hospital's role in such events
   - Determining communication strategies for events
   - Managing resources during events, including alternative sources (*See also* FMS.08.01, ME 1)
   - Managing clinical activities during an event, including alternative care sites
   - Identifying and assigning staff roles and responsibilities during an event (including contract staff, vendors, and others identified by the hospital) (*See also* GHI.05.00, ME 4)
   - Managing emergencies and disasters when personal responsibilities of staff conflict with the hospital's responsibility for providing patient care
2. Ⓓ The hospital identifies major internal and external emergencies and/or disasters such as community emergencies, and natural or other disasters that pose significant risks of occurring, taking into consideration the hospital's geographic location. (*See also* GHI.05.00, ME 2)
3. Ⓓ The hospital identifies and conducts annual evaluation of critical elements of the emergency and disaster management program. At a minimum, critical elements include the following:
   - Type, likelihood, and consequences of hazards, threats, and events
   - Structural and nonstructural vulnerabilities of the hospital's patient care environments and how the hospital will perform in the event of an emergency or disaster (*See also* GHI.05.00, ME 3)
   - Alternative sources of power and water in emergencies and disasters
4. Follow-up actions identified from testing and debriefing are developed and implemented.

Standard FMS.09.01

The hospital implements and evaluates an emergency management program to respond to the presentation of global communicable diseases.

Intent of FMS.09.01

In addition to community emergencies and disasters that may be unique based on the hospital's geographic location, the hospital also requires an emergency management program for global communicable diseases. The globalization of society has increased the likelihood of the rapid spread of communicable diseases from one country to another as seen during the COVID-19 pandemic. During the COVID-19 pandemic, hospitals were faced with an unprecedented high demand for health care services and had to quickly implement an emergency management program to address the COVID-19 crisis. To respond effectively to the presentation of global communicable diseases, the hospital develops a program to manage these emerging infectious diseases.

The World Health Organization (WHO) has identified the importance of detecting communicable disease outbreaks early and stopping the mortality, spread, and potential impact. An essential element in detecting and limiting the spread of infection is communications—with local and regional governmental agencies or university centers of excellence participating in worldwide surveillance activities that identify and track globally emerging infections. Examples of organizations participating in surveillance activities include the UK Public Health Laboratory Service, the French Pasteur Institutes, the Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET), and the US Centers for Disease Control and Prevention (CDC). In addition, organizations need to connect with the epidemiology department of their local public health agencies when available.

The program is evaluated to ensure proper response when an actual event occurs. Evaluation involves local, regional, and/or national authorities, when applicable; for example, a communitywide response drill or participation in a tabletop drill led by national public health authorities. If the hospital experiences an actual event, activates its program, and debriefs properly afterward, this represents the equivalent to an annual evaluation. Debriefing following an annual evaluation or actual event can identify vulnerable processes that may need to be reevaluated.

Measurable Elements of FMS.09.01

1. Ⓓ The hospital develops and implements an emergency preparedness program to respond to global communicable diseases that includes the following:
   - A process to determine when emergency management procedures are activated in response to emerging or reemerging infectious diseases (*See also* PCI.07.00, ME 1)
   - Internal and external communication strategies, including local and global disease surveillance authorities
   - Identification and assignment of staff roles and responsibilities
   - Identification of alternative supply chains for personal protective equipment and other critical supplies (*See also* PCI.07.01, ME 2)
2. The hospital implements emergency staffing plans to ensure continuity of operations and provision of patient care.
3. Ⓓ The hospital identifies the first points of patient entry into the hospital system and has a procedure to restrict access to predetermined access points. (*See also* PCI.07.02, ME 1)
4. Ⓓ The hospital evaluates the entire program at least annually and, when applicable, involves local, regional, and/or national authorities.
5. Follow-up actions identified from the evaluation process and debriefing are developed and implemented.
6. The hospital implements a process for managing a sudden influx of patients with contagious diseases.

Construction and Renovation

Standard FMS.10.00

When planning for construction, renovation, and demolition projects, or maintenance activities that affect patient care, the organization conducts a preconstruction risk assessment.

Intent of FMS.10.00

Construction, renovation, demolition, and maintenance activities in a hospital can have an impact on everyone in the organization; however, patients may suffer the greatest impact. For example, the noise and vibration associated with these activities can affect patients' comfort level, and dust and odors can change air quality, which may pose a threat to a patient's respiratory status. The risks to patients, staff, visitors, independent business entities, and others in the hospital will vary depending on the extent of the construction, renovation, demolition, or maintenance activity and its impact on patient care, infrastructure, and utilities. For example, maintenance activity that involves medical gases may impact patient care; however, resurfacing the staff parking lot may have no impact on patient care.

Demolition, construction, renovation, and routine maintenance projects anywhere within the hospital can also be a major infection control risk. Exposure to construction dust and debris, and other hazards, can transmit infection and be potentially dangerous to the health and safety of staff, patients, and visitors.

In order to assess the risks associated with a construction, renovation, or demolition project, or a maintenance activity that affects patient care, the hospital brings relevant departments together, including, as needed, representatives from project design, project management, facilities engineering, facility security/safety, infection prevention and control, fire safety, housekeeping, information technology services, and clinical departments and services.

Risks are evaluated by conducting a preconstruction risk assessment, also known as PCRA, throughout the life cycle of the project. The risk assessment is used to comprehensively evaluate risks in order to develop plans and implement preventive measures that will minimize the impact the project will have on the quality and safety of patient care. For example, measures to reduce fire risk and ensure safe exit are implemented when fire safety risks are identified.

In addition, the hospital ensures that contractor compliance is monitored, enforced, and documented. As part of the risk assessment, patient risk of infection from construction is evaluated through an infection control risk assessment, also known as ICRA.

Measurable Elements of FMS.10.00

1. Ⓓ When planning for construction, renovation, or demolition projects, or maintenance activities that affect patient care, the hospital conducts a preconstruction risk assessment (PCRA) that includes, at minimum, the following:
   - Air quality
   - Infection prevention and control
   - Utilities
   - Noise
   - Vibration
   - Hazardous materials and waste
   - Fire safety
   - Security
   - Emergency procedures, including alternate pathways/exits and access to emergency services
   - Other hazards that affect care, treatment, and services

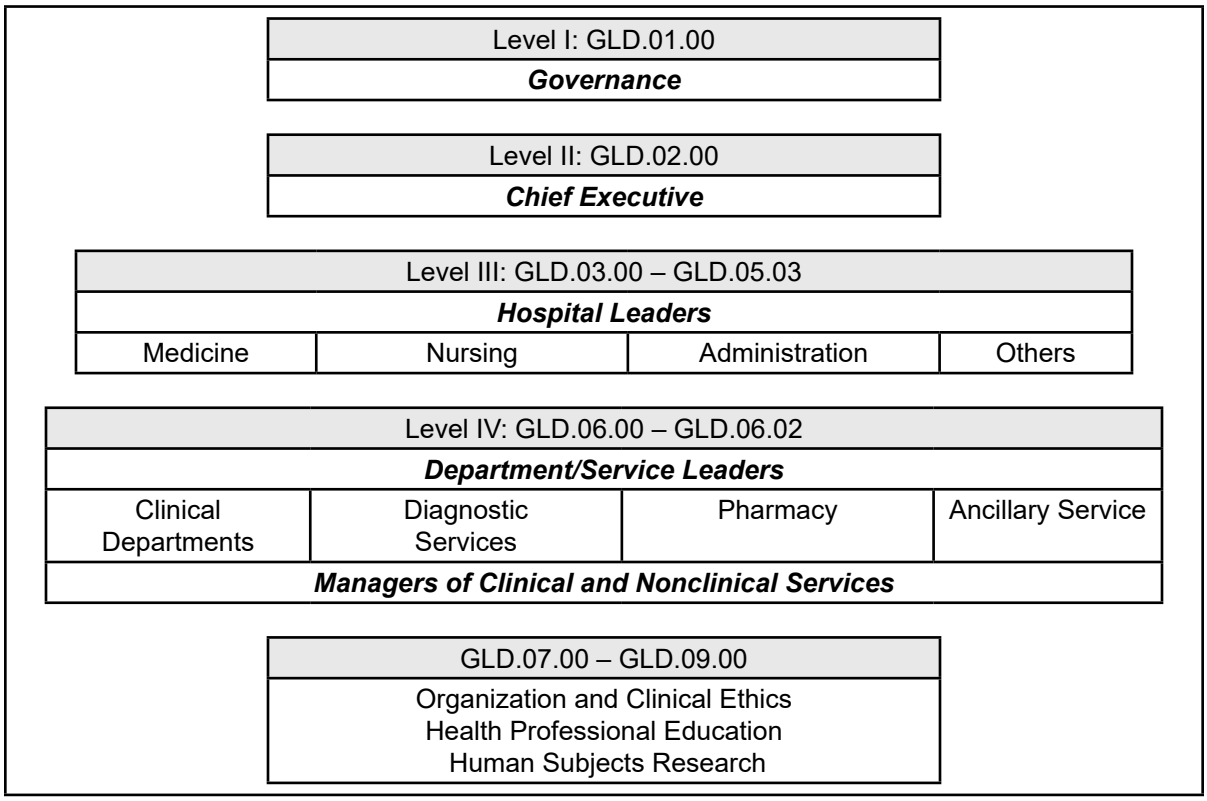
   (*See also* FMS.02.00, ME 1)
2. The hospital takes action based on its assessment to minimize risks during construction, renovation, and demolition projects, and maintenance activities that affect patient care.
3. Ⓓ The hospital ensures that contractor compliance is monitored, enforced, and documented.

Governance, Leadership, and Direction (GLD)

Overview

Providing excellent patient care requires effective leadership. Effective leadership begins with understanding the various responsibilities and authority of individuals in the organization and how these individuals work together. Those who govern, manage, and lead an organization have both authority and responsibility. Collectively and individually, they are responsible for complying with laws and regulations and for meeting the organization's responsibility to the patient population served.

Organization leaders promote safety culture across the organization. Over time, effective leadership helps overcome perceived barriers and communication problems between departments and services in the organization, and the organization becomes more efficient and effective. Services become increasingly integrated. In particular, the integration of all quality management and improvement activities throughout the organization results in improved patient outcomes.



Standards in this chapter are grouped using the following leadership hierarchy:

Level I: Governance

Governance refers to the governing entity of the hospital and can exist in many configurations. For example, the governing entity may be a group of individuals (such as a community board), one or more individual owners within a corporate structure, or in the case of public hospitals, the Ministry of Health. Any individual(s) or board member(s) responsible for the requirements found in GLD.01.00 is considered the governing entity of the hospital.

Level II: Chief Executive

The most senior hospital executive, commonly termed the *chief executive*, is a position occupied by one or more individuals selected by the governing entity to manage the organization on a day-to-day basis. In academic medical centers, the dean of the medical school may be at this executive level in the hospital. GLD.02.00 describes the accountabilities and expectations of the chief executive.

Level III: Hospital Leaders

The standards assign to hospital leaders a variety of responsibilities intended to collaboratively guide the hospital in meeting its mission. Most frequently, hospital leadership consists of a chief medical officer representing the medical staff of the hospital, a chief nursing officer representing all levels of nursing in the hospital, senior administrators, and any other individuals the hospital selects, such as a chief quality officer, chief information officer, or vice president of human resources. In larger hospitals with different organizational structures, such as divisions, hospital leadership may include the leaders of these divisions. Each hospital identifies hospital leadership, and standards GLD.03.00 through GLD.05.03 describe the accountabilities of this group.

Note: GLD.06.00 describes the responsibilities of leaders of clinical services; however, they may be formally or informally organized. In academic medical centers, the leader of medical education and leader of clinical research may be a part of hospital leadership.

Level IV: Department/Service Leaders

For effective and efficient daily delivery of clinical services and management of the organization, hospitals are most frequently divided into cohesive subgroups such as departments, services, or units, each under the direction of a department/service leader(s). Standards GLD.06.00 through GLD.06.02 describe the expectations of these department/service leaders. The subgroups consist of departments such as medicine, surgery, obstetrics, pediatrics, and others; one or more nursing subgroups; diagnostic services or departments such as quality and patient safety, radiology, and clinical laboratory; pharmacy services, both centralized and distributed throughout the hospital; and ancillary services such as transportation, social work, finance, purchasing, facility management, and human resources, among others. Most larger hospitals also have managers within these subgroups. For example, nursing may have a manager of the operating theatres and one for outpatient services, the department of medicine may have managers of each patient clinical unit, and the hospital business office may have managers for the different business functions such as bed control, billing, and purchasing, among others.

Finally, there are requirements in the GLD chapter that touch on all the levels described above. These requirements are found in GLD.07.00 through GLD.09.00 and include the organization and clinical ethics, health professional education, and human subjects research when present.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Leadership Structure

GLD.01.00 The structure, authority, and responsibilities of the hospital's governing entity are described in bylaws, policies and procedures, or similar written documents.

Chief Executive(s) Accountabilities

GLD.02.00 A chief executive(s) is responsible for operating the hospital and complying with applicable laws and regulations.

Leader Accountabilities

GLD.03.00 Hospital leaders are identified and are collectively responsible for defining the hospital's mission and creating the programs and policies needed to fulfill the mission.

GLD.03.01 Hospital leaders identify, plan, and communicate the type of clinical services required to meet the needs of the patients served by the hospital.

GLD.03.02 Hospital leaders ensure effective communication throughout the hospital.

Leadership for Quality and Patient Safety

GLD.04.00 Hospital leaders plan, develop, and implement a quality and patient safety program.

GLD.04.01 Hospital leaders report quality improvement and patient safety information to the governing entity and hospital staff.

GLD.04.02 Hospital leaders collaborate to prioritize which hospitalwide processes will be measured, which hospitalwide improvement and patient safety activities will be implemented, and how success of these hospitalwide efforts will be measured.

Leadership for Contracts and Resources

GLD.05.00 Hospital leaders are accountable for the review, selection, and monitoring of clinical and nonclinical contracts and inspect compliance with contracted services as needed.

GLD.05.01 Hospital leaders ensure that health care practitioners and clinical staff not employed by the hospital have the right credentials and are competent and/or privileged for the services provided to the hospital's patients.

GLD.05.02 Hospital leaders use data and information in resource decision-making to understand its implications on patient safety and quality.

GLD.05.03 Hospital leaders establish a supply chain strategy that includes protection of patients and staff from unstable, contaminated, defective, and counterfeit supplies.

Direction of Hospital Departments and Services

GLD.06.00 The hospital identifies the scope of services and structure of each department or service.

GLD.06.01 Department/service leaders participate in hospitalwide improvement priorities and in monitoring and improving patient care specific to the department/service.

GLD.06.02 Department/service leaders select and implement clinical practice guidelines, clinical pathways, and clinical protocols when designing or improving processes.

Organizational and Clinical Ethics

GLD.07.00 Hospital leaders establish a framework for ethical management that promotes a culture of ethical practices and decision-making to ensure that patient care is provided within business, financial, ethical, and legal norms and protects patients and their rights.

GLD.07.01 Hospital leaders create and maintain a culture of safety and quality throughout the hospital.

GLD.07.02 The hospital implements a workplace violence prevention program to provide a safe and secure workplace.

Health Professional Education

GLD.08.00 Health professional education, when provided within the hospital, is guided by the educational parameters defined by the sponsoring academic program and the hospital's leaders.

Human Subjects Research

GLD.09.00 Human subjects research, when provided within the hospital, is guided by laws, regulations, and hospital leaders.

Standards, Intents, and Measurable Elements

Leadership Structure

Standard GLD.01.00

The structure, authority, and responsibilities of the hospital's governing entity are described in bylaws, policies and procedures, or similar written documents.

Intent of GLD.01.00

There is a governing entity—for example, a group of individuals (such as a board of directors or a community board), one or more individual owners who are appointed by the corporate structure, or in the case of many public hospitals, the Ministry of Health—that is responsible for overseeing the hospital's provision of care, treatment, and services.

Every hospital has a leadership structure to support operations and the provision of care, treatment, and services. In many hospitals, this structure is formed by various leadership groups and includes the governing entity, executive leaders, and department or senior leaders.

Individual leaders may participate in more than one group and have several distinct roles. Many leadership responsibilities directly affect the provision of care, treatment, and services, as well as the day-to-day operations of the hospital. As such, it is important to identify the responsibilities of the various levels of hospital leadership.

Evaluation of the hospital's top leaders is critical to ensure strategic alignment and to monitor organizational and individual performance. These evaluations align the CEO's understanding of the governing entity's performance expectations and provide feedback on the governing entity's assessment of progress and improvement toward attaining the mission and vision of the organization as well as realigning the strategy, as necessary.

The hospital's governing entity is represented or displayed in an organizational chart or other document that shows lines of authority and accountability. The governing entity's responsibilities are described in a written document(s). These responsibilities are primarily at the approval level and include the following:

- Approving and periodically reviewing the hospital's mission and ensuring that the public is aware of the hospital's mission
- Approving the hospital's various strategic and operational plans and the policies and procedures needed to operate the hospital day to day
- Approving the hospital's participation in health care professional education and in research and the oversight of the quality of such programs
- Approving or providing a capital and operating budget(s) and other resources
- Appointing and evaluating the hospital's chief executive(s)

The governing entity oversees the effectiveness of strategic plans through periodic reports provided by the hospital leadership team.

Measurable Elements of GLD.01.00

1. Ⓓ The structure, authority, and responsibilities of the hospital's governing entity are described in a written document, bylaws, and/or policies and procedures, with those responsible for governance of the hospital identified.
2. The governing entity approves the hospital's capital and operating budget(s) that aligns with the hospital's services, and provides for the resources required to meet the hospital's mission.
3. The governing entity approves the hospital's participation in health care professional education and research and in the oversight of the quality of such programs.
4. Ⓓ The governing entity appoints, and annually evaluates, the hospital's chief executive(s), and the evaluation is documented.
5. Ⓓ The hospital has written policies that describe when and how the authority of the governing entity, and the chief executive(s), can be delegated.

Chief Executive(s) Accountabilities

Standard GLD.02.00

A chief executive(s) is responsible for operating the hospital and complying with applicable laws and regulations.

Intent of GLD.02.00

Effective leadership is essential for a hospital to be able to operate efficiently and to fulfill its mission. As the most senior hospital executive leader appointed by the governing entity, the chief executive(s) is ultimately responsible for the hospital's overall operations.

The chief executive(s) cooperates with hospital leaders to define the hospital's mission and to plan the policies, procedures, and clinical services related to that mission. When approved by the governing entity, the chief executive(s) is ultimately responsible for implementing all policies and ensuring that all staff comply with policies and all applicable laws and regulations.

Measurable Elements of GLD.02.00

1. The education and experience of the chief executive(s) match the requirements in the position description.
2. The chief executive(s) recommends policies, strategic plans, and budgets to the governing entity.
3. The chief executive(s) ensures consistent implementation of the hospital's approved policies.
4. The chief executive(s) ensures compliance with applicable laws and regulations.
5. The chief executive(s) responds to any reports from inspecting and regulatory agencies.

Leader Accountabilities

Standard GLD.03.00

Hospital leaders are identified and are collectively responsible for defining the hospital's mission and creating the programs and policies needed to fulfill the mission.

Intent of GLD.03.00

Although the governing entity names the chief executive(s), the chief executive(s) is responsible for the selection and appointment of other hospital leadership team members who are collectively responsible for fulfilling the organization's mission.

Hospital leaders may have formal titles, such as Medical Director or Director of Nursing; may be leaders of clinical or nonclinical departments or services; or may be informally recognized for their seniority, stature, or contribution to the hospital. It is important that hospital leaders are recognized and brought into the process of defining the hospital's values and mission. Hospital leaders work collectively and collaboratively to develop the programs, policies, and services needed to fulfill the mission. When the mission and policy framework are set by owners or agencies outside the hospital, hospital leaders work collaboratively to carry out the mission and policies.

Measurable Elements of GLD.03.00

1. Hospital leaders are responsible for defining the hospital's mission, vision, and goals.
2. Hospital leaders are responsible for creating the policies and procedures necessary to carry out the mission.
3. Hospital leaders ensure that policies and procedures are followed.

Standard GLD.03.01

Hospital leaders identify, plan, and communicate the type of clinical services required to meet the needs of the patients served by the hospital.

Intent of GLD.03.01

Hospital leaders determine essential services that meet the needs of the patient population and reflect the strategic direction of the hospital and the perspective of the patients cared for by the hospital.

Hospital leaders plan with the department/service leaders the scope and intensity of the various services to be provided by the hospital directly or indirectly. When applicable to the mission, hospital leaders plan and participate with the community, local hospitals, and others in meeting community health care needs.

Part of the planning is providing uniform services to similar patient populations in multiple departments. Services are guided by policies and procedures that result in their uniform delivery of care. Department/service leaders ensure that the same level of care is available each day of the week, and all work shifts each day.

Those policies and procedures adhere to applicable laws and regulations that are best developed collaboratively. Uniform patient care results in the efficient use of resources and permits the evaluation of outcomes of similar care throughout the hospital.

Planning patient care services involves hospital leaders defining its communities and patient populations, identifying community needs for services, and planning ongoing communication with those key community stakeholder groups. The communications may be directly to individuals or through public media and through agencies within the community or third parties. The types of information communicated include information on services, hours of operation, and the process to obtain care and on the quality of services, which is provided to the public and to referral sources.

Measurable Elements of GLD.03.01

1. Hospital leaders determine and plan with department/service leaders the type of care, treatment, and services to be provided by the hospital that are consistent with the hospital's mission and needs of the patients served. (*See also* SQE.01.05, ME 1)
2. Hospital leaders communicate with key stakeholders in the hospital's community to facilitate access to care and access to information about its patient care services. (*See also* MOI.01.00, ME 1)
3. Hospital leaders provide data and communicate information related to safety and quality of the hospital's services to stakeholders, which include nursing staff, nonclinical and management staff, patients, families, and external interested parties.
4. Ⓓ Hospital leaders implement written policies to provide uniform care in the following ways:
   - The hospital provides care and treatment for the patient's immediate needs and refers them to the appropriate level of care.
   - Access to immediate care and treatment by qualified practitioners does not depend on the day of the week or time of day.
   - Acuity of the patient's condition determines the resources allocated to meet the patient's needs.
   - The scope, level of care, treatments, and services available and provided to patients are comparable throughout the hospital.

Standard GLD.03.02

Hospital leaders ensure effective communication throughout the hospital.

Intent of GLD.03.02

Effective communication within a hospital is the responsibility of hospital leaders. Hospital leaders not only set the parameters of communication, but leaders also serve as role models with the effective communication of the hospital's mission, strategies, plans, and other relevant information. Hospital leaders pay attention to the accuracy and timeliness of information shared and communicated throughout the hospital.

Hospital leaders understand the dynamics of communication between professional groups; between structural units, such as departments; between professional and nonprofessional groups; between health care practitioners and management; between health care practitioners and families; and between health care practitioners and outside organizations.

To coordinate and to integrate patient care, hospital leaders develop a culture that emphasizes cooperation and communication. Formal (for example, standing committees, joint teams) and informal (for example, newsletters and posters) methods for promoting communication among services and individual staff members are used. Coordination of clinical services comes from an understanding of each department's mission and services and collaboration in developing common policies and procedures.

Measurable Elements of GLD.03.02

1. Hospital leaders ensure that processes are in place for communicating relevant information throughout the hospital in a timely manner. (*See also* MOI.01.00, ME 1)
2. Hospital leaders ensure effective communication among clinical and nonclinical departments, services, and individual staff members. (*See also* MOI.01.00, ME 1)
3. Hospital leaders communicate the hospital's vision, mission, goals, policies, and plans to staff.

Leadership for Quality and Patient Safety

Standard GLD.04.00

Hospital leaders plan, develop, and implement a quality and patient safety program.

Intent of GLD.04.00

Hospital leaders are responsible for establishing and providing ongoing support for an organizational commitment to quality. Hospital leaders develop the quality and patient safety program for approval by the governing entity, and through its vision and support, shapes the quality culture of the hospital.

Leadership and planning are essential to successfully initiate and maintain improvement and reduce risks to patients and staff. Leadership and planning begin with the governing entity of the hospital and those who manage and lead the daily clinical and managerial activities of the hospital. These individuals represent the leaders of the departments and services of the hospital. Hospital leaders select the method to measure, assess, and improve quality and patient safety. Hospital leaders also determine how the program will be directed and managed daily, such as through a quality department, and ensure that the program has adequate resources to be effective.

Hospital leaders implement a structure and process for the overall monitoring and coordination of the program throughout the hospital. These actions ensure coordination among all the departments and services in measurement and improvement efforts. Coordination can be achieved through a quality management council, committee, department, or other structure. Coordination encourages a systemwide approach to quality monitoring and improvement activities while reducing duplication of effort; for example, two departments independently measuring similar processes or outcomes.

Careful identification, investigation, and analysis of serious patient safety events, as well as strong corrective actions that provide effective and sustained system improvement, is essential to reduce risk and prevent patient harm (*see also* Sentinel Event Policy at https://www.jointcommissioninternational.org/contact-us/sentinel-event-policy/ and Standards QPS.04.00 and QPS.04.01). Although organizations are not required to report sentinel events to Joint Commission International, accredited organizations must have a policy defining sentinel events and describing how the organization addresses sentinel events.

Measurable Elements of GLD.04.00

1. Ⓓ Hospital leaders participate in developing and implementing a hospitalwide quality and patient safety program. (*See also* PCI.08.00, ME 1; QPS.01.00, ME 3; QPS.03.03, ME 1)
2. Hospital leaders select and implement a hospitalwide process to measure, assess data, plan change, and sustain improvements in quality and patient safety, and provide staff education on this quality improvement process. (*See also* QPS.02.00, ME 2; QPS.04.00, ME 4)
3. Hospital leaders determine how the program will be directed and managed daily and ensure that the program has adequate resources to be effective. (*See also* QPS.01.00, ME 1)
4. Hospital leaders implement a structure and process for the overall monitoring and coordination of the quality and patient safety program. (*See also* PCI.08.00, ME 3)
5. Ⓓ Hospital leaders define, in writing, patient safety events, including sentinel events as described in the "Sentinel Event Policy" (SE) chapter of this manual, and encourage voluntary external reporting to programs such as the Joint Commission International Sentinel Event Database in addition to mandatory programs in accordance with laws and regulations when applicable.
6. The hospital conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Event Policy" (SE) chapter of this manual.
7. Hospital leaders establish a process to actively provide support systems for staff who have been involved in an adverse event or a sentinel event. (*See also* FMS.07.01, ME 2)

Standard GLD.04.01

Hospital leaders report quality improvement and patient safety information to the governing entity and hospital staff.

Intent of GLD.04.01

Communication of quality improvement and patient safety information promotes a proactive identification of potential system failures. Hospital leaders analyze and act on problems that have occurred, and they encourage the reporting of adverse events and close calls ("near misses"), both internally and externally.

Establishing a safety program that integrates safety priorities into all processes, functions, and services within the hospital is part of leadership responsibilities. Hospital leaders are also responsible for providing periodic quality reports for review by the governing entity and for seeing that the actions and directives of the governing entity related to the quality and patient safety program reports are carried out.

The governing entity approves the quality and patient safety program on an annual basis, and on a quarterly basis receives quality reports. The reports can be global in nature or focus on a particular clinical service, a patient group, or some operational aspect. Therefore, over a period of time, all aspects of the quality and patient safety program, including adverse events and sentinel events, are presented to the governing entity for their information and discussion. When the discussion results in actions, such as allocation of additional resources, those actions are recorded in minutes and are reexamined at a future meeting(s).

Obtaining review and action on reports of the quality and patient safety program from the governing entity may be a challenge for some hospitals, particularly those that are one of many organizations reporting to a governing entity, such as a Ministry of Health (MOH). If the governing entity continues to be unresponsive, the hospital makes a credible effort to contact them. A credible effort includes contacting the governing entity multiple times by various methods and documenting the attempts/outcomes of the communications.

It is essential that hospital leaders also communicate information about the quality and patient safety program to staff. This flow of quality communications is through effective channels, such as newsletters, storyboards, staff meetings, and human resources processes.

The information can be about new or recently completed improvement projects, including the following:

- Progress in meeting the International Patient Safety Goals
- Results of the analysis of sentinel events and other adverse events
- Recent research or benchmark programs

Measurable Elements of GLD.04.01

1. The governing entity annually reviews and approves the hospital's program for quality and patient safety. (*See also* FMS.02.00, ME 4)
2. Ⓓ At least quarterly, hospital leaders provide the governing entity with written reports on quality and patient safety that, at minimum, include the following:
   - All system or process failures (*See also* QPS.02.00, ME 3)
   - The number and type of sentinel events (*See also* Sentinel Event Policy)
   - Whether the patients and the families were informed of the event
   - All actions taken to improve safety, both proactively and in response to actual occurrences
   - Follow-up of actions taken, when necessary
3. Hospital leaders regularly communicate information on quality improvement and the patient safety program to staff.

Standard GLD.04.02

Hospital leaders collaborate to prioritize which hospitalwide processes will be measured, which hospitalwide improvement and patient safety activities will be implemented, and how success of these hospitalwide efforts will be measured.

Intent of GLD.04.02

Due to staff and resource limitations, not every process within a hospital can be measured and improved at the same time. Thus, a primary responsibility of hospital leaders is to work with the chief executive(s) in prioritizing hospitalwide measurement and improvement activities.

Measurement and improvement efforts impact activities in multiple departments and services. Hospital leaders provide focus for the hospital's quality measurement and improvement activities, including measurement and activities regarding compliance with the International Patient Safety Goals; for example, measuring the effectiveness of the patient identification process for IPSG.01.00 or monitoring the process for reporting critical results of diagnostic tests as noted in IPSG.02.00.

Priorities may focus on the achievement of strategic objectives; for example, to become the leading regional referral center for cancer patients. Similarly, hospital leaders may give priority to other projects, including those that do the following:

- Increase efficiency.
- Reduce readmission rates.
- Eliminate patient flow problems in the emergency department.
- Create a monitoring process for the quality of services provided by contractors.

Understanding both the impact of an improvement on patient outcomes and the relative cost and resulting process efficiency contributes to improved priority-setting in the future, both at an organizational level and at a departmental/service level. When this information is combined hospitalwide, hospital leaders can better understand how to allocate available quality and patient safety resources.

Hospital leaders collectively work to consider priorities at a system level to spread the impact of improvements broadly throughout the hospital; for example, improving the hospital's medication management system. The priority-setting process includes the consideration of available data on which systems and processes demonstrate the most variation in implementation and outcomes.

Using available data, hospital leaders assess the impact of hospitalwide improvements. Measuring improvement in efficiency of a complex clinical process, and/or identifying reductions in cost and resource use following improvement in a process, are examples. Measuring the impact of an improvement supports an understanding of the relative costs for investing in quality and the human, financial, and other returns on that investment. Hospital leaders support the creation of simple tools to quantify resource use of the old process and for assessing a new process.

It is also important to collect and analyze data on diagnostic errors, and hospital leaders should include this in their data-driven decision-making. *Diagnostic errors* are diagnoses that are missed, wrong, or delayed, as detected by subsequent definitive test findings, according to the Society to Improve Diagnosis in Medicine. Diagnostic errors were found to make up 17% of preventable errors in patients in one study (Harvard). Another study (Johns Hopkins) found that the most common diagnostic errors were related to vascular events, cancer, and infections. These are also the largest causes of medical malpractice claims.

Causes of diagnostic errors are complex, and rarely the fault of an individual clinician or staff member. Factors leading to diagnostic errors include diagnostic complexity, breakdowns in communication or care coordination, lost test results, equipment malfunctions, availability of specialty clinicians, and cognitive errors or bias. Closed-loop communication is an essential method to reduce diagnostic errors, and it means every test result is always sent, received, acknowledged, and acted on.

Often, following up on actions taken is a necessary step, and can even be critical, for patient care. This requires care coordination throughout the continuum to hand off test results, interpret the results, and communicate them in language patients can understand. Implementing a closed-loop communication process requires a number of interventions, such as redesigning communication processes, improving patient engagement, establishing data-driven measures to monitor and act on diagnostic results communication on an ongoing basis, and evaluating patient outcomes.

Measurable Elements of GLD.04.02

1. Ⓓ Hospital leaders use available data to set collective priorities for hospitalwide measurement and improvement activities and consider potential system improvements. (*See also* QPS.04.00, ME 1)
2. Hospital leaders set priorities for compliance with the International Patient Safety Goals.
3. Ⓓ Hospital leaders conduct a data-driven, risk-focused assessment of data annually for diagnostic errors that focuses on at least one of the following areas:
   - Radiology
   - Pathology
   - Laboratory/microbiology
   - Care coordination
4. Hospital leaders implement evidence-based interventions based on the diagnostic error risk assessment and data analysis with the intent to improve the diagnostic area(s) of focus and evaluate the effectiveness of the interventions on an ongoing basis, reevaluating when indicated.

Leadership for Contracts and Resources

Standard GLD.05.00

Hospital leaders are accountable for the review, selection, and monitoring of clinical and nonclinical contracts and inspect compliance with contracted services as needed.

Intent of GLD.05.00

Evaluation of all services provided through contracted services impacts the quality and safety of patient care. To provide and maintain continuity of patient services, hospital leaders describe and monitor the scope of services provided through contractual agreements.

The patient care processes in hospitals are supported by a range of operational activities that includes distribution of supplies and services throughout the organizations. Health care logistics encompasses the process of handling services (for example, radiology and diagnostic imaging services, financial accounting services, housekeeping, food, linens) and physical goods (for example, pharmaceuticals, surgical medical products, medical equipment, sterile items, linens, food). Hospitals frequently have the option to either provide clinical and management services directly or to arrange for such services through referral, consultation, contractual arrangements, or other agreements.

The COVID-19 pandemic highlighted the need to increase the capacity of hospitals to respond to and maintain access to essential health services. The World Health Organization identifies *contracting* as an important tool for increasing capacity and maintaining critical resources for patient care. Reviewing and monitoring contracts also allows the hospital to prepare for continuity of services during an emergency. The World Health Organization guidance for contracting services recommends that hospital leaders do the following:

- Define the purpose and structure of the contract.
- Plan the procurement process.
- Procure and sign the contract.
- Monitor the contractual relationship.

The hospital needs to receive, analyze, and act on quality information and performance data from outside sources. The contract with the outside source of service includes quality and patient safety expectations and the data that are to be provided to the hospital, their frequency, and their format. Department/service leaders receive and act on quality reports from contracting agencies that relate to the scope of services provided within their department/service and ensure that the reports are integrated into the hospital's quality measurement process.

Hospital leaders are accountable for such contracts or other arrangements to ensure that the services meet patient needs and are included as part of the hospital's quality management and improvement activities. Department/service leaders participate in the review and selection of all clinical and nonclinical contracts and are accountable for monitoring those contracts.

Measurable Elements of GLD.05.00

1. Hospital leaders identify an individua(s) with oversight responsibility for contracts to meet patient and management needs. (*See also* AOP.03.00, ME 3)
2. Ⓓ The hospital has a written description of the nature and scope of those services to be provided through contractual agreements.
3. Department/service leaders participate in the review, selection, and monitoring of clinical and nonclinical contracts. (*See also* ASC.01.00, ME 6)
4. Hospital leaders monitor compliance with contracted services and take actions to maintain continuity of services when contracts are renegotiated or terminated. (*See also* AOP.03.09, MEs 3 and 4; AOP.05.06, MEs 3 and 4)
5. Ⓓ All contracts stipulate the quality and performance data that are to be reported to the hospital, the reporting frequency and mechanism, and how the hospital will respond when quality requirements or expectations are not met. (*See also* AOP.03.09, MEs 3 and 4; AOP.05.06, MEs 3 and 4)
6. Ⓓ Quality data reported under contracts are integrated into the hospital's quality monitoring program.

Standard GLD.05.01

Hospital leaders ensure that health care practitioners and clinical staff not employed by the hospital have the right credentials and are competent and/or privileged for the services provided to the hospital's patients.

Intent of GLD.05.01

Hospital leaders have the responsibility to confirm that health care practitioners and clinical staff are competent and/or privileged to provide the services to their patients.

Contracts with independent health care practitioners and other clinical staff may include preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services for patients; or interpretative services for patients, such as pathology, radiology, or laboratory services. The services provided by independent health care practitioners may also include telehealth or teleradiology. In some cases, these individuals may be located outside the region or country of the hospital. The contracts stipulate that the clinical staff provided meet the patient needs and the hospital's requirement for similar staff.

Independent health care practitioners may be accompanied by staff reporting to them and who are not part of the hospital (for example, surgical assistant accompanying a surgeon). Any support staff accompanying independent health care practitioners and providing care and services in the hospital are compliant with requirements for primary source verification.

Measurable Elements of GLD.05.01

1. Ⓓ All diagnostic, consultative, and treatment services provided by independent health care practitioners outside the hospital are credentialed and privileged by the hospital to provide such services.
2. Ⓓ Independent health care practitioners who provide patient care services on the premises of the hospital but are not employees or members of the clinical staff are credentialed, privileged, and evaluated as required in SQE.05.00 through SQE.07.01.
3. Any support staff accompanying independent health care practitioners and providing care and services in the hospital are compliant with requirements for primary source verification.
4. The quality of services by independent practitioners outside the hospital is monitored as a component of the hospital's quality improvement program.

Standard GLD.05.02

Hospital leaders use data and information in resource decision-making to understand its implications on patient safety and quality.

Intent of GLD.05.02

Hospital leaders use data and information to appropriately guide their decisions regarding the purchase and use of human and technical resources to better understand its impact on overall hospital operation.

Hospital leaders improve decision-making when they have data, information, and tools to support decisions. For example, when the hospital needs to replace or add infusion pumps: Information on maintenance requirements, staff training or retraining requirements, information on previous failure rates and patient safety incidents, preferences of staff, and alarm issues will result in decisions based more on quality and patient safety than on cost alone. Similarly, when making decisions regarding the reduction or reassignment of nursing staff, consideration of the implications for patient care quality and patient safety needs to be brought forward to inform the decision. The COVID-19 pandemic placed unprecedented demands on entire health systems and drove them to full capacity. Hospitals were confronted with the difficult problem of ensuring appropriate staffing and resources to a high number of critically ill patients. Hospitals are better prepared when leaders

develop a process to gather data and information for resource decisions that will ensure patient safety and quality of care

One component of data gathering related to resource decisions is to understand the required or recommended staffing, medical equipment, supplies, and medications necessary to continuously provide service. Recommendations on medical equipment, supplies, and medication can come from a government agency, national or international professional organizations, or other authoritative sources. It is also important to gather input from clinicians, clinical engineers, and frontline staff. When resource decisions are made by a third party—for example, a Ministry of Health—hospital leaders provide data and information to the third party on their experiences and preferences to better inform future resource choices.

Measurable Elements of GLD.05.02

1. Hospital leaders use data and information when making decisions on purchasing, replacing, or retiring medical equipment. (*See also* FMS.07.00, ME 1)
2. Hospital leaders use data and information when making decisions on staffing needs to continuously support patient safety and quality.
3. Hospital leaders use the recommendations of professional organizations and other authoritative sources in making resource decisions. (*See also* GHI.04.00, MEs 1 and 2)
4. Hospital leaders monitor the results of their decisions and use the data to evaluate and improve the quality of their resource purchasing and allocation decisions.

Standard GLD.05.03

Hospital leaders establish a supply chain strategy that includes protection of patients and staff from unstable, contaminated, defective, and counterfeit supplies.

Intent of GLD.05.03

Hospitals require a variety of items, and the issues of storing and distributing these items throughout the hospital are important to providing high-quality patient service. Hospital leaders need to understand the flow of all supplies to continuously provide safe and high-quality patient care services.

Supply chain management is key to ensuring the safety and quality of the hospital's supplies. The supply chain includes the steps from origination to delivery of supplies to the hospital. Due to staff and resource limitations, not every supply chain can be tracked and evaluated at the same time. Therefore, hospitals identify the most critical and highest-risk supplies that impact hospitalwide patient care services. These most critical and highest-risk supplies vary in each organization depending on the hospital's scope of services, settings, and local laws and regulations. As part of the supply chain strategy, hospital leaders define the most at-risk supplies and outline mitigating steps that will ensure continuity of services.

Supply chain strategy is not only about a prospective evaluation of supplies that are at high risk, it also includes retrospective tracing of supplies after they have entered the hospital. The hospital has a process to identify medications, medical supplies, and medical devices that are unstable, contaminated, defective, or counterfeit and trace them back through the hospital to determine the source or cause of the problem, if possible. When applicable, the hospital notifies the manufacturer and/or distributor when unstable, contaminated, defective, or counterfeit supplies are identified through retrospective tracing. Supply chain strategy must outline recommendations that will ensure continuity of safe and high-quality patient care services. For example, the supply chain strategy recommends that the hospital not only maintain inventory of masks and disinfectants but also include two backup suppliers who can provide these critical supplies in an event of COVID-19 resurgence.

When hospital supplies are purchased, stored, and distributed by a governmental authority, the hospital participates in programs to detect and report suspected unstable, contaminated, defective, and counterfeit

supplies and takes measures to prevent potential patient harm. Although a public hospital may not know the integrity of each supplier in the chain, it can become aware of how supplies are purchased and managed by the governmental or nongovernmental agency.

Measurable Elements of GLD.05.03

1. Ⓓ Hospital leaders establish a written supply chain strategy that does the following:
   - Defines the steps in the supply chain.
   - Identifies risk within the steps of the supply chain.
   - Defines supplies at most risk.
   - Outlines recommendations on mitigating risks that will ensure continuity of safe and high-quality patient care services.
2. The hospital has a process for performing retrospective tracing of supplies found to be unstable, contaminated, defective, or counterfeit.
3. The hospital notifies the manufacturer and/or distributor when unstable, contaminated, defective, or counterfeit supplies are identified.

Direction of Hospital Departments and Services

Standard GLD.06.00

The hospital identifies the scope of services and structure of each department or service.

Intent of GLD.06.00

The clinical care, patient outcomes, and overall management of a hospital are only as good as the clinical, managerial, and operational activities of each individual department or service. Good departmental or service performance requires clear leadership from qualified individuals.

Hospital leaders provide for the coordination of care, treatment, and services among the hospital's different programs, services, sites, or departments. In larger departments or services, there may be multiple leaders. The responsibility of each role is defined in writing.

Each department/service leader reports their resource requirements to hospital leaders. This helps ensure that adequate staff, space, medical equipment, technology, and other resources are available to meet patients' needs at all times.

Department/service leaders consider the services provided and planned by the department or service and the education, skills, knowledge, and experience needed by the department's professional staff to provide those services. Department/service leaders develop criteria reflecting this consideration and then select staff. Department/service leaders may also work with human resources or other departments in the selection process based on their recommendations.

Department/service leaders ensure that all staff in the department or service understand their responsibilities and establish the orientation and training for new staff. The orientation includes the hospital's mission, the department's or service's mission, the scope of services provided, and the policies and procedures related to providing services. For example, all staff understand the infection prevention and control procedures within the hospital and within the department or service. When new or revised policies or procedures are implemented, staff are trained.

Clinical services provided to patients are coordinated and integrated within each department or service. Also, each department or service coordinates and integrates its services with other departments and services. Unnecessary duplication of services is avoided or eliminated to conserve resources. Although the department/service leaders make recommendations regarding human and other resource needs, those needs sometimes

change or are not fully met. Thus, department/service leaders have a process to respond to resource shortages to ensure safe and effective care for all patients.

Each department/service leader identifies, in writing, the services to be provided by the department, and integrates or coordinates those services with the services of other departments. The department/service leaders collaborate to determine the uniform format and content of the department-specific planning documents. In general, the documents prepared by each clinical department define its goals, as well as identify current and planned services.

Department policies and procedures reflect the department's goals and services as well as the knowledge, skills, and availability of staff required to assess and to meet patient care needs.

Measurable Elements of GLD.06.00

1. Each department or service in the hospital is directed by an individual with the qualification, training, education, and experience comparable to the services provided. (*See also* AOP.03.01, ME 1; AOP.04.00, ME 1; AOP.05.01, ME 1; MMU.01.00, MEs 1 and 5; FMS.01.01, ME 1; HCT.01.00, ME 2; PCI.01.00, ME 1; QPS.01.00, ME 1; GHI.01.00, ME 3)
2. Department/service leaders recommend space, medical equipment, staffing, technology, and other resources needed by the department or service and have a process in place to respond to shortages. (*See also* SQE.01.00, ME 1)
3. Ⓓ The departmental or service documents describe the current and planned services provided by each department or service. (*See also* ACC.02.02, ME 3)
4. There is coordination and/or integration of services within and among other departments and services. (*See also* ACC.02.02, ME 4; ACC.03.00, ME 1; ACC.05.00, ME 1)

Standard GLD.06.01

Department/service leaders participate in hospitalwide improvement priorities and in monitoring and improving patient care specific to the department/service.

Intent of GLD.06.01

Each department participates in improvement activities that reflect and contribute to the hospitalwide priorities to establish an integrated quality and patient safety program.

Department leaders are responsible for ensuring the quality of care and services provided by their department/service. Department/service leaders identify improvement priorities that address clinical or nonclinical activities specific to the department or service. For example, a clinical department or service would participate in the hospitalwide effort to improve handover communications and may monitor and reduce variation in an internal process such as the ordering of diagnostic tests for patients with the same condition. Similarly, a managerial department may be involved in automation projects to improve handover communications and may monitor and improve the accuracy of patient bills.

Quality measurement activities can be important to ensuring that the department/service leader has objective information to support improvement activities. Over time, quality measurement includes all the services provided by the department or service and includes the clinical privileges of all the physicians. In some cases, the measures will be linked to the clinical practice guidelines, clinical pathways, and clinical protocols implemented in the department or service. Data are needed to support the evaluation of the nurses and other health care practitioners in the department. Although these individuals have job descriptions rather than clinical privileges, the department/service leader is still accountable for evaluating their work. In many cases, the clinical practice guidelines implemented in the department or service will have associated pathways and protocols that will support the collection of measurement data for nursing staff and other health care practitioners.

Leaders of the department or service implement the selection and monitoring of measures or indicators specific to the department or service that include the following:

- Those hospitalwide measurement and improvement priorities set by hospital leaders that relate to their specific department or service
- The measures associated with specific department/service priorities to reduce variation, improve the safety of high-risk procedures/treatments, improve patient satisfaction, or improve efficiency

Selection of measures should be based on those activities and processes that need improvement in the department or service. For each measure, a target should be set. It is expected that initial measurement will not reach the target; however, when strategies for improvement are implemented, department/service leaders should expect to see improvement toward the target. When the target has been met and sustained for at least four measurement periods, a new measure is selected.

The leader of the clinical department or service is responsible for ensuring that the measurement activities provide the opportunity for the evaluation of staff as well as the processes of care. Thus, measurement includes, over time, all the services provided. The resulting data and information are important to the department's or service's improvement efforts but are also important to the hospital's quality and patient safety program.

Measurement activities provide the opportunity for evaluation of services. Department/service leaders are involved in the appointment, privilege delineation, ongoing professional practice evaluation, and reappointment of the physicians within the department or service.

Some departments, such as infection prevention and control, facility management, radiology, and the clinical laboratory, have ongoing quality monitoring or control programs that are included in the measurement priorities and are described in the standards related to those services.

Measurable Elements of GLD.06.01

1. Ⓓ Department/service leaders implement hospitalwide quality measures that relate to the services provided by their department or service, including any contracted services for which they are responsible. (*See also* FMS.02.00, ME 2)
2. Ⓓ Department/service leaders implement quality measures to reduce variation and improve processes within the department or service. (*See also* FMS.02.00, ME 3)
3. Ⓓ Department/service leaders select measures based on the need for improvement, and when improvement has been sustained, select a new measure. (*See also* QPS.04.00, ME 2)
4. When applicable, assessment of participation in quality activities and the results of measurement activities are included in the evaluation of the department's staff.

Standard GLD.06.02

Department/service leaders select and implement clinical practice guidelines, clinical pathways, and clinical protocols when designing or improving processes.

Intent of GLD.06.02

Clinical practice guidelines, clinical pathways, and clinical protocols are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.

Clinical guidelines are issued by the scientific sources (for example, medical associations and societies) or governmental authorities (outside sources). Pathways and protocols may be used interchangeably and are used to implement and streamline the requirements of the "clinical pathways."

The goals of hospitals include the following:

- Standardizing clinical care processes
- Reducing risks within care processes, particularly those associated with critical decision steps

- Providing clinical care in a timely, effective manner using available resources efficiently
- Consistently delivering high-quality care using evidence-based practices

Hospitals use a variety of tools to reach these and other goals. For example, health care practitioners seek to develop clinical care processes and make clinical care decisions based on the best available scientific evidence. Clinical practice guidelines, clinical pathways, and clinical protocols are useful tools in this effort to understand and to apply the best science to a particular diagnosis or condition. The hospital uses only those clinical practice guidelines, clinical pathways, and clinical protocols that have been reviewed and endorsed by relevant authoritative sources; for example, a national professional association or council, or an international organization that publishes approved guidelines. If the clinical practice guidelines, clinical pathways, and clinical protocols were developed by the hospital, they would be submitted to an authoritative source (for example, Ministry of Health or professional organizations) for endorsement.

Frequently, the effective implementation of clinical practice guidelines, clinical pathways, and clinical protocols will require clinical pathways and clinical protocols to be adapted or developed. Pathways and protocols are useful tools in this effort to ensure effective sequencing, integration, and coordination of care and efficient use of available resources.

Clinical practice guidelines, clinical pathways, and clinical protocols relevant to the hospital's patient population and mission meet the following criteria:

- Are selected from among those applicable to the services and patients of the hospital (mandatory national guidelines are included in this process, if present).
- Are evaluated for their relevance to identified patient populations.
- Are adapted when needed to the technology, drugs, and other resources of the hospital or to accepted national professional norms.
- Are assessed for their scientific evidence and endorsement by an authoritative source.
- Are formally approved or adopted by the hospital.
- Are implemented and measured for consistent use and effectiveness.
- Are supported by staff trained to apply the guidelines or pathways.
- Are periodically updated based on changes in the evidence and evaluation of processes and outcomes.

As many guidelines, and related protocols and pathways, impact multiple clinical departments or services, the leaders are expected to collectively determine at least five priority areas on which to focus—for which guidelines would impact the quality and safety of patient care and reduce unwanted variation in outcomes.

This collective selection process does not prohibit an individual department or service from selecting additional guidelines, nor any associated protocols or pathways, more specific to the services provided in that department or service.

Measurable Elements of GLD.06.02

1. On an annual basis, department/service leaders collectively determine at least five priority areas on which to focus the use of clinical practice guidelines.
2. Department/service leaders collaborate with appropriate clinical staff to select, review, approve, and modify the clinical practice guidelines, clinical pathways, and clinical protocols as needed.
3. Department/service leaders implement clinical practice guidelines, clinical pathways, and clinical protocols for each identified priority area as relevant to the department/service.
4. Department/service leaders demonstrate how the implementation of the clinical practice guidelines, clinical pathways, and clinical protocols supports the reduction of variation in the process and improved outcomes.

Organizational and Clinical Ethics

Standard GLD.07.00

Hospital leaders establish a framework for ethical management that promotes a culture of ethical practices and decision-making to ensure that patient care is provided within business, financial, ethical, and legal norms and protects patients and their rights.

Intent of GLD.07.00

Hospitals face many challenges in providing safe, high-quality health care. With advances in medical technology, financial constraints, and increasing expectations, ethical dilemmas and controversies are much more common. Hospital leaders have a professional and legal responsibility to create and promote an environment and culture that operates within an ethical framework.

The ethical framework must apply to both the hospital's business and clinical activities. Hospital leaders must demonstrate ethical behaviors and develop guidelines for organizational performance and conduct. Hospital leaders' actions and the hospital's guidelines for ethical behavior must be aligned with organizational policies and the hospital's vision, mission, and value statements.

The framework supports the hospital's health care practitioners, other staff, and patients and family when confronted by ethical dilemmas in patient care, such as interprofessional disagreements, disagreements between patients and their health care practitioners, and disagreements among family members about their relative who lacks decision-making capacity. Support is readily available and includes ethics resources and training for all staff. In addition, national and international norms related to human rights and professional ethics must be taken into consideration when creating an ethical framework and guiding documents.

The hospital operates within this framework to do the following:

- Disclose ownership and any conflicts of interest (for example, relationships between the referring physician and outside sources of laboratory or diagnostic imaging services).
- Honestly portray its services to patients.
- Protect confidentiality of patient information.
- Provide clear admission, transfer, and discharge policies.
- Bill accurately for its services and ensure that financial incentives and payment arrangements do not compromise patient care.
- Establish a mechanism by which health care practitioners and other staff may report clinical errors and raise ethical concerns with impunity, including disruptive staff behavior related to clinical and/or operational issues.
- Support an environment that allows free discussion of ethical concerns without fear of retribution.
- Provide an effective resolution to ethical conflicts within a clearly defined time frame.
- Ensure nondiscrimination in employment practices and provision of patient care in the context of the cultural and regulatory norms of the country.
- Reduce disparities in health care access and clinical outcomes by identifying vulnerable populations.

Measurable Elements of GLD.07.00

1. Hospital leaders establish a framework for the hospital's ethical management that promotes the following:
   - A culture of ethical practices and decision-making to ensure the protection of patients and their rights (*See also* COP.10.02, ME 2; HRP.01.02, ME 1; HRP.01.03, ME 3)
   - A mechanism by which health care practitioners and other staff may raise ethical concerns without fear of retribution (*See also* GLD.07.01, ME 5)
   - Structure(s) and processes support oversight of professional and business ethical issues.
2. The ethical framework ensures that patient care is provided within business, financial, ethical, and legal norms.
3. The hospital ensures nondiscrimination in employment practices and provision of patient care in the context of the cultural and regulatory norms of the country.
4. Hospital leaders identify applicable national and international ethical norms when developing the hospital's framework for ethical conduct.
5. The hospital accurately bills for services and ensures that financial incentives and payment arrangements do not impact patient care, treatment, or services.
6. The hospital provides an effective resolution to ethical conflicts that arise within a defined time frame.

Standard GLD.07.01

Hospital leaders create and maintain a culture of safety and quality throughout the hospital.

Intent of GLD.07.01

Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the hospital. Hospital leaders demonstrate their commitment to a culture of safety, and leaders set expectations for those who work in the hospital.

A *culture of safety* has been defined as "a collaborative environment in which clinicians treat each other with respect, leaders drive effective teamwork and promote psychological safety, teams learn from errors and near misses (or close calls), caregivers are aware of the inherent limitations of human performance in complex systems (stress recognition), and there is a visible process of learning and driving improvement through debriefings."

Hospital leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Behavior that intimidates others and affects morale or staff turnover undermines a culture of safety and can be harmful to patient care. Leaders must address such behavior in individuals working at all levels of the hospital, including management, medical, clinical, and administrative staff, and governing body members. Key features of a program for a culture of safety include the following:

- Acknowledgment of the high-risk nature of a hospital's activities and the determination to achieve consistently safe operations
- An environment in which individuals can report errors or near misses without fear of reprimand or punishment
- Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- Organizational commitment of resources, such as staff time, education, a safe method for reporting issues, and the like, to address safety concerns

Health care continues to have a culture of individual blame, which impairs the advancement of a safety culture. There are instances in which individuals should not be blamed for an error; for example, when there is poor communication between patient and staff, when there is a need for rapid decision-making, or when there are human factor design flaws in a treatment process. However, certain errors are the result of unsafe behavior and

do require accountability. Examples of unsafe behavior include failure to follow hand-hygiene guidelines, not performing the time-out before surgery, or not marking the surgical site.

A maturing safety culture is reflected in the increasing number of patients and families who are highly satisfied with your care and sustained decrease or absence of near misses and all adverse events, including sentinel events.

A culture of safety includes identifying and addressing issues related to systems that lead to unsafe behaviors. At the same time, though, hospitals must maintain accountability by establishing zero tolerance for unsafe behavior. Accountability distinguishes between human error (such as a mix-up), at-risk behavior (for example, taking shortcuts), and unsafe behavior (such as ignoring required safety steps). Establishing and supporting an organizational culture of safety may include committee appointments involving different hospital departments (for example, pharmacy, laboratory, engineering, nursing departments). The appointed committee presents periodic updates to the governing entity to identify issues that impact overall quality and patient safety. Hospital leaders evaluate the culture on a regular basis using a variety of methods, such as formal surveys, focus groups, staff interviews, and data analysis. Hospital leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Hospital leaders must address undesirable behaviors of individuals working at all levels of the hospital, including management, clinical and nonclinical staff, independent health care practitioners, and governing entity members.

Measurable Elements of GLD.07.01

1. Hospital leaders establish and support an organizational culture that encourages reporting and discussion of opportunities for improving culture of safety in the organization. (*See also* Sentinel Event Policy and APR.09.00, ME 1)
2. Ⓓ Hospital leaders develop a code of conduct that identifies and corrects behaviors that are unacceptable.
3. Hospital leaders establish regularly scheduled education and provide resources (such as literature and advisories) relevant to the hospital's culture of safety to all individuals who work in the hospital. (*See also* SQE.01.07, ME 3; SQE.07.00, ME 2)
4. Hospital leaders provide an accessible and confidential system for reporting issues relevant to a culture of safety in the hospital.
5. Hospital leaders implement a process to prevent retribution against individuals who report culture of safety issues and ensure that all reports are investigated within a defined time frame. (*See also* GLD.07.00, ME 1)
6. Hospital leaders identify and act on systems issues that lead health care practitioners to engage in unsafe behaviors.

Standard GLD.07.02

The hospital implements a workplace violence prevention program to provide a safe and secure workplace.

Intent of GLD.07.02

A workplace violence prevention program establishes a framework for hospitals to effectively implement and manage workplace violence prevention systems, including leadership oversight, policies and procedures, reporting systems, data collection and analysis, and post-incident strategies.

The rate of violence against health care workers has reached epic proportions. What is more, with only an average of 20% to 60% of incidents reported, the full scope of the problem has not yet been realized. *Workplace violence* is defined as "an act or threat occurring at the workplace that can include any of the following: verbal, nonverbal, written, or physical aggression; threatening, intimidating, harassing, or humiliating words or actions; bullying; sabotage; sexual harassment; physical assaults; or other behaviors of concern involving all staff, patients, or visitors." Violence in the workplace has become an increasingly

common problem in health care organizations. Staff shortages, increased patient acuity, and the misconception that violence does not occur in health care organizations—or if violence does occur, it is part of the job—are just a few of the barriers to acknowledging that workplace violence exists and to developing violence prevention programs.

Designating a leader to be accountable for the hospital's workplace violence prevention program establishes clear lines of accountability. In addition, establishing policies and standardized processes to prevent, respond to, report, and follow up on events or near misses decreases variation in the program. Data collection and simple, accessible reporting structures show commitment to providing a safe and secure work environment. Regularly reporting incidents and trends to the governing body promotes transparency and further establishes accountability for the program. Examples of outcomes that measure a program's success include the following:

- Decrease of incidence of harm from violent behavior
- Employee Engagement Survey results and organizationwide staff reports indicate staff feeling "very safe."
- Patients and families report feeling safe in the health care setting.
- Staff feel comfortable reporting incidents and involving persons of authority.

Measurable Elements of GLD.07.02

1. The workplace violence prevention program is led by a designated individual and developed by an interdisciplinary team.
2. Ⓓ The hospital develops and implements written policies and procedures to prevent and respond to workplace violence. (*See also* FMS.03.00, ME 1; FMS.04.00, ME 7; SQE.02.02, MEs 1 and 3)
3. The hospital implements a process to report incidents in order to analyze incidents and trends. (*See also* FMS.03.00, MEs 3 and 5; FMS.04.00, ME 9)
4. The hospital implements a process for follow-up and support to victims and witnesses affected by workplace violence, including trauma and psychological counseling, if necessary.
5. The hospital implements a process for the reporting of workplace violence incidents to the governing body. (*See also* SQE.02.02, ME 3)

Health Professional Education

Note: For hospitals that meet the eligibility criteria for academic medical center hospital accreditation, GLD.08.00 applies to education provided to nursing students and/or other nonmedical, health professional students. For hospitals that are not academic medical centers, GLD.08.00 applies to education provided to medical students and trainees, nursing students, and/or other health professional students.

Standard GLD.08.00

Health professional education, when provided within the hospital, is guided by the educational parameters defined by the sponsoring academic program and the hospital's leaders.

Intent of GLD.08.00

Frequently, hospitals incorporate a teaching role in their mission and are the clinical setting for portions of medical, nursing, other health care practitioners, and other student training. For example, students and trainees in medicine may spend a few months gaining clinical experience in a community teaching hospital, or a nursing program may be based in the hospital. These hospitals serve an important role; however, they are not considered academic medical centers for the purposes of these standards.

Hospital leaders liaise with the training institution for proper oversight when the hospital participates in any type of training program. As part of this coordination, the hospital does the following:

- Obtains and accepts the parameters of the sponsoring academic program.
- Obtains the complete record of all students and trainees within the hospital.
- Understands and provides the level of supervision for all trainees.
- Integrates students and trainees into the hospital's orientation, quality and patient safety, infection prevention and control, and other programs.

Measurable Elements of GLD.08.00

1. The hospital provides a mechanism(s) for oversight of the training program(s).
2. Ⓓ The hospital has a complete record of all students and trainees within the hospital.
3. Ⓓ The hospital has documentation of the enrollment status, licensure or certifications achieved, and academic classification of the students and trainees.
4. The hospital provides the required level of supervision for each type and level of student and trainee.
5. The hospital provides an opportunity for students and trainees to evaluate the education program and to receive feedback.

Human Subjects Research

Note: Academic medical centers are required to meet these requirements in addition to the "Human Subjects Research Programs" (HRP) chapter.

Standard GLD.09.00

Human subjects research, when provided within the hospital, is guided by laws, regulations, and hospital leaders.

Intent of GLD.09.00

Human subjects research is a complex and significant endeavor for a hospital. Hospital leaders recognize the required level of commitment and personal involvement required to advance scientific inquiry. With differing local regulations, hospital leaders must protect the patient and respect their rights during research, investigation, and clinical trials.

A hospital's commitment to human subjects research is not separate from its commitment to patient care—commitment is integrated at all levels. Thus, ethical considerations, effective communication, responsible leaders, regulatory compliance, and financial and nonfinancial resources are components of this commitment. One such resource is indemnity insurance to compensate patients for adverse events due to the research protocol. Hospital leaders recognize the obligation to protect patients irrespective of the sponsor of the research.

Individuals from the research or other programs are involved in developing the criteria or protocol. Admission to such programs is documented in the patient's medical record and includes the criteria or protocol conditions under which the patient was admitted.

To comply with local laws and regulations, the hospital establishes a committee or identifies a qualified individual(s) to oversee all research in the hospital involving human subjects. A committee or other mechanism such as a hospital-specific or shared Institutional Review Board (IRB) to provide oversight for all such activities in the hospital is established. The hospital develops a statement of purpose for the oversight activities. Oversight activities include the review process for all research protocols, a process to weigh the relative risks and benefits to the subjects, and processes related to the confidentiality and security of the research information.

Measurable Elements of GLD.09.00

1. Hospital leaders identify the official(s) responsible for the development and compliance with human subjects research policies aligned with regulatory and professional requirements.
2. Ⓓ To help the patient determine whether to participate in research, investigation, or clinical trials, the hospital provides the patient with all the following information:
   - An explanation of the purpose and scope of the research
   - The expected duration of the patient's participation
   - A clear description of the procedures to be followed
   - A statement of the potential benefits, risks, discomforts, and side effects
   - Alternative care, treatment, and services available to the patient that might prove advantageous to the patient
3. Ⓓ The hospital documents the following in the research consent form:
   - That the patient received information to help determine whether to participate in the research, investigation, or clinical trial
   - That the patient was informed that refusing to participate in the research, investigation, or clinical trial or discontinuing participation at any time will not jeopardize their access to care, treatment, and services unrelated to the research
   - The name of the person who provided the information and the date the form was signed
   - The patient's right to privacy, confidentiality, and safety (*See also* PCC.01.02, ME 1)
4. Hospital leaders ensure that there is a source of indemnity insurance to compensate patients participating in clinical research who experience an adverse event.
5. Oversight of human subjects research activities includes processes to provide confidentiality and security of research information.

Health Care Technology (HCT)

Overview

The health care industry is facing a fast-moving digital revolution. Hospitals are adopting new methods of technology to streamline processes and procedures and reduce costs. From electronic health records (EHRs) to telehealth capabilities, artificial intelligence (AI), and medical equipment advancements, technological innovations have enhanced clinical outcomes, improved patient care, and transformed the possibilities for care delivery.

As the demand for specialized health care services continues to increase, technology will continue to play a critical and necessary role in the comprehensive care process. Management of technology and medical equipment requires a high level of communication and collaboration to maintain an integrated system of care, services, and providers that make up the continuum of care. Establishing processes and procedures for efficient integration and oversight is paramount for success.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Information Technology in Health Care

HCT.01.00 Hospital leaders identify a qualified individual to oversee the hospital's health information technology and processes.

HCT.01.01 When patient data and information are sent electronically, via mobile devices or other forms of electronic communication, the hospital implements processes to ensure quality of patient care, compliance with local laws and regulations, and maintenance of security and confidentiality of patient information.

HCT.01.02 For hospitals providing telehealth services, the hospital implements guidelines for the protection of patient data and information.

HCT.01.03 For hospitals using artificial intelligence clinical decision support tools, there are processes for selection, implementation, oversight, and improvement.

HCT.01.04 The hospital develops, maintains, and tests a program for response to planned and unplanned downtime of data systems.

HCT.01.05 The hospital develops and maintains processes and procedures for cybersecurity and cyber risk management.

Management of Lasers, Electrosurgical, and Other Optical Radiation Devices

HCT.02.00 The hospital establishes and implements a program for the safe use of lasers, electrosurgical, and other optical radiation devices used for performing procedures and treatments.

Standards, Intents, and Measurable Elements

Information Technology in Health Care

Standard HCT.01.00

Hospital leaders identify a qualified individual to oversee the hospital's health information technology and processes.

Intent of HCT.01.00

Technology systems can be complex and require oversight for successful implementation and coordination with existing processes.

Investment in information technology is an important resource for hospital systems. Technology systems and processes can significantly improve efficiency, patient safety, dissemination of data, and error reduction.

Health information technology includes the following:

- Electronic health records for documentation and information sharing
- Patient portals
- Health information exchange platforms
- Systems for storing, managing, and securing data
- Platforms for communication among health care practitioners for care coordination
- Interfaces with other systems to facilitate patient care and treatment
- Electronic prescribing tools
- Telehealth technology and applications
- Medical billing software

Without proper evaluation and testing, health information technology can pose increased risks to patients. Successful implementation and integration of health information technology systems requires resources and direction from hospital leaders. The leadership team appoints a qualified individual to oversee technological systems and processes. A qualified individual has education, training, and/or experience relevant to the role and responsibilities.

The hospital's information technology systems must be managed effectively and in a comprehensive and coordinated manner. The individual who oversees the health information technology systems is responsible for at least the following:

- Recommending space, equipment, technology, and other resources to hospital leaders to support information technology systems in the hospital
- Selecting and testing new technologies/systems
- Conducting risk assessments to assess security risks, prioritize risks, and identify improvements
- Ensuring that staff are educated and trained on technology security, applicable policies, and procedures
- Implementing metrics to assess how technology systems are functioning and impacting hospital operations

When technology systems are implemented, it is important for the hospital to establish a process to evaluate their usability and effectiveness. Evaluation includes the following:

- Whether or not the technology is being used as designed and intended
- How well the technology integrates with existing technologies
- What effects technology has on improving patient safety, reducing errors, and enhancing performance
- What effect technology has on staff (for example, increasing efficiency, increasing or reducing stress and burnout)

Depending on the size and scope of the hospital, there may be several individuals who support the point person to manage aspects of the program. This individual may also have responsibilities with the health information systems.

All or part of integrating new and existing health information technology may be done through contracted services. Oversight of the contract is provided by the individual who oversees health information technology or health information management.

Measurable Elements of HCT.01.00

1. Hospital leaders provide support and resources for technology services in the hospital.
2. Hospital leaders identify a qualified individual to oversee technological systems and processes. (*See also* GLD.06.00, ME 1)
3. Ⓓ Hospital leaders and a qualified individual(s) participate in processes such as selection, testing, implementation, and evaluation of new and evolving health information technology systems.
4. New and evolving health information technology systems are monitored and evaluated for usability, effectiveness, intended use by staff, and patient safety, and improvements are identified and implemented based on results.

Standard HCT.01.01

When patient data and information are sent electronically, via mobile devices or other forms of electronic communication, the hospital implements processes to ensure quality of patient care, compliance with local laws and regulations, and maintenance of security and confidentiality of patient information.

Intent of HCT.01.01

Time-sensitive data sent electronically may not be viewed by the physician in a timely manner and delay immediate actions that may be needed. The information may be secured on the physician or hospital side, but the patient may not have the same securities in place.

As technology has evolved, many health care practitioners have begun to use electronic forms of communication to do the following:

- Communicate patient data and information through text messages and e-mails (critical results, referrals, and notes).
- Exchange communications with other practitioners.
- Receive text messages or e-mails from patients.

These electronic forms of communication may include mobile devices, e-mail, and secure messaging platforms.

Hospitals may provide mobile or portable devices to their health care practitioners or may allow practitioners to use their personal devices. When mobile or portable devices are used, the hospital needs to ensure that patient data and information are kept secure and confidential, in accordance with laws and regulations and hospital policy. When these devices are provided to staff by the hospital, there are procedures to retrieve the devices when staff are no longer employed by or associated with the hospital.

When the hospital allows confidential and private patient information to be transmitted through text messaging (for example, patient identification, diagnoses, history, test results, other confidential information), the hospital ensures that a formal, secure messaging platform is implemented and includes the following:

- Secure, encrypted sign-on processes for authentication of users (password protected, unique to each user, and end-to-end encrypted for all contents)

- Processes for ensuring that only authorized individuals are in the platform directory for receiving messages
- Delivery and read receipts for messages
- Date and time stamp for messages
- Processes for protecting and securing patient information against unauthorized access and use

If the content of the message cannot be guaranteed to be secure, confidential information should be excluded from the message. Sensitive patient information should not be sent through a less secure platform.

The hospital establishes processes for ensuring that e-mails or text messages with patient information are documented in the medical record when the content relates to the care of the patient. For example, text messages exchanged among health care practitioners that contain information used to make decisions about a patient's care need to be documented in that patient's medical record.

Patient portals also allow communication between practitioners and patients and provide a range of services that can be performed online or through an app on a mobile device, such as the following:

- Completing registration forms
- Requesting prescription refills
- Accessing test results
- Scheduling nonurgent appointments
- Sending/receiving messages with the physician
- Downloading educational materials
- Making electronic payments

Hospitals that implement patient portals ensure confidentiality and security of the patient information stored and exchanged through the portal. The implementation and use of patient portals require encryption of patient data/information, a secure, encrypted sign-on process with password requirements for users, audit trails that log and record key activities, and consent from patients to participate in the patient portal.

Data confidentiality can be achieved in several ways, including the following:

- Implementation of access controls with authentication
- Establishing a secure password policy as defined by the hospital (for example, minimum number of characters, use of special characters, combination of letters and numbers, use of uppercase and lowercase letters, limited reuse of previous passwords, password renewal schedule throughout the year)
- Implementation of remote access to disable or remove patient data from mobile devices in the event they are lost or stolen
- Enhanced security controls
- Limiting e-mail use to areas where risk of breach of confidentiality or delay in response is lower

The hospital implements a process to monitor the quality of communications conducted through text, e-mail, and patient portals, and makes improvements where needed. The hospital ensures that patients have adequate understanding of data and information received through text, e-mail, and patient portals, and encourages patients to contact their health care provider for questions. The hospital collects data to monitor the process for clarifying questions that arise from messages received via text, e-mail, and patient portals. For example, the hospital may collect data on how often staff need to clarify patient information that has been texted and the process for obtaining clarification. Where applicable, the hospital abides by health information management rules or standards set by the country/region in which it operates.

Measurable Elements of HCT.01.01

1. When patient data and information are transmitted through mobile text messaging or electronic communication tools, the hospital ensures that the process is through a secure platform and complies with the following:
   - Secure, encrypted sign-on processes for authentication of users (password protected and unique to each user)
   - Processes for ensuring that only authorized individuals are in the platform directory for receiving messages
   - Delivery and read receipts for messages
   - Date and time stamp for messages
   - Processes for protecting and securing patient information against unauthorized access and use (*See also* MOI.01.02, ME 3)
2. Ⓓ When mobile devices are used for communicating patient data and information, the hospital implements written guidelines and processes to protect and secure patient information. (*See also* MOI.01.02, ME 3)
3. The hospital establishes processes to ensure that information relating to a patient's care sent electronically (for example, through text messages or e-mails) is documented in the patient's medical record. (*See also* MOI.03.00, ME 4)
4. When the hospital implements a patient portal or communicates with patients via text messages or e-mails, the hospital does the following:
   - Educates the patient on the patient portal and confirms readiness for use. (*See also* PCC.04.00, ME 1)
   - Obtains consent from patients to participate in the portal and/or receive text messages or e-mails.
5. Ⓓ When the hospital allows patient information to be communicated via text messages, e-mails, and patient portals, the hospital has a process to ensure that questions that arise about the information exchanged are addressed in a timely manner and monitors for improvements needed to the communication processes.

Standard HCT.01.02

For hospitals providing telehealth services, the hospital implements guidelines for the protection of patient data and information.

Intent of HCT.01.02

Established guidelines for telehealth services provide a framework for standardization, safety, security, and quality of care.

Telehealth requires a more comprehensive and integrated approach for delivery of patient care. A high degree of collaboration and communication among health care providers is mandatory for successful implementation.

A hospital providing telehealth services should establish a framework for delivering patient services in a consistent manner, regardless of the physical location of the patient or provider. Having a standardized process for providing services results in best practice, efficient use of resources, and improved patient outcomes. Providers operating within an integrated system will ensure a "seamless delivery" of care and services. The processes in place shall ensure integration measures to prevent fragmentation of data. Patient data and information that would be entered into a medical record during an in-person visit must be incorporated into the medical record during a telehealth visit (for example, patient history, diagnosis, treatment, instructions).

The hospital implements guidelines to ensure that patient data and information remain confidential and that telehealth services are secure from data breaches and other cybersecurity threats. This begins with an effective employee training program.

Data breaches can result in harm to patients and potential fines to the organization. Hospitals using telehealth platforms should implement processes to ensure that data are correct and remain confidential to prevent inappropriate delivery of care. Methods that may be used include the following:

- Multifactor authentication
- Decentralized storage of data
- Encrypted data
- Use of secured networks or virtual private networks (VPNs)
- Access control monitoring

Employee training programs must include cybersecurity awareness with specific topics that ensure security of confidential information.

Measurable Elements of HCT.01.02

1. Ⓓ The hospital implements written guidelines and processes to secure patient information when telehealth services are used.
2. The hospital establishes processes to ensure that patient information remains confidential when telehealth services are used.
3. The hospital establishes processes to ensure the integration of information when multiple touchpoints and platforms within the system are used.
4. Ⓓ All staff involved in providing telehealth services receive cybersecurity training and continuing education, and the training and ongoing education are documented. Training for staff accessing health information technology systems includes the following:
   - Device security
   - Access privileges
   - Password protection
   - Social engineering and phishing
   - Cybersecurity threats

Standard HCT.01.03

For hospitals using artificial intelligence clinical decision support tools, there are processes for selection, implementation, oversight, and improvement.

Intent of HCT.01.03

Artificial intelligence (AI) technology is rapidly progressing within the health care setting and requires guidelines to ensure that biases are avoided, ethical standards are maintained, information is stored privately and securely, and the tools are performing as intended to meet expectations of the end users.

AI advancements are providing opportunity for hospitals to improve outcomes, reduce organizational costs, and impact public health. AI–based decision support tools are being implemented across multiple settings and specialties within health care settings to transform decision-making processes. These tools are used to improve quality of care, increase efficiency in the delivery of care, and enhance decision-making by analyzing patient data and generating predictions based on those data. Machine learning and algorithms analyze data, learn from patterns or trends, and offer insight to health care providers across the continuum.

The health care industry is one of a few whose clients turn to the Internet to search for their problems before consulting with a professional. Individuals research their symptoms online and have a tendency to diagnose themselves based on those search results. Countering the need for a growing demand of services, use of AI chatbots or technology of the like are on the rise. AI use in this manner can allow for these services to be provided to a wider population range, save time for providers, and increase data analysis capabilities. When incorporating chatbots, there is a concern for data to remain private, be safeguarded, and remain encrypted during use.

A qualified individual(s), identified by relevant training and background, as well as the leadership team and key stakeholders, should be involved in the selection process and ongoing oversight of AI tools. Hospitals using AI technology should have methods in place to evaluate the decision-making support tools to ensure that they meet expectations of the hospital and patient population. Ongoing monitoring is necessary for usability, intended use, up-to-date capabilities, data safety, data quality, system risks, and any ethical concerns. There should also be consideration that a human practitioner is involved in final decision-making when it involves patient care. Practitioners should still physically examine patients, review any documentation prompts, and be held responsible for the care of the patient. The hospital should establish a process for reporting any adverse outcomes to the leadership team and key stakeholders.

Education and training of all pertinent staff members who interact with the AI decision support tools is required to ensure effective and safe integration into practice and care delivery. Having established users on-site to troubleshoot or provide training sessions can be beneficial to the organization.

AI clinical decision support tools include diagnostic decision support tools, treatment decision support tools, predictive analytics tools, and population health management tools. Examples of commonly used types of clinical decision support tools used in the hospital setting include but are not limited to the following:

- Sepsis triggers
- Wound management
- Medication reconciliation
- Medication dosing
- Diagnostic code selection
- Aide in rapid response procedures
- Creation of treatment guidelines for urgent conditions
- Interpretation of lab and testing results

Factors to consider when assessing the AI technology and algorithms are as follows:

- Is it meaningful or useful to the setting?
- Is it providing up-to-date data?
- Does it meet clinical workflow expectations?
- What is the impact on clinical decision-making?
- What is the confidence level of the output data?
- What is the likelihood of bias being introduced?

Monitoring effective use of AI technology for clinical decision-making includes the following:

- Reviewing usage logs, including common uses, areas for improvement, and user satisfaction
- Identifying discrepancies in diagnoses, treatment recommendations, or medications
- Analyzing feedback from providers
- Evaluating patient outcomes
- Performing updates to the tool or the system

Measurable Elements of HCT.01.03

1. The hospital identifies qualified individuals to select the relevant AI tools for their respective areas of expertise (for example, pharmacy, wound care, surgery).
2. Ⓓ The hospital establishes written guidelines and processes for oversight of the effectiveness of AI tools used by the hospital. These include the following:
   - Approval and implementation processes
   - Human practitioner involvement in final decision-making of patient care
   - Security and privacy of patient data (*See also* PCC.01.02, ME 1)
   - Identification of system discrepancies
   - Analysis from providers and relevant third-party sources
   - Updates to software/technology as deemed appropriate
   - Ethical considerations
3. The hospital tracks usage and trends on an ongoing basis and reports outcomes to the relevant parties (for example, key stakeholders, leadership team, third-party sources).

Standard HCT.01.04

The hospital develops, maintains, and tests a program for response to planned and unplanned downtime of data systems.

Intent of HCT.01.04

Data systems are an important part of providing safe, high-quality patient care, and downtime—whether planned or unplanned—can affect an entire system.

Whether or not a hospital has implemented an electronic health record (EHR), a form of information technology exists in a majority of hospitals. Information technology can be found in digital imaging, laboratory testing and reporting of results, communication systems, pharmacy support systems, and the like.

Data system interruptions and failures, referred to as downtime, are unavoidable events. Planned downtime is scheduled for the purpose of conducting maintenance, repairs, upgrades, and other changes to the system. Unplanned downtime occurs as a result of power or equipment failures, heating/cooling system failures, natural disasters, human error, and interruptions to Internet or intranet services, among other disruptions. Unplanned downtime can result in data system failures, such as loss of data, hardware failures, and data corruption. It can also result from cybersecurity threats or attacks. Hospitals may be in danger of permanently losing data if systems are not in place to copy and archive data.

Hospitals must prepare all departments and services with training specific to tactics and interventions for managing downtime in their particular area. When unplanned downtime occurs, staff need to be notified immediately upon discovery of the event.

The hospital must develop strategies and measures for continuing patient care during data system interruptions to maintain quality and safety. Following downtime, patient care and services provided during the period of downtime may need to be entered manually, through a document management/scanning system, or through transcriptions of hard copy to soft copy during periods of inactivity.

Recovery plans should be tested at least once a year. Simple backups should be tested at least once a quarter and whenever there is a major hardware or software change in the backup system. It is important to run a test after an upgrade to ensure that the upgrade works properly with the rest of the systems.

The hospital plans for interruptions by doing the following:

- Training staff on alternative procedures
- Testing the hospital's emergency management program
- Conducting regularly scheduled data backups
- Testing data restoration procedures
- Addressing processes for continuity with electronic, paper-based, and/or knowledge-based information

Communication is essential to continuity of care during downtime. Notifying staff about planned downtime allows them to make necessary preparations to ensure that business continues in a safe and effective manner. Communication prior to planned downtime should include at least the following information:

- The information technology system or application that will be down and the department/service areas that will be affected
- The time that the downtime will begin and the expected length of time the system or application will be unavailable
- The reason for the downtime and what changes can be expected after the planned downtime is completed (for example, regular maintenance with no changes expected, or an enhancement to the system)

Downtime recovery tactics must include disaster recovery and failover systems for backing up, recovering, and maintaining data systems. Recovery systems are typically located at remote locations to recover data that may

have become corrupted or unintentionally deleted. These systems must be backed up periodically, usually every night. Failover systems minimize disruptions in patient care and loss of data and are usually on the premises and switched over within a few seconds or minutes of the primary system becoming unavailable due to planned or unplanned downtime. In hospitals that use a cloud-based system for data backup, the vendor must have adequate backup systems in place to minimize disruptions to care, prevent loss of data, and maintain data integrity.

Hospitals that plan for maintaining access to electronic information systems by using various backup and recovery processes are likely to experience seamless continuity of patient care and minimal data loss.

The way information is communicated to staff depends on the system that is down. For example, if the hospital's network goes down, communication to staff via telephone may be required. Multiple communication strategies should be developed to address the different systems that may be affected. In addition to internal communication strategies, it may be necessary to develop strategies for external communication. For example, if the hospital has an interfacing application with outside/contracted laboratory or radiology services and it becomes unavailable due to downtime, there needs to be a process for obtaining the results during downtime and a plan to have results reported back via the interface when the downtime is over.

One approach to managing downtime is the practice of having a packet of hard-copy downtime forms or a downtime binder available to continue care if unplanned downtime exceeds a certain time threshold (typically greater than 30 minutes). Another approach is to maintain a downtime computer that allows read-only access to patient data.

Hospitals need to define what data may need to be reentered in a discreet format (for example, all medications prescribed during downtime, select orders, allergies, problem lists), what data may need to be scanned in, and what data may need to be transcribed from hard copy to soft copy. To ensure confidentiality and security of information, the hospital should have a documented process for the management of any paper documentation used during downtime.

Many tools are available for backing up data. The optimal backup solutions for each hospital depend on many factors, including the amount of data requiring backup, the speed at which data can be backed up and recovered, the location of recovery systems, costs, and other factors.

Measurable Elements of HCT.01.04

1. Ⓓ The hospital maintains, and tests at least annually, a written program for response to planned and unplanned downtime of data systems. (*See also* FMS.08.00, ME 1; HCT.01.05, ME 1)
2. The hospital identifies the probable impact that planned and unplanned downtime of data systems will have on all aspects of care and services.
3. The program includes continuity strategies for the provision of ongoing safe, high-quality patient care and services, including services provided by outside vendors, during planned and unplanned downtime of data systems.
4. The program identifies internal and, when applicable, external communication strategies for planned and unplanned downtime.
5. The hospital implements downtime recovery tactics and ongoing data backup processes to recover and maintain data and ensure data integrity and maintain confidentiality and security of patient information.
6. Staff are trained in the strategies and tactics used for planned and unplanned downtime of data systems.

Standard HCT.01.05

The hospital develops and maintains processes and procedures for cybersecurity and cyber risk management.

Intent of HCT.01.05

Cyberattacks in health care carry more risk due to the type and widespread use of information and can be detrimental to patient safety and hospital operations if not properly managed.

Cyberattacks have the potential to interrupt and delay a variety of services throughout a hospital system, including ambulance transport, surgeries, medication delivery, and system operations (HVAC) to name a few. Information technology, whether in the form of the electronic health record (EHR) or that used throughout the hospital system, is susceptible to cyberattacks. As technology advances within the system, cybersecurity advancements need to be made as well to ensure patient safety and prevent operational delays. Areas that are vulnerable to cyberattacks include but are not limited to the following:

- EHR
- E-prescribing software
- Remote patient monitoring
- Laboratory information systems
- Medical billing software
- Scheduling software
- Communication systems

Measures and procedures for cybersecurity are necessary to protect valuable patient information during attacks. For example, penetration testing can be used to simulate a variety of attacks using similar tools that cyberattackers would use to find weaknesses within the system. From these test results, a response program could be constructed.

Downtime related to cyberattacks requires a differentiated plan from the standard planned or unplanned downtime for hospitals that use an electronic health record and communication system. In the event of a cyberattack, there must be a process to report details to the information technology (IT) department, hospital leaders, and a cyber team if applicable.

Most departments in the hospital handle information that is highly sensitive and valuable to cyber hackers. Staff, including providers of care, billing agents, administrative staff, and scheduling agents, manage this information daily and require specialized training to understand safe practices and consequences of a cyberattack or breach. Initial and ongoing training should be conducted and documented for completion.

In many hospitals, resources allocated to the IT department may be limited due to a number of constraints. Leaders must consider all the medical devices that are interconnected throughout the system, the thousands of people using those devices, and inconsistent business/user processes.

In the event downtime occurs because of a cyberattack, there must be downtime recovery procedures for backing up, maintaining, and potentially recovering system data. There is no single correct way to manage a cyberattack, but having plans in place beforehand can reduce the impact. Both the US National Institute of Standards and Technology (NIST) and European Union Cybersecurity Agency (ENISA) have frameworks for establishing a risk-based approach.

A strong posture for security includes the following:

- Having a high-quality, stable application base and infrastructure (for example, hardware, software applications, operating systems, networking tools, and telecommunication tools)
- Having IT infrastructure with configuration management, change management, logging, and monitoring
- Having a proactive stance and security measures in place (for example, resources and budgeting)
- Having training and awareness for all employees who interact in any way with hospital technology

Strategies for reducing exposure to a cyberattack include but are not limited to the following:

- Filtering e-mail and checking suspicious content
- Updating security configurations on devices, servers, and systems
- Installing antivirus software

- Running penetration tests
- Limiting control of physical access
- Maintaining regularly scheduled backups, which are stored in a physical, offline location

Provisions should be made for communicating a security breach internally and notifying any affected party externally. For example, the General Data Protection Regulation (GDPR), in the European Union, implemented regulations for breach notification and penalties when not adhered to.

Measurable Elements of HCT.01.05

1. Ⓓ The hospital maintains, and tests at least annually, a written incident response program that includes the following:
   - Identifying the probable impact a cyberattack on data systems will have on all aspects of care and operations (*See also* HCT.01.04, ME 1)
   - Identifying strategies for the provision of ongoing safe and high-quality care and services
2. The program identifies internal and external communication strategies for those affected by cyberattacks or events.
3. The hospital implements recovery tactics and ongoing data backup processes to recover and maintain data, ensuring data integrity, confidentiality, and security.

Management of Lasers, Electrosurgical, and Other Optical Radiation Devices

Standard HCT.02.00

The hospital establishes and implements a program for the safe use of lasers, electrosurgical, and other optical radiation devices used for performing procedures and treatments.

Intent of HCT.02.00

Nearly all lasers, electrosurgical, and other optical radiation devices that are used in the clinical setting pose potential hazards for patients and staff if safety procedures and guidelines are not established and followed.

Lasers are a source of optical radiation, which includes ultraviolet radiation, high-intensity visible light, and infrared radiation. The narrow beam of high-intensity light from a laser can be targeted and focused for precise surgical procedures. As technology evolves, the use of lasers is becoming more common with surgical procedures, and their clinical use is broadening.

Laser surgeries are generally minimally invasive with less blood loss than conventional surgery, and patients typically experience shorter recovery times. Lasers are also used in noninvasive procedures providing safer alternatives for treating conditions without surgical intervention.

Lasers and other optical radiation devices can generate intense concentrations of heat, light, and reflected light. When the skin and eyes are exposed to the heat and light without adequate protection, skin burns and eye injuries, such as retinal burns, cataracts, and macular degeneration, may result. Injuries can come from direct contact with the light or with the reflected light from the laser.

Plumes are another potential hazard. These are the vapors, smoke, and particles produced during some surgical procedures. Plumes produced by lasers and electrosurgical devices (for example, cautery units) introduce a potential respiratory hazard for patients and staff, as they may contain irritants, toxins, tissue, bacteria, viruses, blood fragments, and other particles, depending on the type of procedure.

To prevent these hazards and address safety risks to patients and staff, the hospital establishes and implements a program for the safe use of lasers, electrosurgical, and other optical radiation devices using industry standards and professional guidelines. The program complies with laws and regulations and includes the following:

- A qualified individual who has oversight and supervision of the laser, electrosurgical, and optical radiation safety program
- Training in safety practices and procedures for all staff who are involved in the use of lasers electrosurgical, and other optical radiation devices
- Ongoing education and training are provided for new procedures, practices, devices, and equipment.
- Documentation of training and ongoing education
- Administrative and engineering controls to promote safety and prevent injury
- Availability of personal protective equipment for staff and patients appropriate to the type of laser, electrosurgical, or other optical radiation device being used, or type of procedure performed in the hospital (for example, goggles, corneal shields, masks, gloves, and/or gowns as applicable)
- A maintenance program for lasers, electrosurgical, and other optical radiation devices, and a process for routine performance checks such as calibration and alignment
- Coordination with the facility management and infection prevention and control programs; all facility safety events and infection control events need to be reported.
- Detecting and reporting adverse health effects and identifying and implementing improvements to prevent recurrence

Laser surgery interventions include the following:

- LASIK and cataract surgery
- Removal of skin lesions
- Treatment of varicose veins
- Dentistry procedures to remove tooth decay or recontour soft tissue

Noninvasive, optical radiation treatments can include the following:

- Intense pulsed light therapy to treat skin conditions
- Ultraviolet radiation to treat psoriasis
- Lasers to whiten teeth
- High-intensity visible light for dental procedures
- Light therapy for treatment of pain and inflammation
- Infrared radiation to treat strained muscles and soft tissue

Adverse events resulting from the use of lasers, electrosurgical, and other optical radiation devices are reported, and action plans to prevent recurrence are implemented and monitored. Controls used to promote safety and prevent injury are implemented. Examples include the following:

- Criteria and processes for authorizing staff who enter and/or work in the areas (hazard zones) where lasers and other optical radiation are used
- The hospital identifies any additional staff who may require access to hazard zones.
- Warning signs placed outside procedure areas to alert staff, patients, families, and visitors when a treatment or procedure is being performed
- Appropriate ventilation and plume evacuation to help manage smoke plumes
- Use of nonreflective instruments to prevent exposures to reflective light
- Use of drapes and other barriers to prevent staff, patients, families, and visitors from inadvertently being exposed to direct or reflected light

Measurable Elements of HCT.02.00

1. Ⓓ The hospital's written program for the safe use of lasers, electrosurgical, and other optical radiation devices meets the following criteria:
   - Is based on industry standards and professional guidelines and complies with applicable laws and regulations.
   - Is part of the hospital's facility management and safety structure.
   - Provides reports at least annually and when any safety events occur.

   (*See also* FMS.03.00, ME 1)
2. A qualified individual with the appropriate training and experience has oversight and supervision of the laser, electrosurgical, and optical radiation safety program.
3. Ⓓ All staff involved in the use of lasers, electrosurgical, and other optical radiation devices receive safety training and continuing education; the training and ongoing education are documented.
4. The hospital establishes and implements administrative and engineering controls for the laser, electrosurgical, and optical radiation safety program to promote safety and prevent injury for patients and staff.
5. Personal protective equipment appropriate to the type of lasers, electrosurgical, and other optical radiation devices and type of procedures is available for staff and patients, and staff use it correctly and ensure that patients and staff are protected during procedures.
6. The hospital has processes for inspection, testing, and maintenance of lasers, electrosurgical, and other optical radiation devices, including routine calibration and alignment checks of lasers, and these activities are performed by qualified and trained individuals.

Management of Information (MOI)

Overview

Providing patient care is a complex endeavor highly dependent on information communication. This communication is to and with patients and their families, other health care practitioners, and the community. Failures in communication are one of the most common root causes of patient safety incidents. Often, these communication failures result from illegible handwriting, and the nonuniform or nonstandardized use of abbreviations, symbols, and codes across an organization. An integral part of information management in health care is monitoring and protecting the use of patients' information. To provide, coordinate, and integrate services, health care organizations rely on information about the science of care, individual patients, care provided, results of care, and their own performance. Like human, material, and financial resources, information is a resource that must be managed effectively by the hospital's leaders. Every hospital seeks to obtain, manage, and use information to improve patient outcomes and individual and overall organizational performance.

Over time, hospitals become more effective in the following areas:

- Identifying information and information technology needs
- Designing or deploying information management systems
- Defining and capturing data and information
- Analyzing data and transforming data into information
- Transmitting and reporting data and information
- Protecting confidentiality, security, and integrity of data and information
- Integrating and using information for performance improvement

Although computerization and other technologies improve efficiency, the principles of good information technology management apply to all documentation methodologies. These standards are designed to be equally compatible with noncomputerized systems and current/future technologies.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Planning for Management of Information

MOI.01.00 The hospital plans for managing information and selects processes to meet the needs of those who require data and information.

MOI.01.01 The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes to manage and control access.

MOI.01.02 The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes that protect against loss, theft, damage, destruction, ransomware, and other cyberattacks.

MOI.01.03 The hospital determines the retention time of patient medical records, data, and other information.

MOI.01.04 Clinical staff, decision-makers, and other staff members are educated and trained on information systems, information security, and the principles of information use and management.

Standardized Use of Information

MOI.02.00 Documents, including policies, procedures, and programs, are managed in a consistent and uniform manner.

MOI.02.01 Leaders review, approve, and manage implementation of policies and procedures that guide and support patient care and services.

MOI.02.02 The hospital uses standardized diagnosis and procedure codes and ensures the uniform use of approved symbols and abbreviations across the hospital.

MOI.02.03 The hospital retrieves, disseminates, and transmits health information on a timely basis in a format that meets user expectations, and with the desired frequency.

Patient Medical Record

MOI.03.00 The hospital initiates and maintains a standardized, accurate medical record for every patient assessed or treated and determines the record's content, format, and location of entries.

MOI.03.01 As part of its monitoring and performance improvement activities, the hospital regularly assesses patient medical record content.

Standards, Intents, and Measurable Elements

Planning for Management of Information

Standard MOI.01.00

The hospital plans for managing information and selects processes to meet the needs of those who require data and information.

Intent of MOI.01.00

Information is generated and used during patient care, treatment, and services and for managing a safe and effective hospital.

The ability to capture and to provide information requires effective planning. Planning for information management may include the following:

- The hospital's mission
- Services provided
- Resources
- Access to affordable technology
- Usability and interoperability assessments
- Support for effective communication among caregivers

Planning incorporates input from a variety of sources who use data and information, including the following:

- Health care practitioners and other staff who provide clinical services
- Hospital leaders and department/service leaders

- Individuals, services, and agencies outside the hospital who use data or information about the hospital's operation and care processes

The information needs of these sources should inform the hospital's information management strategies and ability to implement those strategies. The strategies must meet the needs of the hospital based on the hospital's size, complexity of services, availability of trained staff, and other human and technical resources.

The information processes are comprehensive and include all the departments and services of the hospital. Planning for the management of information does not require a formal written information program but does require evidence of a planned approach that identifies the hospital's information needs and processes for meeting those needs.

Measurable Elements of MOI.01.00

1. The hospital selects processes to meet the information needs of the following:
   - Those who provide clinical services
   - The hospital's leaders and department/service leaders (*See also* GLD.03.02, MEs 1 and 2)
   - Individuals, services, and agencies outside the hospital (*See also* GLD.03.01, ME 2)
   - Patients accessing personal data
2. The processes implemented are appropriate to the hospital's size, complexity of services, availability of trained staff, technical resources, and other resources.
3. The planning and designing of information management processes of the hospital include the following:
   - The hospital's mission
   - Services provided
   - Resources
   - Access to affordable technology
   - Usability and interoperability assessments
   - Support for effective communication among caregivers

Standard MOI.01.01

The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes to manage and control access.

Intent of MOI.01.01

The hospital establishes processes to protect sensitive patient information and prevent unauthorized access to data, which can have larger consequences.

The balance between data sharing and data confidentiality is addressed. The hospital should follow established processes for the safe movement within and release of patient medical record information.

Whether a hospital uses paper and/or electronic information systems, it implements measures to secure and protect data and information at all times. Data and information include the following:

- Patient medical records
- Data from medical equipment and devices
- Research data
- Quality data
- Billing data
- Human resources data
- Other applicable sources

Security measures include processes to manage and control access. The hospital determines who is authorized to access medical records and implements processes for assigning privileges to authorized users in accordance

with their level of access. An authorized user may be able to enter, modify, and delete information, or may have read-only or restricted access to some systems or modules. Level of access may identify who can make entries in the medical record, who can enter patient orders, who can access high-security patient cases, who can access quality improvement data, and so on.

For hospitals with electronic information systems, monitoring access to patient data and information through security audits of access logs can help protect confidentiality and security. The hospital implements regular security audits to proactively monitor access logs and identify system vulnerabilities or confidentiality policy violations.

Hospitals that use documentation assistants, or scribes, have a process to ensure protection of patient information, including training, competencies, stated job responsibilities, and a clearly identified scope of documentation activity. When electronic health records are used, additional security measures are implemented (for example, unique credentials assigned only to them).

Each authorized individual's level of access to data and information is based on need and defined by the person's role and responsibilities. Students, trainees, scribes, and others, as determined by the hospital, are included. An effective process defines the following:

- Who is authorized to have access to data and information, including patient medical records
- The information to which an authorized individual has access (level of access)
- The process for granting access privileges to authorized individuals
- The individual's obligation to keep information confidential and secure
- The process for maintaining data integrity (accuracy, consistency, and completeness)
- The process followed when confidentiality, security, or data integrity is violated or compromised

Security audits can identify system users who have altered, edited, or deleted information and can track changes made to the electronic health record. This information can be used to validate that user permissions are set appropriately according to current roles and identify user permissions that need to be removed due to staff changes.

If a hospital is planning to transition from a physical to an electronic health record system, considerations must be made to ensure the safety and confidentiality of patient information. Factors to consider include the following:

- Time frame for conversion of data
- Which information needs to be converted
- Destroying data no longer necessary
- How the information will be converted (for example, direct data entry or scanning)
- Where the data entry occurs (for example, centralized or decentralized)

Measurable Elements of MOI.01.01

1. The hospital implements processes consistent with laws and regulations to ensure the confidentiality, security, and integrity of data and information. (*See also* PCC.01.02, ME 1)
2. Ⓓ The hospital identifies, in writing, those authorized to access data and information, including those authorized to make entries in the patient medical record, and determines their level of access based on each individual's role and responsibilities.
3. The hospital has a process in place to grant authorized individuals access privileges to data and information in accordance with their level of access.
4. The hospital implements processes to ensure that data and information are accessed by authorized individuals only and in accordance with their level of access. (*See also* ACC.03.00, ME 2)
5. The hospital implements processes to ensure that only authorized individuals make entries in the patient medical record and in accordance with their level of access.
6. The hospital monitors compliance with the processes and release of information and acts when violations occur.

Standard MOI.01.02

The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes that protect against loss, theft, damage, destruction, ransomware, and other cyberattacks.

Intent of MOI.01.02

Vulnerabilities that lead to the breach of sensitive information and data can be severe and widespread for the hospital and the patients it serves.

The hospital ensures that paper and electronic health records, data, and other information are protected from loss, theft, tampering, damage, and unintended destruction.

Vulnerabilities that pose a security risk include response to phishing e-mails, sending unencrypted e-mails, password misuse, or misplaced technological equipment. The hospital also assesses for external/remote cybersecurity vulnerabilities, including hacking, breach of information, ransomware, or other malware.

To protect data and information, the hospital implements best practices for data security and ensures safe and secure storage of medical records, data, and information. Examples of security measures and strategies include but are not limited to the following:

- Ensuring that security software and system updates are current and up to date
- Encrypting data, such as data stored in digital form
- Protecting data and information through backup strategies such as off-site storage and/or cloud backup services
- Storing physical medical records in locations where they will be protected from heat, water, fire, pests, or infestation
- Storing active medical records in areas where only authorized health care practitioners have access
- Ensuring that server rooms and areas where physical medical records are stored are secured and accessible only by authorized individuals
- Ensuring that server rooms and areas where physical medical records are kept are at proper temperature and humidity levels to protect servers/records
- Ensuring that server rooms and areas where physical medical records are kept are protected from fire hazards
- Conducting and documenting an ongoing information security risk assessment, at least annually

A risk assessment considers a review of processes and new and planned services that may pose risks to data and information. Risks are prioritized from the risk assessment, and improvements are identified and implemented to address the risks. Improvements are monitored to ensure that risks are prevented or eliminated.

Technology advancements create increased opportunities for electronic information to be breached. The hospital ensures that staff are trained, at least annually, in such topics as the following:

- Log-in processes and behaviors (for example, not sharing credentials)
- Malware training
- E-mail phishing reporting

Measurable Elements of MOI.01.02

1. Ⓓ The hospital conducts and documents an annual information security risk assessment throughout the organization, and data security risks are identified and prioritized from the risk assessment.
2. Data and information are stored in a manner that protects against loss, theft, damage, destruction, ransomware, and other cyberattacks.
3. The hospital implements data security best practices to protect and secure data and information. (*See also* PCC.01.02, ME 1; HCT.01.01, MEs 1 and 2)
4. The hospital identifies goals, implements improvements to address data security risks, and monitors improvement data to ensure that risks are reduced or eliminated.
5. Ⓓ The hospital establishes a written policy with procedures to follow in the event a successful cyberattack occurs.

Standard MOI.01.03

The hospital determines the retention time of patient medical records, data, and other information.

Intent of MOI.01.03

The hospital determines the retention time of medical records, data, and other information that are retained for sufficient periods to comply with laws and regulations and to support patient care, management, legal documentation, research, and education as applicable.

The retention process for medical records, data, and other information, including text messages and e-mails that contain information for medical records, is consistent with hospital policies and procedures for maintaining the confidentiality and security of such information. After the retention period, patient medical records, data, and other information are destroyed in a manner that does not compromise confidentiality and security.

Measurable Elements of MOI.01.03

1. Ⓓ The hospital determines the retention time of patient medical records and other data and information and complies with laws and regulations.
2. The retention process provides expected confidentiality and security.
3. Patient medical records, data, and other information are destroyed or deleted in a manner that does not compromise confidentiality and security.

Standard MOI.01.04

Clinical staff, decision-makers, and other staff members are educated and trained on information systems, information security, and the principles of information use and management.

Intent of MOI.01.04

Individuals in the hospital who generate, collect, enter, review, analyze, and use data and information are educated and trained to effectively perform their job functions.

This education and training enable these individuals to do the following:

- Use information systems, such as an electronic health record system, to carry out their job responsibilities efficiently and safely.
- Comply with policies and procedures to ensure security and confidentiality of data and information.
- Implement tactics and strategies for the management of data, information, and documentation during planned and unplanned downtime.
- Use data and information to help in decision-making.
- Educate and support patients and families regarding participation in care processes.

- Use measures to assess and improve care and work processes.

Hospitals with electronic health record systems ensure that staff who need to access, review, and/or document in the patient medical record receive education, ongoing training, and assessment to effectively and efficiently use the system.

Cybersecurity breaches can pose safety issues for patients and be costly to the hospital system. Hospitals also ensure that staff receive cybersecurity training related to their responsibilities and job descriptions to maintain security of information.

The information management process makes it possible to combine information from various sources and generate reports to support decision-making with longitudinal and comparative data. The combination of clinical and managerial information helps department/service leaders to plan collaboratively.

Various methods can be used for ongoing training that are relevant to staff needs and provide helpful guidance on system use. Examples include the following:

- "Tips and tricks"
- Quick reference guides
- Short educational modules
- Newsletters (posted or e-mailed)

Cybersecurity education and training topics can include the following:

- Password protection
- Malware and ransomware
- E-mail phishing
- Device management
- Safeguards for sensitive data
- Device updates
- Reporting suspicious activity

Measurable Elements of MOI.01.04

1. Clinical staff, decision-makers, and others are provided education and training on information systems, information security, and the principles of information use and management, as appropriate to their role and responsibilities.
2. Staff who use an electronic health record system receive education, ongoing training, and assessment to ensure that they can effectively and efficiently use the system to carry out their job responsibilities.
3. Staff receive education and ongoing, annual training related to cybersecurity based on their roles and responsibilities.
4. Clinical and managerial data and information are integrated as needed to support decision-making.

Standardized Use of Information

Standard MOI.02.00

Documents, including policies, procedures, and programs, are managed in a consistent and uniform manner.

Intent of MOI.02.00

Policies and procedures are intended to provide uniform knowledge on organizational clinical and nonclinical functions.

A written document guides how all policies, procedures, and programs in the hospital will be developed and controlled.

Being able to identify changes to policies, procedures, and programs is essential to maintain efficiency, effectiveness, and staff compliance. Methods for identifying changes may include the following:

- Regular review and updates based on a time schedule established by the hospital
- Monitoring compliance to assess areas of improvement or gaps in performance
- Review of current and relevant research to assess industry changes
- Staff feedback opportunities, including surveys, suggestion boxes, or feedback sessions
- Communication channels to inform staff of policy changes, including e-mail announcements, newsletters, and team meetings
- Employee education and training
- Incident reporting

Measurable Elements of MOI.02.00

1. Ⓓ There is a written guidance document that defines the requirements for reviewing policies and procedures, including the following:
   - Review and approval of all documents by an authorized person before issue
   - Frequency of review and continued approval of documents
   - Controls for ensuring that only current, relevant versions of documents are available
   - Method for identifying changes
2. Ⓓ There is a written guidance document that defines requirements for management of policies and procedures, including the following:
   - Maintaining identity and legibility
   - Managing documents originating outside the hospital
   - Retaining obsolete documents for the time required by laws and regulations while ensuring that they are not used
   - Tracking all documents in circulation (for example, identified by title, date of issue, edition and/or current revision date, number of pages, and who authorized and/or reviewed the document)
3. Ⓓ There are standardized formats for all similar documents (for example, all policies).
4. The requirements of the guidance document are implemented and evident in the policies, procedures, and programs found throughout the hospital.

Standard MOI.02.01

Leaders review, approve, and manage implementation of policies and procedures that guide and support patient care and services.

Intent of MOI.02.01

Throughout the accreditation standards found in this manual, policies, procedures, plans, and other written documents are required (noted with the icon Ⓓ), as they reduce process variation and reduce the risk inherent in processes to improve quality and patient safety.

There is a process to ensure that staff members have read and are familiar with policies, procedures, and plans relevant to their work. This process may be part of the orientation of staff members to their department and responsibilities or may be part of groupwide or hospitalwide special training sessions. When a policy, procedure, or plan is relevant to the assignment of an individual, the intended actions described in the document are evident in the actions of the individual.

Measurable Elements of MOI.02.01

1. Required policies, procedures, and plans are available, and staff understand how to access those documents relevant to their responsibilities.
2. Staff are trained and understand those documents relevant to their responsibilities.
3. The requirements of the policies, procedures, and plans are fully implemented and evident in the actions of individual staff members.
4. The implementation of policies, procedures, and plans is monitored, and the information supports full implementation.

Standard MOI.02.02

The hospital uses standardized diagnosis and procedure codes and ensures the uniform use of approved symbols and abbreviations across the hospital.

Intent of MOI.02.02

Standardization of codes and uniform use of symbols and abbreviations prevents miscommunication and potential errors in patient care and supports data aggregation and analysis.

Abbreviations can be problematic and even dangerous, particularly in the context of prescribing medications. When abbreviations are allowed in the hospital, processes are implemented to prevent or reduce risks to patient safety. Abbreviations are not used on high-risk, patient-specific documents that are crucial to continuity of care, including the following:

- Informed consent documents
- Patient rights documents
- Discharge instructions
- Discharge summaries

Patients and families may not understand the hospital's approved abbreviations. With discharge summaries, there is a patient safety risk in using abbreviations if a provider from a different organization does not use the same list. Abbreviations are typically used on reports of laboratory and diagnostic imaging test results.

The hospital's use of standardized codes and uniform use of approved symbols and abbreviations is consistent with standards of professional practice and complies with local laws and regulations as applicable. Staff are educated and trained on the principles of the standardization and uniform use of the hospital's codes, symbols, and abbreviations.

When a hospital uses abbreviations, the hospital implements a process for the uniform use of approved abbreviations, such as a reference list. This uniform use includes each abbreviation having only one meaning. When abbreviations have more than one meaning, confusion as to what the author meant may result in medical errors. For example, the abbreviation *MS* could mean mitral stenosis in cardiology; however, in neurology, the abbreviation *MS* may be used for multiple sclerosis. In addition, confusion may arise when two abbreviations have the same letters but different letter cases. For example, *Pt* for patient and *PT* for physiotherapy. Even though the use of uppercase and lowercase letters differs between the two examples, they are essentially the same abbreviation with more than one meaning. It is important that abbreviation use is uniform and consistent across the hospital without differences in meanings between different departments or services.

When a hospital uses abbreviations, the hospital develops and/or adopts a do-not-use list of abbreviations and symbols. For example, the Institute for Safe Medication Practices (ISMP) maintains a list of abbreviations, symbols, and dose designations that "should never be used when communicating medical information." The items in the list were reported to ISMP as being frequently misinterpreted and involved in harmful medication errors.

If abbreviations are necessary, the first occurrence of the term should be completely spelled out, with the abbreviation listed in parentheses.

Measurable Elements of MOI.02.02

1. Ⓓ The hospital uses standardized diagnosis codes and procedure codes.
2. Ⓓ The hospital implements the uniform use of approved symbols and identifies those not to be used.
3. If the hospital allows abbreviations, it meets the following criteria:
   - The hospital implements a uniform use of approved abbreviations with only one meaning.
   - The hospital implements a do-not-use list of abbreviations.
   - The hospital does not use abbreviations on informed consents, patient rights documents, discharge instructions, or discharge summaries. (*See also* PCC.01.01, ME 1)
   - When an abbreviation is first used in documentation, the term must first be spelled out in complete form, with the abbreviation in parentheses.
   - The hospital monitors use of abbreviations and takes action to improve processes as needed.

Standard MOI.02.03

The hospital retrieves, disseminates, and transmits health information on a timely basis in a format that meets user expectations, and with the desired frequency.

Intent of MOI.02.03

The dissemination of data and information to meet the needs of those within and outside the hospital is an important aspect of information management.

Internally, health care practitioners, hospital leaders, department/service leaders, and other staff require specific data and information in a timely manner to allow them to carry out their responsibilities effectively and efficiently. For example, health care practitioners caring for a patient, including physicians, nurses, dietitians, pharmacists, and others, need access to up-to-date information and all applicable sections of the patient's medical record to provide safe and effective patient care.

Externally, the hospital may provide data and information to regulatory agencies (such as the Ministry of Health), health care practitioners (such as a patient's primary care physician in the community), health care services and programs (such as an outside laboratory or an organization for patient referral), and individuals (such as patients who request their medical record after discharge from the hospital).

The format and time frame for disseminating data and information are tailored to meet the user's expectations of the individual, service, or program. When data and information are needed for the care of a patient, it is provided in a timely manner that supports continuity of care and patient safety.

Examples of dissemination strategies to meet user expectations include the following:

- Providing the specific data and information requested/required
- Providing reports with the frequency needed by the individual or program
- Providing data and information in a format that facilitates its use
- Linking sources of data and information
- Providing interpretation or clarification of data

Measurable Elements of MOI.02.03

1. Data and information dissemination meets the needs of individuals and programs within and outside the hospital that provide patient care, treatment, and services.
2. The hospital disseminates data and information in useful formats within time frames that are defined by the hospital and consistent with laws and regulations.
3. Staff providing patient care have access to the data and information needed to carry out their job responsibilities and provide patient care safely and effectively.

Patient Medical Record

Standard MOI.03.00

The hospital initiates and maintains a standardized, accurate medical record for every patient assessed or treated and determines the record's content, format, and location of entries.

Intent of MOI.03.00

The integrity of the patient medical record is critical to the quality, safety, and continuity of care, as it is the principal tool for communication between health care practitioners.

Every patient assessed or treated in the hospital has a single medical record assigned with unique identifiers, or some other mechanism used to link the patient with their medical record. The unique identifiers used in medical records are uniform throughout the hospital to ensure ease of locating and documenting on care of patients.

Processes ensure that each entry in the patient medical record identifies the author, the date, and the time of entries, such as for timed treatments and medication orders. There is also a process for how entries in a medical record are corrected or overwritten. This applies to any physician, practitioner, or documentation assistant.

Electronic functions in documentation by practitioners is becoming more common practice as electronic health records systems are being adopted. These can include copy-and-paste (the practice of selecting text or data from an original or previous source to reuse in a different location), templates, autofill, and autocorrect.

Electronic functions can have advantages but also pose safety risks of inaccuracy or duplication of information, as in the following examples:

- A health care practitioner may copy their own notes to reuse, copy a note from another practitioner, or copy from a prior admission without updating appropriately.
- A template used for an emergency examination may include data fields for all body systems. When a focused examination is completed, documentation in the template may indicate that a complete examination was performed and was within normal limits. If an examination did not occur, but is documented as normal, patients and health care practitioners may make treatment decisions based on this misinformation.

Hospitals implement processes to ensure the accuracy of data and information in patient medical records, including guidelines for the proper use of copy-and-paste, autofill, autocorrect, and templates in the electronic health record, as well as monitoring their use.

Hospitals also provide training and education on the proper use of electronic documentation functions to all staff who document in the medical record.

When both an electronic and hard copy of medical records are actively in use, hospitals implement processes to ensure consistency of information between sources. The primary medical record, whichever source, should be comprehensive and should not have missing information from the other source. Duplication of information should be avoided to ensure accuracy of the medical record.

Identifiers for patient medical records can include a combination of the following:

- Medical record number
- Patient's name
- Patient's date of birth

The content, format, and location of entries for a patient's medical record is standardized to help promote the integration among health care practitioners and continuity of care. The hospital determines the specific data and information recorded in the medical record of each patient assessed or treated, including the following:

- Patient demographics
- Medications
- Patient diagnoses/problem list
- Assessment/reassessment
- Testing results
- Care plan
- Health maintenance

The medical record needs to present sufficient information to do the following:

- Support the diagnosis.
- Justify the patient's care, treatment, and services.
- Document the course and results of the patient's care, treatment, and services.
- Facilitate the continuity of care.

Monitoring electronic function use in documentation may involve partnering with the electronic health record vendor to develop a way to track information that has been copied-and-pasted or auto-generated (for example, displaying this information in a different font or underlined) or using a manual process to review for copied-and-pasted information.

Measurable Elements of MOI.03.00

1. The patient medical record contains the following:
   - At least two unique identifiers for each item (*See also* IPSG.01.00, ME 1)
   - Author of each entry
   - Date of each entry
   - Time of each entry
2. The specific content, format, and location of entries for patient medical records is standardized and determined by the hospital.
3. The hospital implements a process on the proper use of copy-and-paste, autofill, autocorrect, and templates and provides education and training on the process to all staff who document in the electronic health record.
4. The hospital implements processes to facilitate accurate and complete documentation in patient medical records. (*See also* HCT.01.01, ME 3)
5. There are processes for how entries are corrected, overwritten, reviewed, and authenticated.

Standard MOI.03.01

As part of its monitoring and performance improvement activities, the hospital regularly assesses patient medical record content.

Intent of MOI.03.01

Each hospital determines the content and format of the patient's medical record and has a process to assess the content and completeness as part of the hospital's performance improvement activities and is carried out regularly.

Patient medical record review is based on a sample representing the practitioners providing care and the types of care provided. The review process is conducted by medical staff, nursing staff, and other relevant health care practitioners authorized to make entries in the patient medical record. The review focuses on the timeliness, accuracy, completeness, and legibility of the record and clinical information. Medical record content required by laws or regulations is included in the review process. The hospital's medical record review process includes medical records of all services provided to both current and discharged patients.

A *representative sample* means medical records from all services and not a specific sample size; however, it should make sense for the organization.

Measurable Elements of MOI.03.01

1. Ⓓ A representative sample of medical records that includes active and discharged medical records in all service areas is reviewed at least quarterly or more frequently as determined by laws and regulations.
2. The review is conducted by physicians, nurses, and others authorized to manage or make entries in patient medical records.
3. The review focuses on the timeliness, accuracy, completeness, and legibility of the medical record.
4. Medical record content required by laws or regulations is included in the review process.
5. Ⓓ The results of the review process are incorporated into the hospital's quality oversight mechanism.

Prevention and Control of Infections (PCI)

Overview

According to the World Health Organization, of every 100 patients in acute-care hospitals, 7 patients in high-income countries and 15 patients in low- and middle-income countries will acquire one or more health care–associated infection (HAI) during their hospital stay, and an average of 1 in every 10 affected patients will die from an HAI. Modern health care, despite its great strides in preventing and treating disease, has yet to eliminate the risk to patients of acquiring an infection in the very place where infection should be least present. However, multidrug-resistant infections can be acquired in almost any setting, including homes, schools, and vacant lots, making the need for effective infection prevention and control in hospitals even more important.

To help reduce the possibility of acquiring and transmitting an infection, hospitals need to establish a systematic infection prevention and control program. The design and scope of your organization's program are determined by the specific risks faced by location, the population(s) served, and the types of services hospitals provide. The infection prevention and control activities hospitals adopt should also be practical and reasonable to follow. After an effective program is in place, the hospital takes measures so that the program operates according to plan and is evaluated appropriately.

Everyone who has clinical contact with patients should wash their hands frequently to help prevent the spread of disease. However, effective infection prevention and control plans go well beyond this approach. A strong plan will have the input and support of hospital leaders and will stress communication and collaboration. Everyone involved in the daily operations of the hospital, from practitioners to receptionists to kitchen staff and dock workers, should play a role. For example, physical rehabilitation specialists should take precautions to prevent germs from passing among patients via medical equipment, or staff who receive patients at intake should take measures to prevent the spread of disease when paperwork is passed back and forth. Everyone should observe proper infection prevention and control techniques.

The processes outlined in the "Prevention and Control of Infections" (PCI) chapter are applicable to all infections and potential sources of infection that hospitals might encounter. The standards are designed to assist hospitals, both large and small, in developing and maintaining an effective program that covers a wide range of situations.

These standards address activities of planning, implementation, and evaluation and are based on the following conditions necessary to establish and operate an effective infection prevention and control program. Every hospital, regardless of its size or the services it provides, should do the following:

- Recognize that its infection prevention and control program plays a major role in its efforts to improve patient safety and quality of care.
- Demonstrate leaders' commitment to infection prevention and control by endorsing and participating in the organization's efforts to control infection, provide resources, and encourage improvement.
- See that staff collaborate with each other when designing and implementing the infection prevention and control program hospitalwide.
- Regularly assess its infection prevention and control program by using an epidemiological approach that consists of surveillance, data collection, analysis, and trend identification.

- Coordinate its program with the larger community, including regional or national public health organizations.
- Develop a hospitalwide prospective preparedness plan for an infectious disease outbreak that could overwhelm the hospital's resources.

Effective infection prevention and control programs have in common executive leader support, qualified department leaders, well-trained staff, methods to identify and to proactively address infection risks in persons and the environment, appropriate policies and procedures, staff education, and coordination throughout the organization.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Responsibilities

PCI.01.00 A qualified individual(s) guides the implementation of the hospital's infection prevention and control program and oversees the activities needed to carry out the program throughout the hospital.

PCI.01.01 The hospital coordinates infection prevention and control activities across all departments and services.

PCI.01.02 Hospital leaders provide resources to support the infection prevention and control program.

Goals of the Infection Prevention and Control Program

PCI.02.00 The hospital uses a risk-based data-driven method to establish priorities, implement interventions, and monitor the effectiveness of the health care–associated infection prevention and control program.

PCI.02.01 The laboratory implements a process to reduce the risks of infection resulting from exposure to infectious diseases and biohazardous materials and waste.

Medical Equipment, Devices, and Supplies

PCI.03.00 The hospital reduces the risk of infections associated with medical/surgical equipment, devices, and supplies by proper cleaning, disinfection, sterilization, and storage.

PCI.03.01 The hospital implements a process for managing the reuse of single-use devices in accordance with manufacturer's requirements and any applicable laws and regulations.

PCI.03.02 The hospital implements a process for managing expired and damaged devices and supplies.

Environmental Cleanliness

PCI.04.00 The infection prevention and control program provides oversight for the cleaning and disinfection of the environment.

PCI.04.01 The infection prevention and control program follows evidence-based guidelines related to cleaning and disinfection of laundry, linens, and scrub attire provided by the hospital.

Infectious Human Tissues and Waste

PCI.05.00 The hospital implements processes for proper disposal of waste, proper management of human tissues, and safe handling and disposal of sharps and needles.

PCI.05.01 The hospital reduces the risk of infections associated with exposure to blood, body fluids, and other potentially infectious materials.

Food Services

PCI.06.00 The hospital reduces the risk of infections associated with the operations of food and dietetics services.

Transmission of Infections

PCI.07.00 The hospital protects patients, visitors, and staff from transmission of infections and communicable diseases.

PCI.07.01 The hospital provides resources and equipment to protect staff, health care practitioners, patients, and visitors from biological, physical, and chemical hazards, and these are readily available for use.

PCI.07.02 The hospital implements processes to support preparedness for epidemiologically significant infectious diseases or special pathogens.

Quality Improvement and Program Education

PCI.08.00 The infection prevention and control process is integrated with the hospital's overall program for quality and patient safety, using data and measures that are epidemiologically important to the hospital.

PCI.08.01 The hospital provides education on infection prevention and control practices to staff, health care practitioners, patients, families, and others when indicated by their role in the hospital.

Standards, Intents, and Measurable Elements

Responsibilities

Standard PCI.01.00

A qualified individual(s) guides the implementation of the hospital's infection prevention and control program and oversees the activities needed to carry out the program throughout the hospital.

Intent of PCI.01.00

This standard is about qualifications and oversight of the infection prevention and control program. The effectiveness of a hospital infection prevention and control program in identifying and reducing the risks of acquiring and transmitting infections between patients, staff, health care practitioners, contract workers, volunteers, students, and visitors is dependent on competent and effective leadership. The structure and scope of the infection prevention and control program is in accordance with all applicable laws and regulations, national or health care industry standards, and evidence-based guidelines, and is based on the hospital's patient population, scope and complexity of services, geographic location, patient volume, level of risks, and number of staff and health care practitioners. The governing entity approves the program, and leaders provide the resources to implement the program. Capable guidance and oversight to carry out the program is necessary to make infection prevention and control a part of how the hospital meets its mission and strategic priorities.

One or more qualified individuals must oversee the operation of the program. This takes knowledge and experience in the many facets of the role, including but not limited to knowledge of the following:

- Disease transmission, including isolation measures for infectious patients or patients who are immunocompromised

- Knowledge of high-risk processes, such as Central Sterile Supply Department activities, sterile medication compounding, and hemodialysis
- Ability to implement evidence-based guidelines
- Ability to conduct data collection and analysis, report writing, and data presentation
- Ability to communicate effectively

The individual(s) leading the infection prevention and control program has experience in both infection prevention and control and leadership. The qualifications required for this role will depend on the program's activities. The individual's qualifications may be met through education, training, experience, certification or licensure, and/or demonstrated leadership ability.

The individual(s) with oversight for the infection prevention and control program also selects infection prevention and control staff with qualifications and capabilities needed for the program as defined by the hospital. Some of the key infection prevention and control program individuals, such as physician champions or nurse infection prevention project team leaders, may be located within a department/service in the hospital and need to be supported by the infection prevention and control program. The infection prevention and control program staff also understand how to take the hospitalwide priorities and the department/service-level priorities and turn them into a coordinated overall program. The program staff coordinate and organize activities throughout the hospital and provide support with those activities related to hospital priorities.

The qualified individual(s) overseeing the infection prevention and control program is responsible for setting priorities and ensuring progress toward meeting those priorities. This individual(s) identifies high-risk areas for infection prevention and control and provides oversight or designates an appointee to provide oversight of these areas. Staff throughout the hospital support the infection prevention and control program. The program is coordinated with the hospital's quality and patient safety program, and the facility management and safety program. The individual(s) is accountable for coordination with hospital leaders regarding priorities, resources, and continuous improvement related to the infection prevention and control program.

Data are reported to local, national, regional, and/or global public health agencies as required.

The hospital also takes actions to respond to reports issued by public health agencies, as applicable to the hospital and its patient population.

Measurable Elements of PCI.01.00

1. Ⓓ One or more qualified individuals oversee the infection prevention and control program and ensure that the program complies with local and national laws and regulations and applicable infection control guidelines. (*See also* GLD.06.00, ME 1)
2. Qualifications of the overseeing individual(s) and the qualifications of staff for the infection prevention and control program are determined by hospital leaders, based on the hospital's patient population, scope and complexity of services, geographic location, patient volume, level of risks, and number of staff and health care practitioners.
3. This individual(s) coordinates with hospital leaders regarding priorities, resources, and quality improvement opportunities related to the infection prevention and control program.
4. Ⓓ The hospital reports infection prevention and control program results to public health agencies as required.
5. The hospital takes appropriate action on reports from relevant public health agencies.

Standard PCI.01.01

The hospital coordinates infection prevention and control activities across all departments and services.

Intent of PCI.01.01

This standard is about integration of the infection prevention and control program with all hospital departments and services, and with the quality and patient safety program. Infection prevention and control activities must be coordinated throughout the hospital and include all services and departments to effectively address the infection risks present throughout the hospital. Infection prevention and control activities impact all areas and functions of the hospital and involve individuals across all departments and services. There must be a formal mechanism to coordinate the program's activities throughout the hospital that includes communicating with all parts of the hospital. The function and actions of this coordination mechanism must be documented. The hospital uses this information to review the effectiveness of coordinated activities and to monitor the continuous improvement of prevention and control of infections.

Hospital leaders must be involved in the coordination mechanism and accountable for the program's effectiveness. Physicians, nurses, and other staff are represented and engaged in the activities with infection prevention and control professionals. Other staff should be included as determined by the hospital's size and complexity of services and may include the following:

- Epidemiologist
- Infectious disease physician or another clinical disease specialist
- Statistician
- Central sterilization manager
- Microbiologist
- Housekeeping services
- Facilities services
- Information technology specialist
- Pharmacist
- Patients and families

The hospital determines the most effective coordination mechanism for its needs. Examples of coordination mechanisms include but are not limited to work groups, a coordinating committee, or a task force.

Responsibilities of this designated coordination mechanism include the following:

- Establishing policies and procedures for the program
- Setting criteria to define health care–associated infections
- Establishing data collection (surveillance) methods
- Designing strategies to address infection prevention and control risks
- Reporting processes
- Communicating with all parts of the hospital
- Coordinating responses to infection outbreaks

Measurable Elements of PCI.01.01

1. There is a formal interdisciplinary coordination mechanism such as a committee for the infection prevention and control program that involves infection prevention and control professionals.
2. All departments and services of the hospital are included in the infection prevention and control program. (*See also* FMS.03.00, ME 1)
3. The function and activities of the coordination mechanism are documented.
4. Ⓓ The hospital defines time intervals for committee meetings and content, based on laws and regulations, and requirements of infection control guidelines and hospital policy.
5. The infection prevention and control program supports staff throughout the hospital for infection prevention and control activities.

Standard PCI.01.02

Hospital leaders provide resources to support the infection prevention and control program.

Intent of PCI.01.02

This standard is about providing adequate resources, including the number of staff members needed for the infection prevention and control program. The infection prevention and control program must be given adequate staff and resources, including administrative support, to meet its goals and responsibilities, to meet the needs of the hospital, and to meet or exceed local laws and regulations. The number of staff is determined by the hospital's size, complexity of services, and level of risks; the program's scope; and laws and regulations, national health care industry standards, and professional association standards.

Hospital leaders ensure that human resources are available to support the infection prevention and control program. This includes the following:

- Appointment of a qualified individual(s) to oversee the program and high-risk areas
- Staff to provide education about the infection prevention and control program
- Clinical staffing numbers that allow for safe practice, including infection prevention and control practices

The infection prevention and control program requires resources to provide education to all staff and to purchase supplies. Hospital leaders ensure that the program has adequate resources to effectively carry out its goals and responsibilities. Hospital leaders approve and allocate resources and ensure that they are provided to the infection prevention and control program as intended and to meet the hospital's needs.

Information management systems are needed to support the data collection, aggregation, and analysis, and tracking and trending of risks, rates, and trends in health care–associated infections. Information management functions support the analysis and interpretation of data and the presentation of findings. Infection prevention and control program data and information are managed with the hospital's continuous improvement program.

Measurable Elements of PCI.01.02

1. Hospital leaders approve staffing levels and provide staff for the infection prevention and control program according to the hospital's size, complexity of activities, level of risks, and the program's scope.
2. Hospital leaders ensure that the infection prevention and control program receives the resources required to meet its goals and responsibilities.
3. Information management systems support the infection prevention and control program.

Goals of the Infection Prevention and Control Program

Standard PCI.02.00

The hospital uses a risk-based data-driven method to establish priorities, implement interventions, and monitor the effectiveness of the health care–associated infection prevention and control program.

Intent of PCI.02.00

Health care–associated infections, including those caused by multidrug-resistant organisms (MDROs), are preventable, cause significant morbidity and mortality, and significantly increase the cost of care to the patient and the hospital. A formal risk assessment using a data-driven approach helps hospitals identify high-risk areas and processes, develop effective interventions, and monitor the effectiveness of those interventions to make changes when necessary. The infection prevention and control process is designed to lower the risk of infection for patients, staff, and others. Health care–associated infections and multidrug-resistant organisms pose a significant risk to patients and communities. Health care–associated infections are generally considered preventable and reflective of a hospital's quality of care. Multidrug-resistant organisms are a serious threat, as there are limited medications that are effective against these rapidly evolving pathogens.

Each hospital must identify infection risks, to its patients, staff, and visitors. Examples of these infection risks include the following:

- Epidemiologically significant infections and infectious organisms (*see* Standard PCI.07.02)
- MDROs
- High-risk patient populations
- Device-associated infections
- Invasive procedures and high-risk practices

The infection prevention and control program identifies other high-risk areas for infection through an annual risk assessment. The hospital conducts infection surveillance for gathering and analyzing the data to guide the risk assessment. Goals for the infection prevention and control program are established based on this risk assessment and surveillance throughout the hospital. Risk assessments may also be completed by the individual(s) with oversight of the infection prevention and control program using information from these activities to implement evidence-based interventions to minimize these infection risks. Ongoing monitoring of identified risks and risk reduction interventions are monitored for effectiveness and includes continuous improvement changes to the program goals based on the trends in monitoring data, including the hospital's performance with internal and external benchmarks.

Some patient care treatments and interventions have been identified as major sources of hospital-associated infections, such as surgical procedures, mechanical ventilation, and insertion of central lines or indwelling catheters. Hospital-associated infections can severely impact a patient's emotional and financial well-being. They are a significant source of complications that can lead to further illness and even death. Many of these infections are preventable. Research studies suggest that implementing practices designed to prevent hospital-acquired infections can lead to as much as a 70% reduction of those infections.

In 2001 the Institute for Healthcare Improvement (IHI) began developing and testing the concept of enhancing teamwork and communication in multidisciplinary teams to improve the clinical care provided to patients. This initiative led to the creation of "bundles" of care. *Bundles* are defined by IHI as "a small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually." Examples of bundles include central line–associated bloodstream infection (CLABSI), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infection (CAUTI), surgical site infection (SSI), and severe sepsis bundle.

Implementing bundles of care will have the greatest impact on patient outcomes when the hospital identifies gaps in best practice or continued poor outcomes in a particular area. Evidence-based infection prevention and control bundles have been shown to reduce the risk of infection more than when individual improvement strategies are implemented separately. It is important for leaders to evaluate compliance with the bundles and track improvements in clinical outcomes.

The hospital must proactively identify and track risks, rates, and trends in health care–associated infections, including special considerations to address the risks from MDROs. When hospitals collect data on colonization rates of MDROs as well as infections caused by those microorganisms, the data should be aggregated separately. The hospital uses infection data to understand its rates and trends, and to compare its performance against other similar hospitals, and contributes data to infection-related databases as required by laws and regulations, infection control organization requirements, and professional organization requirements as applicable. This information is used to prioritize infection prevention and control program activities and to monitor the effectiveness of evidence-based infection prevention and reduction strategies.

The hospital implements evidence-based infection prevention and reduction strategies. Examples of these strategies include the following:

- Clinical practice guidelines
- Care bundles, such as for central lines and ventilators to prevent infections
- Antimicrobial stewardship programs

- Programs to reduce community- and hospital-associated infections
- Initiatives to decrease the use of unnecessary invasive devices

The hospital must also maintain awareness of community data and information on infectious diseases and emerging infectious or novel diseases, such as that compiled by the World Health Organization (WHO), US Centers for Disease Control and Prevention (CDC), national Ministries of Health, local public health agencies, and other official sources.

The infection prevention and control program identifies high-risk areas for infection and develops its goals based on an annual risk assessment. The purpose of the risk assessment is to identify and anticipate the following:

- Trends in current infection data in the hospital, the community, and globally
- Potential sources of infection in the hospital, the community, and globally
- Practices or procedures that do not align with current infection prevention and control recommendations
- Changes to hospital systems or infrastructure (for example, updating ventilation systems)

The goals of the annual infection prevention and control risk assessment include the following:

- Identifying infection risks
- Prioritizing infection risks
- Resetting goals for continuous improvement
- Implementing strategies to minimize or eliminate infection risks
- Defining what infection data to monitor
- Ensuring that the hospital has required supplies, equipment, and structure in place to minimize or eliminate infection risk
- Providing resources and education to staff to minimize infection risk to staff and patients

The infection prevention and control risk assessment includes, at minimum, the following:

Pathogens and HAIs

- Tracking current infection data in the hospital, community, and globally. **Note:** The hospital is not required to collect data from the community, only to maintain awareness of community data on infectious diseases such as that published by WHO, CDC, national Ministries of Health, local health departments, and other official sources.
- Tracking infection rates within the hospital, including community-acquired and health care–associated infections and MDROs
- Employee health and exposures

Emergency Preparedness

- Emerging infectious disease identification and management
- Outbreak management
- Risks associated with geographic location and community environment

Administrative

- Monitoring compliance with infection prevention and control practices
- Monitoring infection prevention and control practices throughout the hospital (for example, hand hygiene)
- Education resources required for staff, patients, and community
- Contracted services

Environmental

- Monitoring air flow and ventilation, temperature, and humidity
- Monitoring engineering controls during construction
- Monitoring of environmental cleaning and disinfection practices
- Management of infectious waste

Supplies/Equipment

- High-level disinfection and sterilization of instruments
- Low- and intermediate-level disinfection of equipment

Other

- Identification of individuals or populations that the risks impact, such as staff, patients, certain high-risk populations, and the community
- The impacts on the identified individuals or populations
- Severity of the risks
- Likelihood of the identified risks occurring
- Level of preparedness to address the identified risks

The goals, strategies, and actions of the infection prevention and control program are updated to reflect the risks identified through the risk assessment.

Measurable Elements of PCI.02.00

1. Ⓓ The hospital completes and documents an infection prevention and control risk assessment to establish the priorities of the health care–associated infection program through data collection and analysis at least annually, and when necessary for specific events, and it includes, at minimum, the following:
   - Respiratory tract infections
   - Urinary tract infections
   - Intravascular invasive devices
   - Surgical sites
   - Multidrug-resistant organisms
   - Epidemiologically significant infections
   - Emerging or reemerging infections within the community
2. Ⓓ The hospital identifies and implements evidence-based interventions to address infection risks identified in the risk assessment.
3. The hospital implements infection prevention and control interventions to reduce the rates of health care associated–infections, including multidrug-resistant organisms, through implementation of evidence-based care bundles wherever these are applicable.
4. Ⓓ The hospital monitors the effectiveness of infection prevention and control interventions through data collection and analysis and updates these as indicated.
5. Ⓓ The hospital performs ongoing data monitoring and surveillance to ensure that infection risks are reduced or eliminated.

Standard PCI.02.01

The laboratory implements a process to reduce the risks of infection resulting from exposure to infectious diseases and biohazardous materials and waste.

Intent of PCI.02.01

Staff working in the laboratory are at risk of exposure to infectious and biohazardous materials and waste. The laboratory must implement processes to identify and reduce risks of infection to staff. The hospital implements policies, procedures, and practices to reduce the hazards of exposure to biohazardous materials. Exposures and infections acquired in the laboratory are immediately reported internally to infection prevention and control, to hospital leaders, and to public health agencies when required. The hospital identifies biosafety hazards in the laboratory and implements policies and procedures to address those hazards. Staff are educated on the policies and procedures and consistently follow these requirements.

Examples of accidents or injuries that may expose staff to biohazards include but are not limited to the following:

- Exposure to infectious agents
- Sharp object and needlestick injuries
- Accidental ingestion
- Contact of potentially infectious agents with mucus membranes

When problems with practice are identified or accidents occur, the hospital takes corrective actions, which are documented and reviewed. Reviewing or evaluating corrective actions ensures that the actions were effective and will prevent future occurrences of the problem or accident.

At minimum, the implemented requirements address the following biosafety hazards and practices:

- Exposures to aerosols and droplets are controlled (for example, when mixing, sonicating, centrifuging, and flaming inoculating loops).
- Laboratory coats, gowns, or uniforms are worn to protect street clothes and prevent contamination.
- Biosafety cabinets are used when required by laws and regulations, manufacturer's guidelines, or professional practice standards.
- Rules govern procedures on how to handle laboratory accidents and injuries, such as exposure to infectious agents, accidental cuts, needlestick injuries, accidental ingestion, and contact of potentially infectious agents with mucus membranes. These rules include the following:
  - Decontamination procedures
  - Whom to contact for emergency treatment
  - Location and use of safety equipment
- There are written procedures defining safe collection, transport, and handling of all specimens, including prohibition of the following for anyone in laboratory technical areas:
  - Eating or drinking
  - Smoking
  - Applying cosmetics
  - Manipulating contact lenses
  - Mouth pipetting
- Safe use of biosafety cabinets in manipulations of infectious materials that may generate aerosols, and use of an appropriate classification of biosafety cabinets for the microorganisms being handled
- Training for laboratory staff about precautionary measures, modes of transmission, and prevention of bloodborne pathogens
- Procedures to manage and reduce risk of exposure to infectious diseases (for example, COVID-19, Ebola, MERS, tuberculosis, Zika, other unknown potentially infectious pathogens)

Measurable Elements of PCI.02.01

1. Ⓓ The laboratory implements written policies and procedures to reduce the risks of infection.
2. Ⓓ The hospital reports infections acquired in the laboratory as defined in the policy and in compliance with laws and regulations.
3. The laboratory follows biosafety rules for relevant practices:
   - Exposures to aerosols and droplets are controlled.
   - Laboratory coats, gowns, or uniforms are worn.
   - Biosafety cabinets are used when required by laws and regulations, or manufacturer's guidelines.
   - Procedures explain how to handle accidents and injuries, including decontamination procedures, emergency treatment procedures, and the location and use of safety equipment.
   - Procedures define safe collection, transport, and handling of all specimens.
   - Training for laboratory staff includes precautionary practices, modes of transmission, and prevention of exposure to bloodborne pathogens.
   - Procedures address how to manage and reduce risk of exposure to infectious diseases.
4. Ⓓ The hospital takes corrective actions, which are documented and reviewed, when problems with practice are identified or accidents occur.

Medical Equipment, Devices, and Supplies

Standard PCI.03.00

The hospital reduces the risk of infections associated with medical/surgical equipment, devices, and supplies by proper cleaning, disinfection, sterilization, and storage.

Intent of PCI.03.00

Failure to properly clean, disinfect, sterilize, and store equipment, devices, and supplies poses high risks to patients, staff, and others in the hospital by exposure to potential pathogens, including MDROs, bloodborne pathogens, endotoxins, chemicals such as preservatives, and other organic or inorganic materials. The US Centers for Disease Control and Prevention (CDC) defines *cleaning* as: "the removal of foreign material (e.g., soil, and organic material) from objects." CDC goes on to say that "[cleaning] is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes."

In 2008 the CDC Healthcare Infection Control Practices Advisory Committee's *Guideline for Disinfection and Sterilization in Healthcare Facilities* recognized Earle H. Spaulding's approach to disinfection and sterilization of patient-care items and equipment using a three-level method. The Spaulding Classification of Surfaces includes the following:

- Level 1—Critical: Objects which enter normally sterile tissue or the vascular system and require sterilization
- Level 2—Semicritical: Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but a small number of bacterial spores
- Level 3—Noncritical: Objects that contact intact skin but not mucous membranes, and require low-level disinfection

Manufacturer's instructions for use for instruments and equipment, as well as the equipment or agents used to clean, disinfect, or sterilize them, must be explicitly followed, along with applicable laws and regulations. Evidence-based guidelines and professional practice standards must also be consulted to determine the level of disinfection or sterilization required for items. However, laws and regulations, and manufacturer's instructions for use, take precedence over evidence-based guidelines or professional practice standards when these conflict. When medical device manufacturers' instructions conflict with manufacturers' instructions for automated high-level disinfection or sterilization equipment, the hospital must have a process to resolve this conflict. This may include contacting manufacturers directly for guidance. In situations in which none of these offer guidance, then a decision for how to proceed must be based on expert consensus using an evidence-based process. In all cases, the stricter standard must be followed if laws and regulations or manufacturer's instructions for use conflict.

Cleaning, disinfection, and sterilization of medical equipment, devices, and supplies involves low-, intermediate-, or high-level disinfection (HLD), or sterilizing agents and processes, based on the manufacturer's instructions for use (IFUs); guidelines from established organizations such as the Association for the Advancement of Medical Instrumentation (AAMI) and International Standards Organization (ISO), and others; the item's intended use; and standards such as the Spaulding Classification. Some equipment or instruments may fall under more than one classification depending on how they are used.

Storage of these items is also determined by the Spaulding Classification, along with manufacturer's IFUs, laws and regulations, national health care industry standards, professional practice standards, and evidence-based guidelines. As previously stated, the hospital must discern how to proceed when the guidance from these sources is in conflict. In all cases, equipment must be stored in a way that prevents contamination or loss of

sterility before use. It is critical that these high-risk processes are integrated into the infection prevention and control program, as well as the quality and patient safety program, with oversight by hospital leaders.

Measurable Elements of PCI.03.00

1. The hospital implements proper infection prevention and control practices when cleaning and performing low-level and intermediate-level disinfection of noncritical medical equipment, devices, and supplies that address the following:
   - Use of approved disinfectants in accordance with the product label directions, including the indication, specified-use dilution when applicable, contact time, and method of application
   - Use of disinfectant agents and methods approved by the equipment or device manufacturers
2. Ⓓ The hospital implements proper infection prevention and control practices when performing high-level disinfection and sterilization of critical medical equipment, devices, and supplies that address the following:
   - Use of approved chemical sterilants and high-level disinfectants in accordance with the product label and the device manufacturer's instructions
   - Required documentation for device reprocessing cycles, including but not limited to sterilizer cycle logs, the frequency of chemical or biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection
   - Resolution of conflicts or discrepancies between medical device manufacturers' instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment
   - Criteria and the process for the use of immediate-use steam sterilization
   - Actions to take in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use
3. Ⓓ Staff who reprocess medical/surgical equipment, devices, and supplies receive initial and ongoing training and demonstrate competency in cleaning and disinfection protocols; the training and staff competency are documented.
4. A qualified individual(s) oversees the cleaning, disinfection, sterilization, and storage processes for equipment, devices, and supplies.
5. Methods for cleaning, disinfection, sterilization, and storage of equipment and devices are coordinated and uniformly applied throughout the hospital.
6. Cleaned, disinfected, and sterilized equipment, devices, and supplies are properly stored in designated storage areas that prevent contamination prior to use.
7. The hospital implements a process to track high-level disinfected and sterilized instruments used for patient procedures to specific disinfection and sterilization cycles, equipment, and individual patients.
8. Ⓓ The hospital has a written procedure to identify and recall instruments for individual sterilization cycles and equipment.

Standard PCI.03.01

The hospital implements a process for managing the reuse of single-use devices in accordance with manufacturer's requirements and any applicable laws and regulations.

Intent of PCI.03.01

The reuse of reprocessed single-use devices and supplies has the risk of inadequate or unsafe performance. Some single-use devices may be reused under specific circumstances only when permitted by local and national laws and regulations. This standard addresses types of single-use critical and semicritical [medical] devices listed in the Spaulding Classification; it is not meant to include noncritical devices.

Medical devices manufactured to be single-use devices may be either marked with a symbol such as ②, or words such as "single-use only," "not to be reused," or "disposable."

There are risks associated with the reuse of reprocessed single-use devices, including an increased risk of infection and a risk of inadequate or unacceptable performance following reprocessing.

When the reprocessing and reuse of single-use devices is allowed, reprocessing must meet the same criteria as the original manufacturer to ensure that the device is safe for reuse, in both function and cleanliness.

Many devices are complex in design and are therefore difficult to clean, disinfect, or sterilize. Reprocessing may impact the effectiveness or function of the device, leading to a risk of the device breaking or failing during use. Chemicals used for reprocessing may corrode the device, and the reprocessing may damage the device. Most single-use devices are not designed for reprocessing, leading to increased risk of cross-infection. If the hospital permits the reuse of reprocessed single-use devices, there is a hospital policy to guide reprocessing and reuse. The policy is consistent with national laws and regulations and professional standards.

There is oversight of the process for the reuse of reprocessed single-use devices based on data, hospital needs, and alternatives to reusing devices. The list of single-use devices approved for reuse is routinely reviewed to ensure that it is accurate and current.

If the hospital permits the reuse and reprocessing of single-use devices, hospital policy includes the following:

- Alignment with local laws and regulations and standards from a recognized agency
- List of single-use devices and materials that may be reused
- Process for identifying when a single-use device is no longer safe or suitable for reuse
- Cleaning process for each device that starts immediately after use and follows a clear protocol
- Process to identify patients on whom reusable medical devices have been used
- Proactive evaluation of the safety of reusing single-use items, including but not limited to adverse events associated with surgery such as surgical site infections or an outbreak of infections or disease
- Collection and analysis of data on adverse events related to reused devices to identify risks, and implementation of actions to reduce these risks

Measurable Elements of PCI.03.01

1. Ⓓ The hospital identifies, in writing, single-use devices and materials that may be reused in accordance with local and national laws and regulations. (*See also* GHI.04.00, ME 4)
2. The hospital has a process for identifying when a single-use device is no longer safe or suitable for reuse.
3. The hospital has a process for cleaning, disinfection, or sterilization for each reusable, single-use device, in accordance with laws and regulations, manufacturer's requirements, or other applicable requirements.
4. Ⓓ The hospital has a written process to track the reuse of single-use devices to individual patients.
5. Ⓓ The hospital collects and analyzes data for any adverse events, and implements improvements related to the reuse process.

Standard PCI.03.02

The hospital implements a process for managing expired and damaged devices and supplies.

Intent of PCI.03.02

The use of expired or damaged supplies presents a risk to patients related to infection, or loss of integrity and function. The hospital must implement a process to manage inventory of devices and supplies, including expiration dates, and remove those items from service when outdated. This includes a process to identify damaged supplies, such as loss of package integrity, or damage that impairs the intended use of the supplies, and remove those from service. Most medical supplies are imprinted with an expiration date. The manufacturer does not guarantee the sterility, safety, or stability of the item after the expiration date. A policy defines the process for ensuring proper management of expired supplies. Damaged supplies pose risks to patients, as the

supplies may no longer function properly, and the cleanliness or sterility of the supplies cannot be guaranteed if the packaging has been compromised.

The hospital ensures storage conditions that protect supplies from contamination and damage that address at least the following:

- Conditions defined by the supply manufacturer
- Temperature and humidity stability
- Exposure to dust, dirt, water, and excessive humidity
- Exposure to other means of contamination such as being stored in a manner that creates the risk they could be touched by contaminated hands or gloves, or otherwise exposed to potentially infectious microorganisms

Measurable Elements of PCI.03.02

1. The hospital implements a process to manage expired supplies.
2. The hospital implements a process to manage damaged supplies.
3. The hospital stores supplies in a manner that prevents contamination or damage, and under environmental conditions recommended by the manufacturer when applicable.

Environmental Cleanliness

Standard PCI.04.00

The infection prevention and control program provides oversight for the cleaning and disinfection of the environment.

Intent of PCI.04.00

Effective environmental cleaning and disinfection practices contribute to the prevention of hospital-acquired infections. The hospital uses evidence-based guidelines to direct its environmental cleaning and disinfection processes. Routine cleaning of the environment includes daily cleaning of the following:

- Nursing units, patient rooms, and other patient care areas
- Diagnostic and treatment locations
- General support services areas, such as central supply, linen services, materials management, and all other departments and areas of the hospital
- Waiting areas and other public spaces
- Staff workspaces
- Kitchens

Terminal cleaning is a more focused and thorough cleaning process than daily maintenance cleaning and is performed in accordance with hospital policies and procedures and infection control guidelines. The hospital must determine how, when, and where terminal cleaning is performed. The process may be different depending on the area being terminally cleaned. For example, cleaning the room after the discharge of a patient on isolation precautions for an infectious disease may require different processes and cleaning agents than terminal cleaning of operating theatres or central sterile supply departments. Terminal cleaning requires further attention to the environment and may include the following:

- Laundering of privacy curtains
- Removal and cleaning of all detachable items in the room
- Disinfecting surfaces with multiple cleaning agents
- Use of specialized tools such as robotic ultraviolet light or ozone machines

Certain areas of the hospital require additional attention during environmental cleaning and disinfection due to their high-risk nature. Hospital leaders conduct risk assessments to determine which hospital areas require additional cleaning and disinfection. Hospital leaders identify appropriate guidelines and practice recommendations for staff to use when cleaning and disinfecting high-risk areas or situations, and staff are trained in the cleaning procedures and the safe use of cleaning agents. The hospital must also assess whether any critical or important clean areas or surfaces are within 1 meter of a sink, as this presents the risk of contamination through splashing of water. For example, countertops in medication rooms used for simple medication preparation prior to administration must be protected from splashing of water if within 1 meter of a sink. The hospital must determine how to prevent contamination, such as installing a barrier shield between the sink and countertop, or moving the area used to prepare medications.

Environmental cleaning and disinfection effectiveness must be monitored. The hospital determines how this monitoring is done based on available resources and technology. Data from monitoring are used to evaluate cleaning and disinfection processes and to direct any changes needed to ensure the cleanliness of the environment. These data are also used during education with environmental cleaning staff.

The hospital defines its routine cleaning practices, including the following:

- Frequency of routine cleanings, including high-touch surfaces
- When terminal cleaning is required
- What additional cleaning and disinfection practices are required for high-risk areas
- What additional cleaning and disinfection practices are required in areas caring for infectious patients
- Cleaning equipment and agents used
- Which staff members are responsible for cleaning tasks
- When areas require more frequent cleaning

The hospital identifies which areas are considered high risk for cleaning and disinfection processes and implements low-level disinfection or intermediate-level disinfection appropriately. Examples of high-risk areas include the following:

- Operating theatres
- Central Sterile Supply Department
- Neonatal intensive care units
- Burn units
- Areas where infectious patients are cared for

Monitoring data may be collected using a variety of methods, including the following examples:

- Patient and family comments and patient experience data, such as room cleanliness and overall hospital cleanliness
- Fluorescent markers and adenosine triphosphate (ATP) bioluminescence may be used to check for residual pathogens.
- Direct observation of the cleaning and disinfection procedures

Measurable Elements of PCI.04.00

1. The infection prevention and control program implements evidence-based cleaning and disinfection guidelines and procedures throughout the hospital. (*See also* MMU.05.00, ME 2)
2. Evidence-based guidelines are used to direct cleaning and disinfection procedures in high-risk areas as indicated by evidence-based cleaning and disinfection standards. (*See also* MMU.05.00, ME 2)
3. Evidence-based guidelines are used to direct cleaning and disinfection of areas where patients with infectious diseases receive care, including after patient discharge.
4. The hospital monitors environmental cleaning and disinfection processes, and data are used to make changes to the process when applicable.

Standard PCI.04.01

The infection prevention and control program follows evidence-based guidelines related to cleaning and disinfection of laundry, linens, and scrub attire provided by the hospital.

Intent of PCI.04.01

Laundering methods comply with local and national laws and regulations and follow guidelines from recognized infection control agencies to ensure safe and thorough processing of laundry, linens, and scrub attire provided by the hospital. Handling of laundry, linens, and hospital-issued scrub attire includes the following processes:

- Collection
- Sorting
- Washing
- Drying
- Folding
- Distribution
- Storage

Staff handling laundry, linens, and scrub attire follow standard precautions and use appropriate transmission-based precautions when handling laundry and linens from isolation rooms. Contaminated laundry, linens, and hospital-issued scrubs that are soaked in blood or other body fluids are separated from other soiled items and are labeled as contaminated to alert staff to the increased infection risk.

Laundering follows guidelines from infection control agencies, including the following:

- Water temperatures
- Length of wash cycles
- Use of cleaning agents, such as bleach and detergents
- Storage, handling, and transport of clean laundered items

Laundry, linens, and hospital-issued scrub attire are processed, transported, and stored in a way that prevents cross contamination of soiled and clean items. When laundry is performed outside of the hospital by a contractor, the hospital must have a means to monitor the quality of the service (*see also* Standard GLD.05.00).

The hospital identifies areas where staff are required to wear hospital-issued scrub attire, including white coats or jackets (for example, the Central Sterile Supply Department, operating theatres, the neonatal intensive care unit). The hospital also implements practices that decrease the risk of infection related to white coats and laboratory jackets. Staff are educated on when to change into scrub attire and when they must cover or change scrub sets. Staff who are not provided hospital-issued scrub attire receive education on home laundering practices to minimize the risk of carrying an infection between the hospital and the community.

Measurable Elements of PCI.04.01

1. Laundering methods comply with local and national laws and regulations and follow guidelines from recognized infection control agencies.
2. Standard precautions are used when handling laundry, linens, and hospital-issued scrub attire, and appropriate transmission-based precautions are used as indicated by infection risk.
3. Laundry, linens, and hospital-issued scrub attire are transported, processed, and stored in a manner that prevents cross contamination of soiled and clean items.
4. Staff wear clean hospital-issued scrub attire in critical areas identified by the hospital, in accordance with applicable infection control, national health care industry standards, and hospital policy.

Infectious Human Tissues and Waste

Standard PCI.05.00

The hospital implements processes for proper disposal of waste, proper management of human tissues, and safe handling and disposal of sharps and needles.

Intent of PCI.05.00

Hospitals produce considerable waste each day. Frequently that waste is or could be infectious. Thus, the proper disposal of waste, proper management of human tissues, and safe handling and disposal of sharps and needles contribute to the reduction of infection risk in the hospital. This is true for the disposal of body fluids and materials contaminated with body fluids, the disposal of blood and blood components, and the disposal or destruction of pathological waste. Human tissues, organs, and body parts require careful and respectful management to reduce the risk of infections during handling, transporting, and processing.

The hospital must also prevent infectious waste from contaminating the environment and transmitting infection outside of the hospital. Materials contaminated with body fluids, blood and blood components, and pathological waste create infection risks for staff handling and disposing of them.

One of the dangers of needlestick and sharps injuries is the possible transmission of bloodborne diseases. Improper handling and disposal of sharps and needles present a major staff safety hazard. Work practices influence the risk of injury and potential exposure to disease. Identifying and implementing evidence-based practices to reduce the risk of injury from sharps ensures that exposure to such injuries is minimal. Hospitals need to provide staff with education related to safe handling and management of sharps and needles.

Proper disposal of needles and sharps also reduces the risk of injury and exposure. Proper disposal includes the use of containers that are closable, puncture-proof, and leakproof on the sides and the bottom. Containers should be easily accessible to staff and should not be overfilled. In addition, containers must be labeled to warn of the potential injury hazard and stored to prevent the sharps from spilling out of the container.

Improper disposal of discarded needles, scalpels, and other sharps can pose a health risk to the public and to those who work in waste management. The disposal of sharps containers in the ocean or in general waste, for example, can pose risks to the public if the containers break open. Hospitals must dispose of sharps and needles safely or contract with organizations that ensure the proper disposal of medical waste containers in accordance with laws and regulations.

The hospital implements a policy that adequately addresses all steps in the process, including identifying the proper type and use of containers, the disposal of the containers, and the surveillance of the process of disposal.

There are special considerations related to the respectful and safe handling of the deceased and of human body parts. Mortuaries are constructed in a way that ensures the security of the bodies and body parts and the safety of the staff handling them. Hospital leaders consult local and national laws and regulations and consider local cultures and customs when designing the hospital mortuary. Additional considerations include how the chain of custody is ensured for bodies, body parts, and any specimens removed for testing; how staff are notified of a known or suspected infection; and how the bodies are preserved to prevent potential cross contamination. For example, a proper chain of custody provides that the hospital has a means of safeguarding the body or body parts until they are no longer under the jurisdiction of the hospital and documentation thereof. The mortuary is also maintained at a temperature and humidity that ensures proper storage. Staff have access to personal protective equipment, hand-cleaning stations, and necessary cleaning agents throughout the mortuary and are trained in respectful, safe handling procedures.

Measurable Elements of PCI.05.00

1. The hospital implements practices to reduce the risk of infection from handling and disposal of infectious waste, blood and blood components, body fluids, and body tissues. (*See also* FMS.05.00, ME 2)
2. The hospital identifies and implements practices to reduce the risk of injury and infection from the handling and management of sharps and needles.
3. Sharps and needles are collected in dedicated, closable, puncture-proof, leakproof containers that are not reused.
4. The hospital disposes of sharps and needles safely or contracts with vendors that ensure the proper disposal of sharps containers in dedicated hazardous waste sites or as determined by national laws and regulations.
5. The mortuary and postmortem area operate in a manner that adheres to laws, regulations, and local cultures/customs and is managed in a manner that minimizes the risk of transmitting infections.
6. Staff are trained in preventing cross contamination, maintaining chain of custody when needed, and respectful, safe handling procedures in postmortem areas.
7. Ⓓ The hospital has a written policy to direct chain of custody for all bodies and body parts handled by pathology, mortuary, and other postmortem areas.

Standard PCI.05.01

The hospital reduces the risk of infections associated with exposure to blood, body fluids, and other potentially infectious materials.

Intent of PCI.05.01

Patients, visitors, staff, and health care practitioners are at risk for exposures to bloodborne pathogens while present in the hospital, or while performing their job duties in the hospital. Exposures to potential bloodborne pathogens occur when a health care practitioner, staff member, patient, or visitor comes into contact with another person's blood or body fluid through nonintact skin, mucus membranes, eyes, nose, or mouth. Various pathogens, including hepatitis B, hepatitis C, and HIV, can be transmitted through blood or body fluid exposure. Body fluids include cerebrospinal, synovial, pleural, peritoneal, pericardial, seminal, and amniotic fluid. Other body fluids that do not carry a risk of bloodborne pathogen transmission unless visibly contaminated with blood include breast milk, sputum, nasal secretions, saliva, sweat, tears, urine, feces, and emesis; exposures to these fluids generally do not need to be reported or tracked unless visibly contaminated with blood or if required by local or national laws and regulations or hospital policy. Proper use of personal protective equipment appropriate to the task can significantly decrease the likelihood of an exposure. The hospital must provide adequate resources such as appropriate personal protective equipment, and safety devices, when possible, for staff who may come into contact with blood and body fluids while performing their job duties.

The hospital establishes a process for handling staff, patient, and visitor blood and body fluid exposures. The process includes to whom the incident should be reported. This process may vary depending on the time of day or day of week; however, staff must be able to report exposure incidents at any time they occur. The process includes reporting the incident to the direct supervisor and to employee health or the emergency department. This ensures timely documentation of and response to the incident. The process also identifies the action requirements for responding following blood or body fluid exposure. These actions follow local and national laws, as well as recommendations and guidelines from infection control organizations, and include how to clean and/or disinfect the exposed area, what testing for bloodborne illnesses must occur, and whether to initiate postexposure prophylaxis therapy. This process also includes steps for notifying any patient involved in the exposure, when appropriate, and provisions for testing involved patients for bloodborne infections separate from the patient's care.

Data from exposure incidents are tracked and monitored, and exposure incident reports are reviewed by applicable personnel and reported to hospital leaders. Information from incident reports is used to evaluate processes that contributed to or caused the blood or body fluid exposure incident, and changes are made to decrease the likelihood of a repeat occurrence. Staff are educated on these changes.

Measurable Elements of PCI.05.01

1. The hospital identifies processes that could result in patient or staff exposure to blood and body fluids.
2. The hospital implements practices to reduce the risk of exposure to blood and body fluids.
3. The hospital uses an expeditious process for reporting patient, staff, and visitor exposures to blood and body fluids that is timely.
4. The hospital uses a process for acting on patient, staff, and visitor exposures to blood and body fluids.
5. Staff are educated in the process for reporting an exposure incident.
6. Ⓓ The hospital tracks and monitors incidents of patient and staff exposures to blood and body fluids.
7. Reports of exposure incidents are reviewed, and actions are taken to minimize the risk of future exposures to blood and body fluids.

Food Services

Standard PCI.06.00

The hospital reduces the risk of infections associated with the operations of food and dietetics services.

Intent of PCI.06.00

Improperly stored and prepared food can cause illnesses, through transmission of pathogens by personnel handling and preparing food or through food-borne microorganisms. Food illnesses can be dangerous and even life-threatening to hospitalized patients whose conditions are already compromised due to illness, disease, or injury. The hospital must provide for the safe and accurate provision of food and nutrition products by ensuring that the food is stored, prepared, and transported in a manner that prevents transmission of pathogens and at temperatures that prevent the risk of microbial growth.

Hospital leaders must understand the food supply chain from start to finish to ensure safe operations of food services. Hospital leaders must also understand how employee illnesses are managed in accordance with hospital policies and procedures, evidence-based guidelines, and applicable laws and regulations to avoid transmission of infection such as hepatitis A and other pathogens that can be transmitted by personnel through food handling, as leaders are ultimately accountable for ensuring that these processes are consistently followed.

The hospital must ensure careful selection of food sources and suppliers, and safe food storage, handling, and preparation processes. There must be a process to ensure integrity of the food supply chain; this includes temperature stability during transport to the hospital, mechanisms to prevent tampering with food, and proper storage containers during transport. Hospitals must ensure appropriate temperatures of prepared food during transport from the kitchen to patients. This can be done in many ways; for example, kitchen staff may conduct random audits and check the temperature of several meals when they leave the kitchen and before they are served to the patient. There must also be a process to ensure that food is not left out for a length of time that would make it unsuitable for consumption. For example, the hospital must ensure that hot and cold foods waiting for consumption must be maintained at safe temperatures for the duration of service. Safe food storage must include maintaining items at appropriate temperatures and protection from pest infestation, and it may include following such principles as first in, first out (FIFO), which helps ensure that food is used before its expiration date. An effective food rotation system is essential for storing food to prevent food-borne illness.

Cross contamination, particularly from raw foods to cooked foods, is another source of foodborne illness; hospital leaders implement practices to minimize this risk and ensure that any suppliers and vendors do so as well. In addition to mixing raw and prepared foods, cross contamination can result from contaminated hands, surfaces on which food is prepared such as countertops and cutting boards, or cloths used to wipe countertops or dry dishes. The utensils, appliances, pots, and pans used for preparing food, and the trays, dishes, and utensils used for serving food can also be a risk for infection if not properly cleaned and sanitized. Personnel who are ill, or who do not perform appropriate hand hygiene, can also transmit infection when handling food. The hospital must have a process, including policies and procedures, to ensure that ill personnel do not handle food. The hospital conducts a risk assessment when food is stored or prepared outside of central kitchen areas, including patient refrigerators, and implements protocols to mitigate risk related to this practice.

Some nutritional products, such as human milk, baby formula, and other enteral nutrition products, have special storage and preparation requirements. Staff refer to professional guidelines to identify safe handling criteria for these products, including storage temperature, length of storage, preparation technique, proper labeling, and administration guidelines.

The food and nutrition program must be integrated with the infection prevention and control program and the employee health program.

Measurable Elements of PCI.06.00

1. Ⓓ The hospital stores food and nutrition products in a manner that reduces the risk of infection, including those stored outside of the kitchen and food preparation areas.
2. The hospital adopts and implements kitchen sanitation measures and guidelines for preparation areas to prevent the risk of cross contamination and infection.
3. Ⓓ The hospital prepares food and nutrition products using proper sanitation and temperature.
4. The hospital uses a process to ensure that proper food temperature is maintained during the preparation, transportation, and distribution process.
5. Professional guidelines are adopted for nutritional products that have special storage and preparation requirements, such as human milk, baby formula, and other enteral products.

Transmission of Infections

Standard PCI.07.00

The hospital protects patients, visitors, and staff from transmission of infections and communicable diseases.

Intent of PCI.07.00

In addition to the use of standard precautions, transmission-based precautions must be used to prevent infection transmission based on the type of microorganism (for example, use of negative pressure rooms and N95 masks for airborne infectious diseases). Transmission-based precautions include all potential modes of transmission, such as contact, droplet, and airborne. They also include special considerations such as *Clostridioides difficile* precautions. Airborne pathogens such as tuberculosis and COVID-19 require negative air pressure isolation rooms to prevent transmission because these pathogens can remain suspended in the air for long periods of time. (For additional considerations regarding highly significant emerging or novel diseases such as COVID-19, *see* Standard PCI.07.02.)

Transmission-based precautions are initiated upon suspicion or diagnosis of infections and include the following:

- Contact precautions for patients with known or suspected infections transmitted via contact
- Airborne precautions for patients with known or suspected infections transmitted via the airborne route

- Droplet precautions for patients with known or suspected infections transmitted via respiratory droplets expelled during talking, coughing, or sneezing
- Reverse/protective isolation to protect immunocompromised patients from transmission of infections from other patients or staff

The hospital implements policies and procedures that establish the isolation and barrier procedures for the hospital. These policies and procedures are based on the disease transmission method and address individual patients who may be infectious and the physical environment.

Temporary negative pressure rooms may be necessary when there is an airborne infectious disease outbreak with many communicable patients. The most effective system for creating temporary negative pressure isolation involves using a high-efficiency particulate air (HEPA) filtration system that discharges air to the outside. The hospital has a program that addresses how to manage patients with airborne infections for short periods of time when negative pressure rooms are not available as well as when there is a large influx of patients with contagious infections. In these cases, hospitals may adjust the air flow for entire wards or units to create a negative pressure ward or unit during an emergency influx.

When the structure of the building prevents the immediate construction of a negative pressure room, or when otherwise necessary such as when there is a sudden influx of infectious patients, the hospital may construct temporary negative pressure isolation rooms. For example, placing a HEPA filter on the exhaust end of an existing mechanical exhaust system can create a room with temporary negative pressure isolation by filtering the air being removed from the room via the exhaust system. When discharging air outside, a HEPA filter is used to exhaust room air outside through a window; the HEPA filter cleans contaminated air and induces negative pressure into the room. Because the discharged air is cleaned, no additional precautions are required for the discharged air. If HEPA–filtered air is discharged through the return air system, caution is required, as large volumes of returned air may overpressurize the air return system and may alter the negative/positive pressure balance.

The use of temporary negative pressure isolation follows all national and local laws and regulations, professional guidelines, or industry standards, and must adhere to all building and fire codes. Discharge outflow is positioned in a location and height that prevents it from creating exposure risks for staff, patients, and visitors. In situations in which resources are insufficient to use HEPA filtration systems for mechanical methods of creating negative pressure ventilation, the World Health Organization (WHO) guidelines for airborne infection prevention state that using cross-ventilation and other methods of natural ventilation are better at preventing the spread of airborne infection than providing no ventilation. Please note, this recommendation applies to temporary instances in which hospital resources are inadequate to use mechanical methods for managing an influx of patients with airborne infectious disease, not for permanent use.

Measurable Elements of PCI.07.00

1. Ⓓ The hospital uses a process to isolate patients with infectious diseases, and staff use transmission-based precautions, in accordance with recommended guidelines. (*See also* FMS.09.01, ME 1)
2. The hospital protects immunocompromised or otherwise vulnerable patients through isolation or the use of reverse/protective isolation in accordance with recommended guidelines. (*See also* PCC.01.04, ME 4)
3. The hospital routinely monitors and makes available negative pressure rooms for infectious patients who require isolation for airborne infections.
4. The hospital implements a process to address management of patients with airborne infections when negative air pressure rooms at not available, including adding temporary negative pressure rooms.
5. Staff are educated in the management of infectious patients when there is a sudden influx or when negative pressure rooms are not available.

Standard PCI.07.01

The hospital provides resources and equipment to protect staff, health care practitioners, patients, and visitors from biological, physical, and chemical hazards, and these are readily available for use.

Intent of PCI.07.01

Hand hygiene (such as the use of sanitizers), barrier techniques (such as the use of personal protective equipment), and disinfecting agents are fundamental tools for proper infection prevention and control and thus need to be available at any site of care at which they could be needed, including laboratories, other areas where specimens are handled, and laundry facilities. Staff and health care practitioners must use appropriate personal protective equipment when indicated, in accordance with laws and regulations and applicable infection control guidelines, and use appropriate hand hygiene methods when indicated. Examples include wearing gloves and a face shield when suctioning a patient, or using gloves, gown, face shield, and appropriate face masks such as N95 or powered air-purifying respirators (PAPRs) for patients in isolation due to a communicable disease and performing hand hygiene prior to and after provision of patient care.

The hospital identifies those situations in which personal protective equipment such as respirators, masks, eye protection, gowns, or gloves are required for protection against biological hazards, including high-risk pathogens that require special isolation precautions such as N95 masks, PAPRs, or higher-level protective gowns; provides the needed equipment; and trains staff and health care practitioners in their correct use. Liquid soap and water, alcohol-based hand sanitizers, and other appropriate disinfectants are in areas where handwashing and hand-disinfecting procedures are required. When personal protective equipment is required, it is readily available for use. It is important to follow guidelines for ensuring that liquid soap dispensers are thoroughly and properly cleaned before refilling. Staff are educated in proper handwashing, hand-disinfection, and surface-disinfection procedures and proper use of personal protective equipment. Patients and visitors are also educated on proper hand-disinfecting procedures and when they are required to use personal protective equipment; for example, when visiting a family member in contact isolation or when a patient on airborne precautions is being transported through the organization.

Measurable Elements of PCI.07.01

1. The hospital identifies situations in which personal protective equipment is required.
2. The hospital ensures that appropriate personal protective equipment and hand hygiene agents are readily available when needed. (*See also* IPSG.05.00, MEs 1 and 2; FMS.09.01, ME 1)
3. Staff are trained and correctly use personal protective equipment in each identified situation.
4. The hospital implements environmental disinfecting procedures for areas and situations in the hospital identified as at risk for infection transmission.
5. Liquid soap and running water, hand disinfectants, and single-use towels are provided in areas where handwashing and hand-disinfecting procedures are required, and hand air dryers are not used in patient care areas. (*See also* IPSG.05.00, MEs 1 and 2)
6. Patients and visitors are educated on when they are required to disinfect their hands, when transmission based precautions such as isolation precaution must be followed, and how to correctly use personal protective equipment when applicable. (*See also* IPSG.05.00, MEs 1 and 2)

Standard PCI.07.02

The hospital implements processes to support preparedness for epidemiologically significant infectious diseases or special pathogens.

Intent of PCI.07.02

High-consequence infectious diseases or special pathogens are novel and reemerging infectious diseases or pathogens that are highly transmissible from person to person (or have an unknown mode of transmission) and have the potential for epidemic or pandemic with high morbidity and mortality. This standard is about highly significant emerging diseases such as COVID-19. The management of these diseases or pathogens requires prompt identification, implementation of infection control activities (for example, timely reporting and information sharing, isolation, special personal protective equipment, a biocontainment unit), and action for public health preparedness to prevent community transmission and social disruption. Examples of high-consequence infectious diseases or special pathogens include Middle East respiratory syndrome (MERS), severe acute respiratory syndrome (SARS), COVID-19, measles, monkeypox, smallpox, novel or new mutation of influenza, and Ebola or other viral hemorrhagic fever diseases.

It is particularly important to educate staff on early recognition, including those nonclinical staff who have first contact with patients, such as registration clerks. Simply knowing that a communicable disease may be spreading is not enough. If staff are not trained to recognize the signs and symptoms and to act early, the extent of exposure and the risks of spreading the infection significantly increase. Early recognition is particularly important at a patient's first point of entry into the hospital, such as the emergency department or the outpatient clinics.

Measurable Elements for PCI.07.02

1. Ⓓ The hospital implements protocols for high-consequence infectious diseases or special pathogens, that are readily available for use at the point of care and address the following:
   - Procedures for screening at the points of entry to the hospital for respiratory symptoms, fever, rash, and travel history to identify or initiate evaluation for high-consequence diseases or special pathogens. (*See also* FMS.09.01, ME 3) **Note:** Points of entry may include the emergency department, urgent care, and ambulatory clinics.
   - Patient isolation procedures
   - Procedures for informing public health authorities and key hospital staff
   - Procedures for required personal protective equipment and proper donning and doffing techniques
   - Infection control procedures to support continued and safe provision of care while the patient is in isolation and to reduce exposure among staff, patients, and visitors
   - Procedures for waste management and cleaning and disinfecting patient care spaces, surfaces, and equipment
2. The hospital implements education and training and assesses competencies for the staff who will implement protocols for high-consequence diseases or special pathogens.
3. The hospital coordinates with transportation services and local public health authorities to implement criteria and procedures for transferring patients to facilities with a higher level of care.
4. Ⓓ The hospital has written policies and procedures for monitoring and managing staff who have been occupationally exposed or are suspected of having been exposed to a high-consequence infectious agent or special pathogen.
5. The hospital response to high-impact pathogens includes a plan for vaccination of all staff, leaders, and health care practitioners when applicable. (*See also* SQE.02.01, ME 2)

Quality Improvement and Program Education

Standard PCI.08.00

The infection prevention and control process is integrated with the hospital's overall program for quality and patient safety, using data and measures that are epidemiologically important to the hospital.

Intent of PCI.08.00

Effective use of measurement data is critical to identify priorities and to implement strategies to improve infection prevention and control activities to reduce health care–associated infection rates to the lowest possible levels. By integrating with the overall hospital quality and patient safety program, the infection prevention and control program can make use of the same data analysis and improvement methodologies, measurement data, and information by understanding similar rates and trends in other similar hospitals and contributing data to infection-related databases. Full integration allows for a consistent approach to improvement and communication structures with leaders and the governing board.

All departments/services should participate in relevant hospitalwide priorities for measurement and also select measures for department/service-specific priorities for the infection prevention and control program. Monitoring data include benchmarking infection rates internally and with external organizations and/or databases. The hospital must define a formal reporting structure that is integrated into the quality and patient safety department. Hospital services or departments sharing the same risks for health care–associated infections should collaborate in these activities by sharing information, data analysis, and successful improvement efforts. For example, critical care units may have similar risks for CLABSI, CAUTI, and VAP. It is important to note that infection prevention and control is not the primary driver of these activities but is supporting and advising within the overall quality and patient safety program.

Measurable Elements of PCI.08.00

1. Ⓓ The hospital integrates infection prevention and control activities into the quality and patient safety program. (*See also* GLD.04.00, ME 1; QPS.01.00, ME 1)
2. Ⓓ The hospital collects and analyzes data for the infection prevention and control activities, including epidemiologically important infections.
3. Ⓓ The hospital uses monitoring data to evaluate and support improvements to the infection prevention and control program at least annually. (*See also* GLD.04.00, ME 4)
4. Monitoring data include internal and external benchmarking infection rates as applicable.
5. Ⓓ The infection prevention and control program documents monitoring data and provides reports of data analysis to leaders on a quarterly basis.

Standard PCI.08.01

The hospital provides education on infection prevention and control practices to staff, health care practitioners, patients, families, and others when indicated by their role in the hospital.

Intent of PCI.08.01

For a hospital to have an effective infection prevention and control program, it must educate staff members about the program when they begin work in the hospital and provide ongoing education. Staff should receive initial and ongoing education and training related to emerging trends in infection prevention and control. The education program includes professional staff, clinical and nonclinical support staff, patients, and families, and even tradespeople and other visitors. Patients and families are encouraged to participate in the implementation and use of infection prevention and control practices in the hospital.

The education is provided as part of the orientation of all new staff and is refreshed periodically, or at least when there is a change in the policies, procedures, and practices that guide the hospital's infection prevention and control program, and this includes a mechanism for reporting to leaders and the governing board.

Measurable Elements of PCI.08.01

1. The hospital provides initial education about infection prevention and control to all staff and health care practitioners when they begin work in the hospital. (*See also* SQE.02.00, ME 2; SQE.02.01, ME 5)
2. The hospital provides ongoing education and training to all staff related to the hospital's infection prevention and control program and emerging trends in infection prevention and control at least annually. (*See also* SQE.02.01, ME 1)
3. The hospital provides education about infection prevention and control to patients and families.
4. The hospital communicates findings and trends from the infection prevention and control program activities to all staff.
5. Ⓓ The hospital communicates information and data from the infection prevention and control program to leaders and the governing body.

Quality and Patient Safety (QPS)

Overview

All hospitals want better patient outcomes and, therefore, are concerned about improving the safety and quality of the care, treatment, and services they provide. The best way to achieve better care is by first measuring the performance of processes that support care and then using those data to make improvements. The standards in this chapter stress the importance of meaningful use of data to inform positive change.

The standards in this chapter address the fundamental principles of performance improvement: collecting and analyzing data, and improving and monitoring performance. Leaders are ultimately responsible for performance improvement. They set performance improvement priorities and provide the resources needed to achieve improvement. They make sure that all individuals who work in the organization participate in performance improvement activities. The leaders' responsibilities are more fully described in the "Governance, Leadership, and Direction" (GLD) chapter. (Standards GLD.04.00 through GLD.04.02 describe the management of important hospitalwide systems that support safety and quality, and the need for leaders to establish performance improvement priorities.)

Collecting data is the foundation of performance improvement (*see* Standard MOI.01.00, addressing the planning of managing information, and Standard MOI.02.03, regarding retrieving, disseminating, and transmitting health information in a timely manner in usable formats). Based on its setting, scope, and services, the hospital selects measures that are meaningful to the organization and that address the needs of the patients it serves. In addition, The Joint Commission has identified important processes (*see* Standard QPS.03.04) that should always be measured because they involve risk and can harm patients.

Regardless of how much data the hospital collects, data are useful only when analyzed. Analysis identifies trends, patterns, and performance levels that suggest opportunities for improvement. The hospital can then make improvements based on the analysis. Of course, there is always the chance that analysis may reveal that more opportunities for improvement exist than an organization can manage at one time. In this case, leaders need to set priorities for improvement.

After a change has been made, the organization monitors that change by collecting and analyzing data to make sure the desired improvement is achieved and sustained. Organizations should identify the results that will signify sustained improvement. If the improvement does not meet expectations, the organization makes additional changes, and the cycle starts again. These principles of performance improvement also apply whenever the organization wants to design new processes, such as a new patient care service or an information management system.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Management of Quality and Patient Safety Activities

QPS.01.00 A qualified individual(s) guides the implementation of the hospital's program for quality and patient safety, and manages the activities needed to carry out an effective program of continuous quality improvement and patient safety within the hospital.

Measure Selection and Data Collection

QPS.02.00 The quality and patient safety program staff support the quality indicator and measure selection process and provide coordination and integration of measurement activities throughout the hospital.

Analysis and Validation of Measurement Data

QPS.03.00 The quality and patient safety program includes the collection, aggregation, and analysis of data to support patient care, treatment, and services; hospital management; the continuous quality improvement program; and participation in external databases.

QPS.03.01 The hospital uses an established, statistically sound process to validate data as a component of its quality and patient safety program.

QPS.03.02 Individuals with specialized experience, knowledge, and skills systematically aggregate, validate, and analyze data in the hospital.

QPS.03.03 The data analysis process includes at least one evaluation of the clinical, financial, and operational impact of hospitalwide improvement priorities per year.

QPS.03.04 The hospital identifies undesirable trends and variation, and always conducts an intensive analysis, or a comprehensive systematic analysis, when these are evident from its data collection.

Gaining and Sustaining Improvement

QPS.04.00 The hospital achieves and sustains improvement in quality and safety.

QPS.04.01 The hospital uses an ongoing program of risk management, overseen by qualified individuals with the appropriate experience, knowledge, and skills, to identify and proactively reduce unanticipated adverse events, and other safety risks to patients and staff.

Standards, Intents, and Measurable Elements

Management of Quality and Patient Safety Activities

Standard QPS.01.00

A qualified individual(s) guides the implementation of the hospital's program for quality and patient safety, and manages the activities needed to carry out an effective program of continuous quality improvement and patient safety within the hospital.

Intent of QPS.01.00

The effectiveness of a hospital quality and patient safety program is dependent on competent and effective leaders to implement it. The governing entity approves the program, and leaders provide the resources to implement the program. Capable guidance and management to carry out the program is necessary to make continuous quality improvement a part of how the hospital meets its mission and strategic priorities. One or more qualified individuals must oversee the operation of the program. This takes knowledge and experience in the many facets of data collection, aggregation, validation, and analysis, and in implementing sustainable

improvements. The individual(s) with oversight for the quality and patient safety program also selects quality and patient safety program staff with qualifications and capabilities needed for the program.

Some of the key quality and patient safety program individuals, such as physician champions or nurse quality team leaders, may be located within a department/service in the hospital and need to be supported by the quality and patient safety program. The quality and patient safety program staff also understand how to take the hospitalwide priorities and the department/service-level priorities and turn them into a coordinated overall program. The quality and patient safety program staff coordinate and organize measures throughout the hospital and provide support with measurement activities related to hospital priorities.

Training and communication are essential. The quality and patient safety program staff help to support data collection throughout the hospital by assisting with data collection issues such as creating forms to collect data, identifying which data to collect, how to validate data, and creating reports. Staff throughout the hospital may need assistance in data validation and analysis, implementing improvements, and evaluating if the improvements were sustained. The quality and patient safety program staff are thus constantly involved in training and communicating quality and patient safety issues throughout the hospital. The hospital must define the necessary qualifications for its quality and patient safety program leaders and staff, in accordance with laws and regulations, national health care industry standards, and other applicable requirements. For example, the hospital may determine that it is necessary for the program leader and staff to have expertise in methodologies such as Lean; Six Sigma; Design, Measure, Analyze, Improve, and Control (DMAIC); Plan-Do-Study-Act / Plan-Do-Check-Act (PDSA/PDCA); and others, as well as minimum degree requirements, clinical licensure, or specific experience.

Measurable Elements of QPS.01.00

1. Hospital leaders select a qualified individual(s) who is experienced in the methods and processes of improvement to lead the implementation of the hospital's quality and patient safety program. (*See also* GLD.06.00, ME 1; GLD.04.00, ME 3; PCI.08.00, ME 1)
2. The individual(s) leading the quality and patient safety program selects and supervises qualified staff for the program.
3. Ⓓ The quality and patient safety program provides support and coordination to department/service leaders for like measures across the hospital and for the hospital's priorities for improvement. (*See also* GLD.04.00, ME 1; QPS.03.03, ME 1)
4. The quality and patient safety program implements a training program for all staff that is consistent with staff members' roles in the quality and patient safety program.
5. The quality and patient safety program is responsible for the regular communication of ongoing performance, results of data analysis, and results of quality improvement efforts to all staff.
6. The hospital defines the qualifications for its quality and patient safety program leaders and its staff.

Measure Selection and Data Collection

Standard QPS.02.00

The quality and patient safety program staff support the quality indicator and measure selection process and provide coordination and integration of measurement activities throughout the hospital.

Intent of QPS.02.00

Quality indicator and measure selection is a leadership responsibility, and all departments and services—clinical and managerial—select measures related to their priorities, in accordance with applicable laws and regulations, national health care industry standards, or other requirements such as those of health care insurers. The quality and patient safety program described in these QPS standards plays an important role in helping

these departments/services agree on a common measurement approach and facilitates the data collection of the measure(s) selected. The hospital should distinguish between measures and indicators, as there are appropriate uses for each. Measures consist of quantifiable data. Indicators are indirect measures that provide information about the dimensions of quality of care, such as whether the care is safe, effective, patient-centered, timely, efficient, equitable, acceptable and/or accessible.

The leaders of the hospital decide the priority areas to measure for the entire hospital, and the measurement selection process for each department/service. It can be anticipated that in large hospitals, there is some opportunity for similar measures to be selected in more than one department. For example, the pharmacy, infection prevention and control, and infectious disease departments/services may each set priorities related to reducing antimicrobial use in the hospital. The quality and patient safety program is in the position to integrate all measurement activities in the hospital, including measurement of the safety culture and adverse event reporting systems. This integration of all the measurement systems will provide the opportunity for integrated solutions and improvements. The hospital should also identify performance indicators, including key performance indicators/high-priority indicators, that address aspects such as the care quality domains of safety, effectiveness, patient-centeredness, timeliness, efficiency, equity, and accessibility.

Measurable Elements of QPS.02.00

1. The quality and patient safety program integrates and supports the selection of measures and indicators throughout the hospital, at the hospitalwide level and at the department or service level.
2. The quality and patient safety program provides coordination and integration of all department and service-specific measurement activities throughout the hospital. (*See also* GLD.04.00, ME 2)
3. The quality and patient safety program integrates patient safety event reporting systems, safety culture measures, quality indicators, and other measures to facilitate integrated solutions and improvements. (*See also* GLD.04.01, ME 2)
4. Ⓓ The quality and patient safety program tracks the progress on the planned collection of measure data and quality indicators for the selected priorities.

Analysis and Validation of Measurement Data

Standard QPS.03.00

The quality and patient safety program includes the collection, aggregation, and analysis of data to support patient care, treatment, and services; hospital management; the continuous quality improvement program; and participation in external databases.

Intent of QPS.03.00

Hospitals are more likely to achieve safety and quality goals when decisions are driven by valid data. Successful hospitals aggregate (compile) performance data from many sources. This includes but is not limited to the following:

- Patient medical records (for example, medical history, demographic information, symptoms, treatment history, lifestyle, genetic or family history, health care practitioner documentation of care, treatment, services)
- Risk management and incident reporting system (for example, medication errors, patient falls, medical errors, care variances)
- Utilization management (for example, blood product utilization)
- Facilities management (for example, medical equipment periodic maintenance, operating theatre temperature and humidity, fire suppression system checks, safety and security issues such as fire drills)
- The infection prevention and control program (for example, postoperative infection rates, catheter-associated urinary tract infection rates, hospital-acquired infections, hand hygiene compliance)

- Results of patient satisfaction surveys, staff culture of safety surveys, and other areas related to safety and quality of care
- All other hospital departments and programs, as all of these must be integrated into the overall quality and patient safety program.

It is critical to analyze the performance data to identify where the hospital is performing well and where a need for improvement exists. Simply collecting data alone is not adequate. When data are analyzed and turned into information, this process helps hospitals see patterns and trends and understand the reasons for their performance. Many types of data are used to evaluate performance on safety and quality initiatives. This should include performance indicator data and outcome data.

The quality and patient safety program identifies, collects, aggregates, and analyzes data to support patient care, treatment, and services and hospital management. The hospital must define a method of data collection and aggregation based on the type of records used, such as paper or electronic, and the nature of its data collected in accordance with laws and regulations, national health care industry standards, and its performance goals. All departments and services of the hospital must be integrated into the program. Analysis of aggregate data provides a profile of the hospital's performance over time and allows the comparison of the hospital's performance with other hospitals, particularly on the hospitalwide measures selected by leaders. Aggregate data are an important part of the hospital's performance improvement activities to help the hospital understand its current performance and identify opportunities for improvement.

By participating in external databases, a hospital can compare itself to that of other similar hospitals locally, nationally, and internationally. Comparison is an effective tool for identifying opportunities for improvement and documenting the hospital's performance level. Health care networks and those purchasing or paying for health care often ask for such information. External databases vary widely from insurance databases to those maintained by professional societies. Hospitals may be required by laws or regulations to contribute to external databases. In all cases, the security and confidentiality of data and information must be maintained.

Measurable Elements of QPS.03.00

1. The quality and patient safety program has a process to aggregate data from multiple sources.
2. Aggregate data and information support patient care, treatment, and services; hospital management; professional practice review; and the overall quality and patient safety program. (*See also* PCC.02.02, ME 2; QPS.03.02, ME 1)
3. Ⓓ The hospital provides aggregate data and information to agencies outside the hospital when required by laws and regulations.
4. The hospital implements a process to contribute to and learn from external databases for comparison purposes.
5. The hospital maintains security and confidentiality when contributing to or using external databases.

Standard QPS.03.01

The hospital uses an established, statistically sound process to validate data as a component of its quality and patient safety program.

Intent of QPS.03.01

Data validation is an important tool for understanding the quality of the data and for establishing the level of confidence decision-makers can have in the data. A quality improvement program is only as valid as the data that are collected. If the data are flawed, quality improvement efforts will be ineffective. The reliability and validity of measurements are thus at the core of all improvements. To ensure that good, useful data have been collected, an internal data validation process must be implemented. Data validation becomes one step in setting priorities for measurement, selecting what is to be measured, extracting or collecting the data, analyzing it, and using the findings for improvement.

When a hospital publishes data on clinical outcomes, patient safety, or other areas, or in other ways makes data public, such as on the hospital's website, the hospital has an ethical obligation to provide the public with accurate information. Hospital leaders are accountable for ensuring that the data are valid. Data should be validated using an evidence-based process appropriate for data collection (for example, electronic health records with automated processing vs. paper records that require manual data mining). Reliability and validity of measurement and quality of data can be established through the hospital's internal data validation process or, alternatively, can be judged by an independent third party, such as an external company contracted by the hospital. Resources such as the World Health Organization's *Data Quality Assurance* toolkit is an example of a tool to assist with data validation. The process can consist of simple measures to validate data, such as a two-person review process to ensure inter-rater reliability.

Measurable Elements of QPS.03.01

1. The hospital validates data when any of the following conditions are noted, at minimum:
   - A new measure is implemented (in particular, those clinical measures that are intended to help a hospital evaluate and improve an important clinical process or outcome).
   - Data will be made public on the hospital's website or in other ways.
   - A change has been made to an existing measure, such as the data collection methods have changed, or the data abstraction process or abstractor has changed.
   - The data resulting from an existing measure have changed in an unexplainable way.
   - The data source has changed, such as when part of the patient health care record has been turned into an electronic format and thus the data source is now both electronic and paper.
   - The subject of the data collection has changed, such as changes in average age of patients, comorbidities, research protocol alterations, new practice guidelines implemented, or new technologies and treatment methodologies introduced.
   - When the data collection method is manual, and data collection staff have changed mid-cycle.
2. The hospital uses an evidence-based methodology for data validation.
3. Hospital leaders assume accountability for the validity of the quality and outcome data made public.

Standard QPS.03.02

Individuals with specialized experience, knowledge, and skills systematically aggregate, validate, and analyze data in the hospital.

Intent of QPS.03.02

Specialized expertise is required to accurately aggregate, analyze, and transform data into useful information. Data aggregation and analysis requires qualified individuals who meet the following criteria:

- Understand information management.
- Have skills in data aggregation methods.
- Know how to use various statistical tools to analyze data.

Results of data analysis must be transformed into reports that are easily understood by those individuals responsible for the process or outcome being measured and who can act on the results. These individuals may be clinical, managerial, or a combination. Data analysis provides continuous feedback of continuous quality improvement information to help those individuals make decisions and continuously improve clinical and managerial processes.

Understanding statistical techniques is critical in data analysis, particularly in interpreting variation and deciding where improvement needs to occur. Run charts, control charts, histograms, and Pareto charts are examples of statistical tools useful in understanding trends and variation in health care.

The quality and patient safety program participates in the determination of how often data are aggregated and analyzed. The frequency of this process depends on the activity or area being measured and the frequency of the measurement, in accordance with laws and regulations and national health care industry standards. For example, clinical laboratory quality control data may be aggregated and analyzed weekly to meet local regulations, and patient fall data may be aggregated and analyzed quarterly if falls are infrequent. Aggregation and analysis of data at points in time enables the hospital to judge the stability of a particular process or the predictability of a particular outcome in relation to expectations.

The goal of data analysis is to be able to compare a hospital in the following ways:

- With itself over time, such as month to month, or one year to the next
- With other similar hospitals, such as through reference databases
- With standards, such as those set by accrediting and professional bodies or those set by laws or regulations
- With recognized desirable practices identified in the literature as best or better practices or practice guidelines

These comparisons help the hospital understand the source and nature of undesirable change and help focus improvement efforts.

Measurable Elements of QPS.03.02

1. The hospital aggregates, analyzes, and transforms data into useful information to identify opportunities for improvement. (*See also* QPS.03.00, ME 2)
2. The hospital defines and approves appropriate qualifications for individuals who participate in data collection, aggregation, validation, and analysis.
3. The hospital uses established statistical tools and techniques in the analysis process.
4. Hospital leaders determine the frequency of reporting the results of analysis to those accountable for action, in accordance with laws and regulations and national health care industry standards.
5. Data analysis supports comparisons internally and externally over time, including comparisons with databases of like hospitals, with best practices, and with objective scientific professional sources.

Standard QPS.03.03

The data analysis process includes at least one evaluation of the clinical, financial, and operational impact of hospitalwide improvement priorities per year.

Intent of QPS.03.03

The analysis provides useful information on which improvements positively impact clinical outcomes and efficiency to justify resource allocation. The quality and patient safety program includes an analysis of the clinical, financial, and operational impact of priority improvements as supported by leaders. For example, the analysis shows that there is evidence to support that the use of clinical practice guidelines to standardize care, treatment, and services has a significant impact on efficiency and a reduction in the length of stay, which ultimately reduces costs. Therefore, hospital leaders can make informed decisions about allocating resources for performance improvement initiatives.

The quality and patient safety program team must use appropriate tools to evaluate the use of resources for the existing process and then reevaluate the use of resources for the improved process. The resources may be human (for example, time devoted to each step in a process) or may involve the use of technology or other resources. The evaluation is then reported to leaders and others who are responsible for making decisions.

Measurable Elements of QPS.03.03

1. Ⓓ The hospital collects data on the amount and type of resources used on at least one hospitalwide priority improvement project per year before and following the improvement. (*See also* GLD.04.00, ME 1; QPS.01.00, ME 3)
2. The quality and patient safety program staff work with other units such as human resources, information technology, and finance in deciding which data are to be collected.
3. The hospital uses the results of the analysis to refine the process and report it through the quality and patient safety program mechanism to leaders.

Standard QPS.03.04

The hospital identifies undesirable trends and variation, and always conducts an intensive analysis, or a comprehensive systematic analysis, when these are evident from its data collection.

Intent of QPS.03.04

There must be a formal structure and processes in place for comprehensive data collection on diverse areas of patient care, treatment, and services; identifying and intensively analyzing undesirable trends; and reporting the results to the governing body as part of the quality and patient safety program. Data collection should be sufficient to detect trends and patterns and will vary depending on the service frequency and/or the risk for patients. The data must include all hospital departments and services.

The hospital determines the scope of data collection to identify patient safety risks throughout the hospital based on the care, treatment, and services it provides, and in accordance with health care industry or national standards, laws and regulations, external reporting requirements, and other identified areas of concern. This also includes efforts to encourage incident or variance reporting by staff and health care practitioners because the hospital cannot identify risks to make improvements without this valuable information. The hospital must be able to identify trends down to the individual patient care unit or specific service line level, and it must be evident that all departments and services are integrated into the quality and patient safety program.

The hospital should incorporate the use of frameworks such as Just Culture, or similar concepts that minimize assigning blame, when addressing errors or variances where staff members are directly involved. The hospital must also use a structured methodology, such as root cause analysis, in its comprehensive systematic analysis processes.

Measurable Elements of QPS.03.04

1. The hospital implements data collection processes to ensure that risks to patient safety are identified.
2. Ⓓ The hospital conducts an intensive analysis, or a comprehensive systematic analysis, of data when adverse events, patterns, or undesirable trends occur.
3. Ⓓ The hospital performs data collection and analysis for all of the following, at minimum, when applicable:
   - All confirmed transfusion reactions
   - All serious drug reactions or drug-related patient safety events as defined by the hospital or laws and regulations
   - All medication errors and near misses, as defined by the hospital (*See also* MMU.07.01, ME 2)
   - All major patient safety events or errors related to surgical procedures
   - All major discrepancies between preoperative and postoperative diagnoses; for example, a preoperative diagnosis of intestinal obstruction and a postoperative diagnosis of ruptured abdominal aortic aneurysm (AAA)
   - Patient safety events or patterns of events during procedural sedation regardless of administration route
   - Patient safety events or patterns of events during anesthesia regardless of administration route
   - Patient safety events or errors related to patient identification
   - Patient safety events or errors related to pathology samples, such as biopsy or other tissue specimens

   (*See also* AOP.04.00, ME 6)
4. The hospital uses the results of analyses to implement actions that improve the quality and safety of the service, treatment, or function.
5. Ⓓ The hospital reports data for identified risks to patient safety to the governing entity as part of the quality and patient safety program.
6. The hospital implements measures designed to encourage patient safety events incident reporting by hospital staff.

Gaining and Sustaining Improvement

Standard QPS.04.00

The hospital achieves and sustains improvement in quality and safety.

Intent of QPS.04.00

Information from data analysis is useful to identify potential improvements or to reduce (or prevent) patient safety events and is a critical element of hospital quality and patient safety programs. Routine measurement data, as well as data from intensive analyses, contribute to the understanding of where improvement is needed and how improvement efforts should be prioritized. Improvements are planned for the priority data collection areas identified by hospital leaders.

After an improvement(s) is planned, data are collected during a test period to demonstrate that the planned change was actually an improvement. To ensure that the improvement is sustained, measurement data are then collected for ongoing analysis. Effective changes are incorporated into standard operating procedures, and any necessary staff education is carried out. The hospital documents those improvements achieved and sustained as part of its continuous quality improvement program. The hospital should reevaluate goals at defined intervals to when a successful goal has been achieved and sustained, and whether it should be retired in favor of identifying a new focus for improvement.

Measurable Elements of QPS.04.00

1. The hospital plans, tests, and implements improvements in quality and patient safety. (*See also* GLD.04.02, ME 1)
2. Ⓓ Data are available to demonstrate that improvements are effective and sustained. (*See also* GLD.06.01, ME 3)
3. The hospital makes policy changes when necessary to plan, to carry out, and to sustain the improvement.
4. Ⓓ Successful improvements are documented and reviewed by the quality and patient safety program and hospital leaders to understand why efforts were or were not successful. (*See also* GLD.04.00, ME 2)

Standard QPS.04.01

The hospital uses an ongoing program of risk management, overseen by qualified individuals with the appropriate experience, knowledge, and skills, to identify and proactively reduce unanticipated adverse events, and other safety risks to patients and staff.

Intent of QPS.04.01

Proactive risk management is essential to the quality and safety of patient care, treatment, and services within a hospital.

There are many types of risks in a hospital setting; for example, risks can include those associated with clinical care and patient safety, such as diagnostic, surgical, or medication errors; risks associated with the environment, such as hazardous conditions; risks associated with operations, such as plans for achieving the hospital's goals; or risks associated with compliance to standards of care and adherence to laws and regulations. Other risks can be associated with finances and strategic planning. Hospitals must adopt a proactive approach to risk management that includes implementing risk mitigation strategies, with the goal being to reduce or eliminate the potentially harmful impact of known or possible risks. One such way is a formalized risk management program.

An important element of risk management is risk analysis, such as a process to evaluate near misses and other high-risk processes for which a failure would result in a sentinel event. There are multiple tools that can provide a proactive analysis of the consequences of an event that could occur in critical, high-risk processes, such as prevention of wrong-site surgery, the care of patients at high risk for suicide, or emergency management of natural disasters. For example, failure mode and effects analysis (FMEA) and hazard vulnerability analysis (HVA) are two common tools.

To use these or similar tools effectively, leaders must identify and prioritize the potential risks that could have the greatest impact on patient and staff safety as well as on the quality and safety of patient care, treatment, and services. This information should be used to prioritize resource allocation to analyze the areas of highest risks and redesign the process or similar actions to reduce the risk in the process. This risk reduction process is carried out at least once per year and is documented.

Measurable Elements of QPS.04.01

1. Ⓓ The hospital's risk management program framework for all hospital departments and services includes the following:
   - A risk management policy that identifies and prioritizes risk urgency and has a plan to minimize impact
   - Risk identification
   - Risk prioritization
   - Risk reporting
   - Scope, objectives, and tools for assessing risk
   - Risk management, to include risk analysis
   - Management of financial liability related to risks, such as legal claims
2. Hospital leaders identify and prioritize the potential risks that could have the greatest impact on patient and staff safety and on the quality of patient care, treatment, and services.
3. Ⓓ The hospital conducts a proactive risk reduction exercise on at least one of the priority risk processes at least annually.
4. Ⓓ The hospital redesigns and implements high-risk processes based on the results of the analysis of the risk reduction exercise.
5. Hospital leaders implement communication strategies to staff, governance, and stakeholders as appropriate.
6. The hospital defines the qualifications for risk management personnel.

Staff Qualifications and Education (SQE)

Overview

A health care organization needs an appropriate variety of skilled, qualified individuals to fulfill its mission and to meet patient needs. The organization's leaders work together to identify the number and types of qualified staff needed based on the recommendations from department and service leaders.

Recruiting, evaluating, appointing, and retaining staff are best accomplished through a coordinated, efficient, and uniform process. It is also essential to document applicant skills, knowledge, education, and previous work experience. It is particularly important to carefully review the credentials of medical, nursing, and other clinical staff because they are involved in clinical care processes and work directly with patients. This represents the first and most important opportunity for the hospital to deliver safe care for your patients and provide a safe environment for the staff.

Orientation to the organization and programs, as well as orientation to specific duties related to the position is an important process. Health care organizations should provide staff with opportunities to learn and to advance personally and professionally. Thus, in-service education and other learning opportunities should be offered to staff.

To ensure staff physical and mental health, productivity, staff satisfaction, and safe working conditions, the organization provides a staff health and safety program that can be offered by the hospital or provided through contracted services. The program is proactive and includes matters affecting the health and well-being of staff such as initial employment health screening, control of harmful occupational exposures, preventive immunizations and examinations, safe patient handling, staff as second victims, and common work-related conditions. In addition, the higher incidence of workplace violence in the last decade has prompted hospitals to increase awareness of workplace violence and institute prevention practices that focus on safety measures such as effective workplace violence prevention systems, including leadership oversight, policies, procedures, reporting systems, data collection and analysis, post-incident strategies, training, and education to decrease workplace violence.

For the standards language in this chapter, the following terminology and associated definitions apply:

Medical Staff

All physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services. All classifications of appointments, all types, and levels of staff (employed, honorary, contract, visiting, and private community staff members), are included. Visiting staff include those who are locum tenentes, or invited experts, "master class" teachers/tutors, and others allowed to provide patient care services temporarily. A hospital must define those other clinical staff, such as "house officers," "hospitalists," and "junior doctors," who are no longer in training, but may or may not be permitted by the hospital to practice independently.

The term *medical staff* is thus inclusive of all physicians and other professionals permitted to treat patients with partial or full independence, regardless of their relationship to the hospital (for example, employed staff or independent consultants). *Partial independence* can be defined as staff working under partial supervision awaiting the final decision for full employment, on probation "for cause," or under medical staff granted temporary clinical privileges for a limited period of time and for circumstances as defined by hospital policy. In some cultures, traditional medicine practitioners may be permitted by law and the hospital to practice independently. Thus, they are considered medical staff members, and these standards apply in full.

Nursing Staff

Nursing professionals within an organization who are accountable for the promotion of health, the prevention of illness and the provision of quality and safe patient care within the parameters of the nursing profession. Such personnel include registered, licensed, and vocational nurses and may include others such as nursing assistants or other designated unlicensed assistive personnel, as well as advanced practice nurses. Advanced practice nurses such as nurse practitioners (NPs) and certified registered nurse anesthetists are nurses who have gained additional knowledge and skills through successful completion of an organized program of nursing education that prepares nurses for advanced practice roles, and who have been certified by the board of nursing to engage in the practice of advanced practice nursing.

Other Clinical Staff

Clinical professionals who are not licensed to practice independently (without supervision) or who are employed or permitted by the hospital to provide care or participate in patient care processes (for example, midwives, surgical assistants, emergency medical care specialists, dietitians, pharmacists, pharmacy technicians). In some countries or cultures, this group also includes traditional healers or those who provide alternative services or services that complement traditional medical practice (for example, acupuncture, herbal medicine). These individuals may not practice or provide service in the hospital; instead, they refer to the hospital or provide continuing or follow-up care for patients in the community. Many of these professionals complete training programs and receive licenses or certificates or are registered with local or national authorities. Others may complete less formal apprentice programs or other supervised experiences.

Note: Some countries allow midwives to practice independently.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Staff Planning

SQE.01.00 Leaders of hospital departments and services define the desired qualifications of all staff.

SQE.01.01 The hospital defines the responsibilities for every staff member in a current job description.

SQE.01.02 Leaders of hospital departments and services implement processes for the recruitment and retention of staff.

SQE.01.03 The hospital evaluates staff performance.

SQE.01.04 There is documented personnel information for each staff member.

SQE.01.05 The hospital has the necessary staff to support the care, treatment, and services it provides.

SQE.01.06 The hospital provides orientation for all staff.

SQE.01.07 Staff participate in education and training.

SQE.01.08 Staff are competent in resuscitative techniques appropriate to their role in the hospital.

Staff Health and Safety

SQE.02.00 The hospital provides a staff health and safety program that addresses staff physical and mental health and safe working conditions.

SQE.02.01 The hospital identifies staff who are at risk for exposure to and possible transmission of vaccine-preventable diseases and implements a staff vaccination and immunization program.

SQE.02.02 Leaders and staff are trained and demonstrate competence in workplace violence prevention.

Nursing Staff

SQE.03.00 The hospital has a uniform process to collect, verify, and evaluate credentials of the nursing staff.

SQE.03.01 The hospital has a standardized process to identify job responsibilities and to plan clinical work assignments based on the nursing staff member's credentials and any regulatory requirements.

SQE.03.02 The hospital has a standardized process for nursing staff participation in the hospital's continuous quality improvement activities, including evaluating individual performance when indicated.

Other Clinical Staff

SQE.04.00 The hospital has a uniform process to collect, verify, and evaluate credentials of other clinical staff.

SQE.04.01 The hospital has a uniform process to identify job responsibilities and to make clinical work assignments based on other clinical staff's credentials and any regulatory requirements.

SQE.04.02 The hospital has a uniform process for other clinical staff participation in the hospital's continuous quality improvement activities.

Medical Staff

SQE.05.00 The hospital has a uniform process for collecting the credentials of medical staff members permitted to provide patient care without supervision.

SQE.05.01 Medical staff members' education, licensure/registration, and other credentials required by laws and regulations and the hospital are verified and kept current.

SQE.05.02 There is a uniform decision process for the initial appointment of medical staff members and others permitted to practice independently.

Medical Staff Appointment and Privileges

SQE.06.00 The hospital has a standardized, objective, evidence-based process to grant or deny privileges for medical staff members and others permitted to practice independently.

SQE.06.01 Hospital leaders grant temporary clinical privileges to medical staff for a limited period of time and for circumstances as defined by hospital policy.

SQE.06.02 At minimum every three years, the hospital decides to grant, deny, and/or modify requested medical staff membership and clinical privileges.

Medical Staff Evaluations

SQE.07.00 The hospital uses an ongoing standardized process to evaluate the quality and safety of the patient care provided by each medical staff member.

SQE.07.01 Hospital leaders define the circumstances requiring monitoring and evaluation of a medical staff member's professional performance.

Standards, Intents, and Measurable Elements

Staff Planning

Standard SQE.01.00

Leaders of hospital departments and services define the desired qualifications of all staff.

Intent of SQE.01.00

A health care organization must maintain an appropriate variety of skilled, qualified people to fulfill its mission and to meet patient needs. Leaders of hospital departments and services define the desired education, skills, knowledge, and other requirements necessary for individual positions or for groups of similar positions (for example, intensive care nurses). To project staffing needs, department/service leaders consider a variety of factors such as the following:

- The hospital's mission and scope of services
- Patient populations
- Patient volumes
- Complex care needs
- Available resources

Multiple chronic conditions require complex patient care, treatment, and services in hospitals, increasing the demand for resources. The increase in demand for resources, which are often limited in supply, even at the outset, is one of the well-known causes of the burdened health care systems. Hospital leaders consider many factors to determine staffing levels and skills to meet the needs of patients. These factors include identifying the following:

- Prevalence of complex chronic conditions and needs
- Scope of services
- Availability of equipment and technologies
- Percentage of the hospital's volume of patients that comprise the complex care population

The hospital and/or service leaders consistently update their staffing needs based on the elements described in ME 1. The patterned staffing needs are considered when determining whether the job responsibilities and staff qualifications are accurately reflected in job descriptions and in the recruitment and retention of staff. In addition, the hospital complies with laws and regulations that identify required education levels, skills, or other requirements of individual staff members or that define staffing numbers or a mix of staff for the hospital.

Measurable Elements of SQE.01.00

1. Ⓓ Department and/or service leaders consider the following elements to project department staffing needs:
   - Hospital's mission
   - Mix of patient populations served by the hospital and the complexity of patient care needs
   - Scope of services provided by the hospital
   - Volume of patients
   - Medical equipment and technology used in patient care

   (*See also* GLD.06.00, ME 2)
2. Ⓓ The hospital defines staff qualifications specific to their job responsibilities.
3. The recruitment and retention of all staff comply with applicable laws and regulations.

Standard SQE.01.01

The hospital defines the responsibilities for every staff member in a current job description.

Intent of SQE.01.01

Job descriptions are the basis for staff member assignments, orientation to their work, and evaluation of how well job responsibilities are fulfilled. Job descriptions may vary for each staff member and are based on a variety of factors. For other clinical staff members who are permitted by law and hospital policy to practice independently, there is a process to identify and to authorize the individual to practice based on education, training, and experience, and where a formal job description is replaced by other requirements such as the privileging process.

The requirements of this standard apply to all "types" of staff who require job descriptions (for example, full-time, part-time, employed, voluntary, temporary, contract). When a hospital uses national or generic job descriptions (for example, a job description for a "nurse"), it is necessary to augment this type of job description (such as an addendum or a set of competencies) with specific job responsibilities for the types of nurses; for example, intensive care, pediatric, or operating theatre nurse.

Individual clinical staff members who are not licensed to practice independently have their responsibilities defined in current job descriptions. For medical staff members and other clinical staff permitted by laws and regulations and the hospital to practice independently, thereby practicing under privileges, and not a formal job description, there may be circumstances in which some roles will require a formal job description. Examples of these circumstances include a managerial role, such as a department manager, learning a new clinical skill which requires supervision; participating in an educational or training program requiring supervision; or temporary staff. Regardless of the type of job description, it is the hospital's responsibility to maintain a policy that specifies how frequently each job description is reviewed and updated and ensures that the job description complies with hospital policy.

Measurable Elements of SQE.01.01

1. Ⓓ Each staff member not permitted to practice independently has a job description.
2. Ⓓ Each job description includes defined responsibilities for the staff member with this job.
3. Job descriptions and/or specified privileges are required for medical staff when present in the hospital for the following circumstances:
   - Serves in primarily a managerial role or in dual clinical and managerial roles, with the managerial responsibilities identified in a job description.
   - Has select clinical responsibilities for which they have not been authorized to practice independently.
   - Involved in an education program and under supervision.
   - Permitted to temporarily provide services in the hospital.
4. Job descriptions are kept current according to hospital policy. (*See also* SQE.01.04, ME 3)

Standard SQE.01.02

Leaders of hospital departments and services implement processes for the recruitment and retention of staff.

Intent of SQE.01.02

The leaders of hospital departments and services implement processes for the recruitment and retention of all staff required to deliver the hospital's scope of services to its patient populations. The hospital and its leaders provide an efficient, coordinated, or centralized process for the following:

- Recruiting individuals for available positions
- Evaluating the training, skills, and knowledge of candidates
- Appointing individuals to the hospital's staff

If the process is centralized, similar criteria, processes, and forms result in a uniform process across the hospital for similar types of staff (for example, for nurses or physical therapists). Department/service leaders participate by recommending the number and qualifications of staff needed to provide clinical care, treatment, and services to patients, as well as nonclinical support functions, and to fulfill any teaching, research, or other departmental responsibilities. Department/service leaders also help make decisions about individuals to be appointed to the staff. The standards in this chapter complement the Governance, Leadership, and Direction (GLD) standards that describe the responsibilities of a department/service leader.

Measurable Elements of SQE.01.02

1. The hospital implements a coordinated process to recruit staff.
2. The hospital implements a coordinated process to evaluate the qualifications of new staff.
3. The hospital implements a coordinated process to appoint individuals to the staff.
4. The hospital implements a process that is uniform across the hospital for similar types of staff.

Standard SQE.01.03

The hospital evaluates staff performance.

Intent of SQE.01.03

Qualified staff members are hired by the hospital through a process that matches the requirements of the position with the qualifications of the prospective staff member. This evaluation process also ensures that the clinical staff member's skills are consistent with the needs of patients, and the nonclinical staff member's skills are consistent with the responsibilities of the nonclinical staff role at the time of hire and throughout employment.

The hospital uses a defined process to ensure that staff qualifications, knowledge, and skills are consistent with the requirements of the position. Orientation to the position includes supervision to ensure that the staff member can fulfill the responsibilities of the job description. The staff member receives the required level of supervision and on a periodic basis is evaluated to ensure continuing competence in the position.

For clinical staff under job descriptions, the process includes the following:

- An initial evaluation to ensure that they can assume the responsibilities listed in the job description. This evaluation is carried out before or at the time of starting to perform work responsibilities. The hospital may have a "probationary" or other period during which the clinical staff member is closely supervised and evaluated, or the process may be less formal. Whatever the process, the hospital ensures that staff providing care, treatment, and services to patients are evaluated at the time they begin providing the care, treatment, and service and before the probationary or orientation period is completed. The department or service leader who manages the staff member evaluates the staff member's skills, knowledge, and work behaviors. Competence is assessed by an individual with similar or relatable education, experience, or knowledge of the skills being reviewed. If the department or service leader does not possess similar or relatable skills and knowledge, the evaluations must be conducted collaboratively with an individual who has the skills, knowledge, and work behaviors to meet the criteria for executing the evaluation.
- The evaluation also includes an assessment of the staff member's ability to operate medical equipment and technology, perform medication management tasks, and conduct complex patient care management unique to the specific area (for example, staff working in intensive care units should be able to effectively manage ventilators, infusion pumps, and continuous cardiac monitoring, and staff working in labor and delivery should be able to effectively manage fetal monitoring equipment).
- The hospital defines the process for and the frequency of the ongoing evaluation of clinical staff performance.

For nonclinical staff under job descriptions, the process includes the following:

- An initial evaluation to ensure that they can assume the responsibilities listed in the job description. This evaluation is carried out before or at the time of starting to perform work responsibilities. The hospital may have a "probationary" or other period during which the nonclinical staff member is closely supervised and evaluated, or the process may be less formal. Whatever the process, the hospital ensures that staff are evaluated at the time they begin performing work responsibilities and before the probationary or orientation period is completed. The department or service leader who manages the staff member evaluates the staff member's skills, knowledge, and work behaviors. Competence is assessed by an individual with similar or relatable education, experience, or knowledge of the skills being reviewed.
- The hospital defines the process for and the frequency of the ongoing evaluation of nonclinical staff performance.

For the hospital's nursing staff the processes are identified in SQE.03.00–SQE.03.02, and for other clinical staff they are identified in SQE.04.00–SQE.04.02. For the medical staff who practice independently (that is, they do not practice under job descriptions), the evaluation process is described in SQE.07.00 and SQE.07.01.

An ongoing evaluation ensures that training occurs when needed and that the staff member can assume new or changed responsibilities. Although such evaluations are best carried out in an ongoing manner, there is at least one documented evaluation of each staff member working under a job description completed each year or more frequently as defined by hospital policy or consistent with laws and regulations.

Measurable Elements of SQE.01.03

1. The hospital uses a defined process to ensure that staff qualifications are consistent with the care, treatment, and services it provides. (*See also* ASC.02.01, MEs 1 and 2)
2. The hospital evaluates staff based on performance expectations that reflect their job responsibilities. (*See also* HRP.02.01, ME 2)
3. New staff are evaluated before or at the time they begin their work responsibilities.
4. The department or service to which the individual is assigned conducts the evaluation.
5. An individual with the educational background, experience, or knowledge related to the skills being reviewed conducts or co-leads the evaluation.
6. Ⓓ Clinical staff evaluations are completed and documented annually or more frequently as defined by hospital policy or consistent with laws and regulations.

Standard SQE.01.04

There is documented personnel information for each staff member.

Intent of SQE.01.04

An accurate personnel record provides documentation of staff knowledge, skill, competency, and training required for carrying out job responsibilities. A staff member's personnel record shows evidence of staff performance and whether they are meeting job expectations. As a result, personnel records may contain sensitive information and must be kept confidential.

Each staff member in the hospital, including those permitted by law and the hospital to work independently, has a personnel record(s) with the following information:

- Their qualifications
- Required health information, such as immunizations and/or evidence of immunity
- Evidence of participation in orientation, ongoing in-services, and continuing education
- Results of evaluations, including individual performance of job responsibilities and competencies
- Work history

The records are standardized and kept current consistent with hospital policy.

Measurable Elements of SQE.01.04

1. Ⓓ Personnel records for each staff member are standardized, current, and maintained.
2. Personnel records are kept confidential and secure consistent with hospital policy.
3. Personnel records contain documented evidence of the following:
   - Current job description that includes job qualifications and responsibilities, as indicated (*See also* SQE.01.01, ME 4)
   - Staff member work history
   - Record of completed orientation to the hospital
   - Record of completed orientation to specific job/role
   - Record of training and education attended by the staff member
   - Completed annual performance evaluations and other evaluations as defined by hospital policy or consistent with laws and regulations
   - Completed annual staff competence assessments and other competence assessments as defined by hospital policy or consistent with laws and regulations

Standard SQE.01.05

The hospital has the necessary staff to support the care, treatment, and services it provides.

Intent of SQE.01.05

Appropriate and adequate staffing is critical to patient care and to all teaching and research activities. Staff planning is carried out by department/service leaders. The planning process uses recognized methods for determining levels of staffing. For example, a patient acuity system is used to determine the number of licensed nurses with pediatric intensive care experience to staff a 10-bed pediatric intensive care unit. The process is written and identifies the number and types of required staff and the skills, knowledge, and other requirements needed in each department and service. The staffing process addresses the following:

- Reassignment of staff from one department or service to another in response to changing patient needs or staff shortages
- Consideration of staff requests for reassignment based on personal, spiritual/religious, and/or cultural beliefs
- Compliance with local laws and regulations

The staff planning process assesses the levels of complexity in care and the volume of these patient populations present in the hospital in comparison with the skill mix of available staffing resources. Medical equipment and the availability of other pertinent patient care resources are considered when planning for hospital allocation of staffing resources. With a global staffing shortage, the impact staffing has on staff retention should also be considered. Planned and actual staffing is monitored on an ongoing basis, and the process is revised as necessary. There is a coordinated process for the department/service leaders to update the overall process.

Measurable Elements of SQE.01.05

1. Ⓓ Hospital leaders implement a hospital staffing process that supports the care, treatment, and services it provides. (*See also* GLD.03.01, ME 1)
2. Ⓓ The hospital staffing process indicates the number, types, and desired qualifications of staff using a recognized staffing method.
3. Ⓓ The hospital staffing process describes the assignment and reassignment of staff.
4. The hospital staffing process complies with local laws and regulations.
5. Ⓓ The effectiveness of the hospital staffing process is monitored on an ongoing basis.
6. The hospital staffing process is reviewed and revised consistent with hospital policy and when indicated.
7. The hospital staffing process involves coordination with various hospital department/service leaders.

Standard SQE.01.06

The hospital provides orientation for all staff.

Intent of SQE.01.06

Orientation to the hospital allows staff members to understand how their specific roles will contribute to the organization. New staff members must understand how their specific role and responsibilities contribute to the hospital's mission. Orientation is accomplished through the following:

- General orientation to the hospital
- Specific orientation to the staff member's role and job responsibilities
- Key safety information related to the staff member's role

The staff member's completed orientation is documented in their personnel record. The orientation includes key safety content according to the staff member's role and as determined by the hospital. Examples of key safety content that may be a part of orientation include the following:

- Reporting of medical errors
- Infection prevention and control practices
- Hospital policies on telephone medication orders
- Hospital safety codes and emergency procedures

Contract staff, volunteers, students, and trainees are also oriented to the hospital and their specific assignments or responsibilities, such as patient safety and infection prevention and control.

Measurable Elements of SQE.01.06

1. The hospital completes orientation before staff provide care, treatment, and services. (*See also* GHI.02.00, ME 4)
2. The hospital orients staff on the following according to their job description:
   - High-risk quality and safety issues (for example, reporting of medical errors, infection prevention and control practices, the hospital's policies on telephone medication orders)
   - The hospital, the department, and/or unit to which they are assigned
   - Their specific job responsibilities and any specific assignments
   - Relevant hospitalwide and department- and/or unit-specific policies and procedures
   - Patient rights, including ethical aspects of care, treatment, or services and the process used to address ethical issues based on their job duties and responsibilities (*See also* PCC.01.01, ME 2)
3. Other clinical staff who accompany the medical staff and provide care, treatment, and services are oriented to the hospital.
4. Students, trainees, and volunteers are oriented to the hospital and assigned responsibilities.
5. Ⓓ Completion of orientation and a description of the objectives is documented for all staff in their personnel record.

Standard SQE.01.07

Staff participate in education and training.

Intent of SQE.01.07

Staff must participate in education and training to maintain acceptable staff performance, to learn new skills, and to be trained on new medical equipment, technology, and procedures. The hospital provides resources such as facilities, educators, and time for ongoing in-service and other education. The training and education provided by the hospital must be relevant to each staff member as well as to the continuing advancement of the hospital in meeting patient needs. For example, medical staff members may receive education on infection

prevention and control, advances in medical practice, culture of safety, or new medical equipment. Each staff member's training and educational achievements are documented in their personnel record.

The hospital collects data from several sources to understand ongoing education needs, including the following examples:

- Results of quality and safety measurement activities
- Monitoring data from the facility management program
- Introduction of new medical equipment
- Skill and knowledge areas identified through job performance review
- New clinical procedures
- Strategic plans to provide new services

The hospital has a process to collect and integrate data from various sources to plan staff training and education programs. The hospital determines which staff are required to obtain continuing education to maintain their credentials and how the education of these staff will be monitored and documented. Hospital leaders support ongoing staff education by providing equipment, time, and other necessary resources for education and training programs. Current scientific information, such as evidence-based guidelines and practices, is used to support the education and training programs. The education and training can take place in a centralized location, various smaller learning and skill development locations throughout the facility, or through online training portals. Educational opportunities can be offered using various methods and at various times and settings, to minimize the disruption to staff scheduling and any potential affects this may have on patient care.

Measurable Elements of SQE.01.07

1. Staff participate in ongoing education and training to maintain or increase their competency, and as needed. (*See also* AOP.05.02, ME 2)
2. Hospital staff are provided ongoing education and training.
3. The hospital uses various sources of data and information, including the results of quality and safety measurement activities, to identify staff education needs. (*See also* GLD.07.01, ME 3)
4. Staff education programs are developed and provided based on these data and information.
5. The education is relevant to each staff member's ability to meet patient needs and/or continuing education requirements.
6. The hospital provides adequate time and resources for all staff to participate in relevant education and training opportunities.
7. Ⓓ Completion of training and education is documented for all staff in their personnel record.

Standard SQE.01.08

Staff are competent in resuscitative techniques appropriate to their role in the hospital.

Intent of SQE.01.08

All staff who provide patient care, treatment, and services, including medical staff, and nonclinical staff whom the hospital identifies, are trained in basic resuscitative techniques. The hospital identifies the level of training (basic or advanced life support), appropriate to their roles in the hospital, for all clinical staff who provide patient care. For example, the hospital may determine that all clinical staff who provide care in specific departments, such as the emergency department or intensive care unit, or all staff who administer or monitor procedural sedation, are required to be trained in advanced life support. The appropriate level of training is repeated based on the requirements and/or time frames identified by a recognized resuscitation training program, or every two years if a recognized training program is not used. Recognized training programs such as the American Red Cross and the American Heart Association are programs that offer medical emergency preparedness globally. As an alternative to offering a recognized training program, the hospital can choose to develop its own training program as long as the program is based on the requirements and/or time frames

established by a recognized training program. Medical emergency preparedness training options include first aid, basic life support (BLS) also known as cardiopulmonary resuscitation (CPR), and advanced cardiovascular life support (ACLS).

It is important that clinical staff are trained to promptly recognize life-threatening emergencies and to respond to them by competently performing CPR and other basic cardiovascular life-support skills according to their roles. The hospital may also determine that nonclinical staff who do not provide patient care, treatment, or services, such as transporters or registration clerks, may require training in basic life support, as appropriate to their role. There must be evidence to show if each staff member who attended and completed the training course in resuscitation achieved the desired competency level appropriate for their role.

Measurable Elements of SQE.01.08

1. Clinical staff who provide patient care, treatment, and services, including medical staff, are trained in at least basic life support (BLS).
2. The hospital identifies the level of training (basic or advanced life support), appropriate to their roles in the hospital, for all clinical staff who provide patient care. (*See also* ASC.02.00, ME 2)
3. Ⓓ Evidence that the clinical staff member completed and passed the level of training appropriate to their role is documented in the personnel record.
4. The level of training appropriate to their role for clinical staff is repeated based on the requirements and/or time frames established by a recognized training program, or every two years if a recognized training program is not used.
5. The hospital identifies nonclinical staff to be trained in basic life support (BLS).
6. Ⓓ Evidence that the nonclinical staff member completed and passed the level of training appropriate to their role is documented in the personnel record.
7. The level of training appropriate to their role for nonclinical staff is repeated based on the requirements and/or time frames established by a recognized training program, or every two years if a recognized training program is not used.

Staff Health and Safety

Standard SQE.02.00

The hospital provides a staff health and safety program that addresses staff physical and mental health and safe working conditions.

Intent of SQE.02.00

A hospital's staff health and safety program is important to maintain staff physical and mental health, satisfaction, productivity, and safe conditions for work. Many factors in the workplace support the health and well-being of staff, including the following:

- Staff orientation and training
- A safe workplace
- Maintenance of medical equipment
- Prevention and control of health care–associated infections

The program includes elements such as education, training, evaluation, interventions, and treatments. The design of the program includes staff input and draws upon the hospital's clinical resources as well as those in the community. Follow-up and/or periodic evaluations for potential impact of work-related injuries are key factors in maintaining staff health and safety. Staff must understand the process for handling work-related injuries, including how to report, be treated for, and receive counseling and follow-up as indicated.

Examples of work-related injuries include the following:

- Needlesticks injuries
- Back injuries
- Exposure to infectious diseases
- Handling of patients
- Hazardous conditions in the facility
- Exposure to chemicals (chemotherapy agents, Central Sterile Supply Department, radiological/nuclear materials)

Nursing and other clinical staff who assist with mobilizing patients are at increased risk of back injuries and other musculoskeletal injuries due to the physical demands of patient handling. Improper patient handling techniques can also have a negative impact on patient safety and quality of care. Interventions appropriate to the care area and type of patient are implemented. Examples of safe handling interventions include the following:

- Use of gait belts
- Lateral transfer aids
- Training on body mechanics
- Implementation of a patient transfer team

The caregiving environment often presents challenges that can be mentally, emotionally, and physically stressful. Repeated exposure to emotional and physical challenges such as providing empathy and emotional support to patients and families, ethical decision-making, and frequent exposure to death and dying, can create compassion fatigue and can lead to many adverse health and quality-of-life outcomes for health care workers. Promoting and sustaining staff resiliency to minimize stress is essential to creating a positive culture for the benefit of patients and staff.

Clinical staff are often the second victims of errors and sentinel events. The European Researchers' Network Working on Second Victims (ERNST) defines the *second victim* as being "any health care worker, directly or indirectly involved in an unanticipated adverse patient event, unintentional healthcare error, or patient injury, and becomes victimized in the sense that also the worker is negatively impacted." Anxiety felt by caregivers and feelings of moral distress are frequently not addressed when patients and their family members are affected by clinical errors. Hospitals need to acknowledge that the emotional health and performance of the clinical staff involved in adverse and sentinel events can have an impact on the quality and safety of patient care.

Compared to the general population, clinical staff historically have higher incidents of depression, anxiety, stress, and thoughts of self-harm and suicide due to the psychological distress attributed to the workplace environment. Common traumatic workplace stressors include the following:

- Constant work demands
- Poor organizational support
- Short staffing
- Long hours
- Exposure to death, dying, and workplace violence

Recurring stressors compounded by the ethical decisions that clinical staff contend with that often create conflict with moral or ethical values has played a pivotal role in the deterioration of mental health in clinical staff, even more so in relation to crisis events. Mental health impairment among clinical staff due to workplace post-traumatic stress and psychological distress was historically present in crisis events. Most recently, the COVID-19 pandemic has increased rates of self-harm and suicidal ideation, high levels of depression, anxiety, sleep disorders, burnout, and post-traumatic stress disorder symptoms among clinical staff.

Research related to compassion fatigue and burnout recommends that hospitals create programs to support staff involved in sentinel and adverse events and to proactively develop skills to promote staff resiliency and staff health and well-being.

Measurable Elements of SQE.02.00

1. Ⓓ The hospital implements a staff health and safety program that is responsive to urgent and nonurgent staff needs through direct treatment and referral.
2. The staff health and safety program at a minimum includes the following:
   - Initial employment health screening
   - Measures to control harmful occupational exposures, such as exposure to toxic drugs and harmful noise levels
   - Education, training, and resources on safe patient handling
   - Education, training, and resources for staff who may be second victims of adverse or sentinel events
   - Treatment for common work-related conditions or injuries

   (*See also* PCI.08.01, ME 1)
3. The staff health and safety program evaluates and provides resources to address the following:
   - Staff mental health
   - Burnout
   - Compassion fatigue
   - Risk of suicide and self-harm
4. The hospital implements a process for follow-up and support to staff who are second victims of adverse or sentinel events.
5. The hospital demonstrates actions taken for staff mental health prevention to, at a minimum, address the following:
   - Burnout
   - Compassion fatigue
   - Risk of self-harm
   - Suicide

Standard SQE.02.01

The hospital identifies staff who are at risk for exposure to and possible transmission of vaccine-preventable diseases and implements a staff vaccination and immunization program.

Intent of SQE.02.01

Many clinical staff are at risk for exposure to and possible transmission of vaccine-preventable diseases due to their contact with patients and infectious materials. Asymptomatic infections are common, and individuals can be infectious prior to having any symptoms, including from highly transmittable diseases such as COVID-19, influenza, and tuberculosis. Studies show that clinical staff often report to work even when ill. Hospitalized patients are at significant risk of injury or death from health care–associated infectious disease transmissions. Infectious disease outbreaks in hospitalized patients have been traced to unvaccinated clinical staff, particularly in cases of COVID-19, influenza A, and tuberculosis.

The incidence of infectious disease transmission can be significantly reduced by doing the following:

- Identifying epidemiologically important infections
- Determining staff at high risk for these infections
- Implementing screening and prevention programs (such as immunizations, vaccinations, and prophylaxis)

Hospitals reduce the risks associated with the transmission of infectious diseases by unvaccinated staff, which includes the implementation of a staff vaccination and immunization program policy and a process to guide the administration and management of staff vaccinations and immunizations. Clinical staff have an ethical and professional obligation to protect themselves, their coworkers, and patients/families. Vaccination is a duty for all clinical staff.

Strategies for reducing patient and staff risk of exposure to infectious diseases, such as COVID-19, influenza A, and tuberculosis, may include efforts to promote vaccination, encouraging staff to get vaccinated, and requiring unvaccinated staff to wear masks at high-risk times of the year such as the flu season, or in high-risk areas such as a unit that frequently cares for patients diagnosed with COVID-19 or tuberculosis. Unvaccinated staff providing care to patients who are vulnerable to infection, such as the immunocompromised, the elderly, and infants, increases the risks to those patients already at high risk for infection. Therefore, staff immunization status needs to be considered when making staff assignments.

Measurable Elements of SQE.02.01

1. The hospital identifies epidemiologically significant infections, as well as staff who are at high risk for exposure to and transmission of infections. (*See also* PCI.08.01, ME 2)
2. Ⓓ The hospital develops and implements a staff vaccination and immunization program. (*See also* PCI.07.02, ME 5)
3. Ⓓ The staff vaccination and immunization program includes a policy and a process for the administration and management of staff vaccinations and immunizations.
4. The hospital evaluates the risks associated with unvaccinated staff and identifies strategies for reducing patient and staff risk of exposure to infectious diseases from unvaccinated staff.
5. The infection prevention and control program guides the evaluation, counseling, and follow-up of staff exposed to infectious diseases. (*See also* PCI.08.01, ME 1)

Standard SQE.02.02

Leaders and staff are trained and demonstrate competence in workplace violence prevention.

Intent for SQE.02.02

Exposure to workplace violence can impair effective patient care and lead to psychological distress, job dissatisfaction, absenteeism, high turnover, and higher costs. Recognition of what constitutes workplace violence begins with awareness of the different types of physical and nonphysical acts and threats of workplace violence. Studies have demonstrated the negative impact that unhealthy cultures have on the work environment; in particular to employee retention, personal well-being, engagement, and ultimately, patient outcomes. A 2022 study concluded that the number one cause of burnout and intention to leave the workplace is toxic work behaviors. Another study determined that a "toxic culture" is greater than 10 times more likely to contribute to attrition than compensation. According to US Bureau of Labor Statistics data, the incidence of violence-related health care worker injuries has steadily increased for at least a decade. Incidence data reveal that in 2018 health care and social service workers were 5 times more likely to experience workplace violence than all other workers—comprising 73% of all nonfatal workplace injuries and illnesses requiring days away from work. However, workplace violence is underreported, indicating that the actual rates may be much higher.

The hospital provides training, education, and resources on the workplace violence prevention program to leaders and staff at time of hire, annually, and whenever changes occur. The required aspects of the workplace violence prevention program training are based on individual roles and responsibilities, but training should begin with clearly defining the matter. *Workplace violence* is defined as "an act or threat occurring at the workplace that can include any of the following: verbal, nonverbal, written, or physical aggression; threatening, intimidating, harassing, or humiliating words or actions; bullying; sabotage; sexual harassment; physical assaults; or other behaviors of concern involving all staff, patients, or visitors."

Workplace violence can occur between staff, patient, and/or visitor to staff; leader to staff; and staff to leader. Education and training should focus on prevention, including early detection and immediate intervention. Training on early detection and communication processes to alert other health care professionals of persons who are at risk for becoming violent can prevent situations from arising. De-escalation and intervention techniques are also important to learn when confronted with incidents of workplace violence. Incorporating

violence prevention tools and encouraging the use of a simple and accessible reporting process can ultimately reduce the likelihood of health care staff being victims of workplace violence.

Measurable Elements of SQE.02.02

1. The hospital provides training, education, and resources (at time of hire, annually, and whenever changes occur regarding the workplace violence prevention program) to leaders, and staff. (*See also* GLD.07.02, ME 2)
2. The hospital determines what aspects of training are appropriate for individuals based on their roles and responsibilities.
3. The training, education, and resources address prevention, recognition, response, and reporting of workplace violence as follows:
   - What constitutes workplace violence (*See also* GLD.07.02, ME 2)
   - Education on the roles and responsibilities of leaders, clinical staff, security personnel, and external law enforcement
   - Training in early detection, de-escalation, nonphysical intervention skills, physical intervention techniques, and response to emergency incidents
   - The reporting process for workplace violence incidents (*See also* GLD.07.02, ME 5)

Nursing Staff

Standard SQE.03.00

The hospital has a uniform process to collect, verify, and evaluate credentials of the nursing staff.

Intent of SQE.03.00

The hospital needs to ensure that it has a qualified nursing staff that appropriately matches its mission, care, treatment, services, and associated resources with the needs of the patient populations it serves. Nursing is the driving force behind patient care, and directly contributes to the overall patient outcomes; Therefore, the hospital must ensure that nurses are qualified to provide nursing care and must specify the types of care they are permitted to provide if not identified in laws or regulations. The hospital ensures that each nurse is qualified to provide safe and effective care and treatment to patients by meeting the following expectations:

- Understanding the applicable laws and regulations that apply to nurses and nursing practice
- Collecting all available credentials on each nurse, including at least the following:
  - Evidence of education/training
  - Evidence of current licensure
  - Evidence of current competence through information from other sources in which the nurse was employed
  - Letters of recommendation and/or other information the organization may require, such as health history and pictures
  - Verification of the essential information, such as current registry or licensure, particularly when such documents are periodically renewed, and any certifications and evidence of completion of specialized or advanced education

The hospital must make every effort to verify essential information, even when the education took place in another country or a significant time ago. Standards compliance requires that primary source verification is carried out for all nurses.

***Exception* for SQE.03.00, ME 1, for initial surveys only.** At the time of the initial JCI accreditation survey, hospitals are required to have completed primary source verification for new nurse applicants within the twelve (12) months leading up to the initial survey. During the twelve (12) months following the initial survey,

hospitals are required to complete primary source verification for all other currently employed nurses. This process is accomplished over the 12-month postsurvey period according to a plan that places priority on the verification of the credentials of currently employed nurses providing high-risk services.

Note: This exception refers only to the verification of credentials. All nursing staff members must have their credentials collected and reviewed, and any advanced practice privileges granted. When verification is not possible, such as loss of records in a natural disaster, this is documented.

The hospital has a process that ensures that the credentials of each contract nurse have also been collected, verified, and reviewed to ensure current nurse competence prior to assignment. Various methods can be used to conduct primary source verification. Examples include secure websites, documented phone confirmation from the source, written confirmation, and third parties, such as a designated, official, governmental, or nongovernmental agency. The hospital collects and maintains a record of each nurse's credentials. The records contain current licenses when regulations require periodic renewal. There is documentation of training related to any additional competencies.

Measurable Elements of SQE.03.00

1. The hospital has a standardized procedure to collect, verify, and document the education, certifications, and experience of each nursing staff member.
2. Ⓓ Education, training, and certifications are verified from the original source consistent with parameters found in the intent of SQE.05.01 and are documented.
3. Ⓓ Licensure is verified from the original source consistent with the following parameters and is documented:
   - The hospital must verify that the third party implements the verification process as described in hospital policy or regulations and that the process meets the expectations described in these standards.
   - The affiliated hospital that has already conducted primary source verification of the nursing staff applicant is acceptable if the affiliated hospital has current Joint Commission International (JCI) accreditation with "full compliance" on its verification process found in SQE.03.00, MEs 1 and 2.
   - The hospital that bases its decisions in part on information from a designated, official, governmental, or nongovernmental agency must evaluate the agency providing the information initially and then periodically thereafter to ensure that JCI standards continue to be met.
4. Ⓓ A record is maintained with the credentials for every nursing staff member.
5. The hospital has a process to ensure that the credentials of contracted nurses are valid and complete prior to assignment.
6. The hospital has a process to ensure that nurses who are not employees of the hospital but accompany private physicians and provide services to the hospital's patients have valid credentials.

Standard SQE.03.01

The hospital has a standardized process to identify job responsibilities and to plan clinical work assignments based on the nursing staff member's credentials and any regulatory requirements.

Intent of SQE.03.01

Review of the qualifications of the nursing staff member provides the basis for assigning job responsibilities and clinical work assignments. Safe and appropriate staffing has been linked to the health status of the workplace. Staffing challenges affect patient and staff safety, patient quality of care and outcomes, hospital costs, staff mental health, and staff performance and retention. Appropriate staffing requires a healthy balance between the assessment of patient needs, including the complexity of care, and the appropriate clinical staff skills to match those needs. Work assignments may be described in more detail in a job description or described in documents

that support how nurse staffing assignments are made, such as assignment to geriatric or pediatric units or to high-acuity units. Assignments made by the hospital are consistent with any applicable laws and regulations regarding nursing responsibilities and clinical care.

Hospitals committed to establishing staffing policies and standardized processes to support staffing models that match patient needs with clinical staff competencies will continuously evaluate their staffing decisions and adjust their processes to ensure that their staffing model continues to support patient and staff safety and high-quality care. It is important to measure how supportive the staffing plan process is. Examples of measures include reviewing independent nursing performance improvement projects, and evidence of nursing participation in departmental and/or service quality improvement activities. Additional supportive measures include continuous data monitoring and analysis, availability of support services, and evaluating the need to adopt technologies, including any training and education reflective of the work assignments and job descriptions supported by hospital policies and processes.

Measurable Elements of SQE.03.01

1. Ⓓ Nursing staff have education, experience, training, and/or certification, consistent with the hospital's scope of services, as indicated in their job description and as applicable to their role.
2. Core criteria for evaluating nursing staff in the program include, at a minimum, current licensure, and current competence.
3. Licensure, education, training, and experience of a nursing staff member are used to plan clinical work assignments.
4. The process considers applicable laws and regulations.
5. The process supports nurse staffing plans.

Standard SQE.03.02

The hospital has a standardized process for nursing staff participation in the hospital's continuous quality improvement activities, including evaluating individual performance when indicated.

Intent of SQE.03.02

The nursing staff's essential clinical role requires them to actively participate in the hospital's continuous quality improvement program. The hospital determines the information that should be kept in the nursing staff's personnel record. Examples include the following:

- Completed education
- Training, in-service, and skills/competency documentation
- Performance reviews
- Job descriptions that include roles and responsibilities
- Disciplinary actions and discussions, license, and credential information

If at any point during clinical quality measurement, evaluation, and improvement, a nursing staff member's performance is in question, the hospital has a process to evaluate that individual's performance. The results of reviews, actions taken, and any impact on job responsibilities are documented in the nurse's personnel record or in a separate credential record.

A standardized process to gather relevant performance data on each nurse for evaluation by appropriate leaders allows for identification of practice trends, negative or positive, that affect the quality of care and patient safety. Including measures related to individual staff member performance in the program in nursing staff evaluations provides opportunities to identify performance deficiencies. When deficiencies or substandard performance are identified, corrective actions are implemented. Documentation of corrective actions taken, and the outcome produced, is necessary when evaluating the performance of nursing staff. Evaluations are accomplished via various methods such as data analysis, peer and leadership feedback, and assessments of competence for knowledge and performance of skills, which are proven to directly impact quality and safety.

Measurable Elements of SQE.03.02

1. Nursing staff participate in the hospital's continuous quality improvement activities.
2. The performance of individual nursing staff members is reviewed when indicated by variances noted on trend or as negative deviations to continuous quality improvement activities.
3. Ⓓ Information from the review process is documented in the nurse's personnel record or in a separate credential record, consistent with hospital policy.

Other Clinical Staff

Standard SQE.04.00

The hospital has a uniform process to collect, verify, and evaluate credentials of other clinical staff.

Intent of SQE.04.00

The hospital is responsible for collecting and verifying credentials of other clinical staff permitted to work or to practice in the hospital. Hospitals employ or may permit other clinical staff to provide care and services to their patients or to participate in patient care processes. Examples of such staff include the following:

- Midwives (unless allowed by law to practice independently)
- Surgical assistants
- Emergency medical care specialists
- Dietitians
- Pharmacists
- Pharmacy technicians

In some countries or cultures, this group also includes traditional healers or those who provide alternative services or services that complement traditional medical practice (for example, acupuncture, herbal medicine). Often, these individuals do not actually practice in the hospital; instead, they refer to the hospital or provide continuing or follow-up care for patients in the community. Many of these professionals complete formal training programs and receive licenses or certificates or are registered with local or national authorities. Others may complete less formal apprentice programs or other supervised experiences.

The hospital must ensure that other clinical staff are qualified to provide care and treatments and must specify the types of care and treatment they are permitted to provide if not identified in laws or regulations. The hospital ensures that other clinical staff are qualified to provide safe and effective care and treatment to patients by doing the following:

- Understanding the applicable laws and regulations that apply to such clinical staff
- Collecting all available credentials on each individual, including at least evidence of education and training and evidence of current licensure or certification when required
- Verifying essential information, such as current registry, licensure, or certification

The hospital must make every effort to verify essential information relevant to the individual's intended responsibilities, even when the education took place in another country or a significant time ago. Standards compliance requires that primary source verification is carried out for all other clinical staff.

***Exception* for SQE.04.00, ME 1, for initial surveys only.** At the time of the initial JCI accreditation survey, hospitals are required to have completed primary source verification for new other clinical staff applicants within the twelve (12) months leading up to the initial survey. During the twelve (12) months following the initial survey, hospitals are required to complete primary source verification for all currently employed other clinical staff. This process is accomplished over the 12-month postsurvey period according to a plan that places priority on the verification of the credentials of currently employed other clinical staff

providing high-risk services. When there is no required formal education process, licensure, or registry process or other credential or evidence of competency, this is documented in the individual's record.

Note: This exception refers only to the verification of credentials.

When verification is not possible, such as with the loss of records in a disaster, this is documented in the individual's record. The hospital gathers and maintains a file of each health care practitioner's credentials. The files contain current licenses or registry when regulations require periodic renewal.

Measurable Elements of SQE.04.00

1. The hospital has a standardized process to collect, document, and verify the education, certifications, and experience of each other clinical staff member.
2. Ⓓ Education, training, and certifications are verified from the original source consistent with the parameters found in the intent of SQE.05.01 and are documented.
3. Ⓓ Licensure is verified from the original source consistent with the following parameters and is documented:
   - The hospital must verify that the third party implements the verification process as described in hospital policy or regulations and that the process meets the expectations described in these standards.
   - The affiliated hospital that has already conducted primary source verification of the other clinical staff applicant is acceptable if the affiliated hospital has current Joint Commission International (JCI) accreditation with "full compliance" on its verification process found in SQE.04.00, MEs 1 and 2.
   - The hospital that bases its decisions in part on information from a designated, official, governmental, or nongovernmental agency must evaluate the agency providing the information initially and then periodically thereafter to ensure that JCI standards continue to be met.
4. Ⓓ A record is maintained with copies of any required license, certification, or registration for other clinical staff.
5. The hospital has a process to ensure that staff who are not employees of the hospital but accompany private physicians and provide services to the hospital's patients have valid credentials that are comparable to the hospital's requirement for credentials.

Standard SQE.04.01

The hospital has a uniform process to identify job responsibilities and to make clinical work assignments based on other clinical staff's credentials and any regulatory requirements.

Intent of SQE.04.01

The hospital is responsible for identifying the types of activities or range of services these individuals will provide in the hospital. This can be accomplished through agreements, job assignments, job descriptions, or other methods. Work assignments may be described in more detail in a job description or described in other ways or documents that support how other clinical staff staffing assignments are made, such as assignment to geriatric or pediatric units or to high-acuity units. Assignments made by the hospital are consistent with any applicable laws and regulations regarding applicable other clinical responsibilities and clinical care.

Hospitals continuously evaluate their staffing decisions and adjust their processes to ensure that their staffing model continues to support patient and staff safety and high-quality care. Additional supportive measures include continuous data monitoring and analysis, availability of support services, and evaluating the need to adopt technologies, including any training and education reflective of the work assignments and job descriptions supported by hospital policies and processes.

Measurable Elements of SQE.04.01

1. Licensure, education, training, and experience of other clinical staff are used to make clinical work assignments.
2. The process considers relevant laws and regulations.
3. The process supports the staffing process for other clinical staff.

Standard SQE.04.02

The hospital has a uniform process for other clinical staff participation in the hospital's continuous quality improvement activities.

Intent of SQE.04.02

The hospital defines the level of supervision (consistent with existing laws and regulations), if any, for these professionals. Other clinical staff are included in the hospital's continuous quality improvement program. The hospital determines the information that should be kept in the other clinical staff's personnel record. Examples include the following:

- Completed education
- Training
- In-service and skills/competency documentation
- Performance reviews
- Job descriptions that include roles and responsibilities
- Disciplinary actions and discussions, license, and credential information

If at any point during clinical quality measurement, evaluation, and improvement, another clinical staff member's performance is in question, the hospital has a process to evaluate that individual's performance. The results of reviews, actions taken, and any impact on job responsibilities are documented in the other clinical staff's personnel record or in a separate credential record.

A standardized process to gather relevant performance data on each staff member allows for identification of practice trends that affect the quality of care and patient safety. Including measures related to individual staff member performance in the program in other clinical staff evaluations provides opportunities to identify performance deficiencies. Corrective actions are implemented when deficiencies or substandard performances are identified. Documentation of corrective actions taken, and the outcome produced, is necessary when evaluating the performance of other clinical staff. Evaluations are accomplished via various methods such as data analysis, peer and leadership feedback, and assessments of competence for knowledge and performance of skills, which are proven to directly impact quality and safety.

Measurable Elements of SQE.04.02

1. Other clinical staff participate in the hospital's continuous quality improvement activities.
2. The performance of other clinical staff is reviewed when indicated by the findings of the continuous quality improvement activities.
3. Ⓓ Appropriate information from the review process is documented in the other clinical staff member's record.

Medical Staff

Standard SQE.05.00

The hospital has a uniform process for collecting the credentials of medical staff members permitted to provide patient care without supervision.

Intent of SQE.05.00

A uniform decision process ensures that the expectations for medical staff membership appointment are understood and that the decision process is unbiased. A hospital's uniform process for the management of credentials requires a singular, structured process for the verification of the education, licensure/registration, and other credentials required by laws and regulations and the hospital's policy for the medical staff membership initial appointment and/or reappointment of each medical staff member.

Definitions and further explanations of terms and expectations found in these standards are as follows:

Credentials

A *credential* is a document issued to an individual from a recognized entity to indicate the completion and/or meeting of requirements that addresses some aspect of the applicant's professional history such as a qualification, competence, or authority. Examples of credentialing documents include the following:

- Diploma from a medical school
- Specialty training (residency) completion letter or certificate
- Completion of the requirements of a medical professional organization
- License to practice
- Recognition of registration with a medical or dental council
- Letters of recommendation
- History of all previous hospital medical staff appointments
- Records of previous clinical care, treatment, services, and health history
- Picture for identification
- Police background check

These documents, some of which are required by law or regulation, but some by hospital policy, must be verified from the original source that issued the document. Credential verification requirements will vary by the position the applicant is seeking. For example, for an applicant for leader of a department/clinical service, the hospital may want to verify information regarding the individual's previous administrative positions and experience. Also, for clinical positions, the hospital may require a certain number of years of experience and thus would verify this level of experience.

Measurable Elements of SQE.05.00

1. The hospital has an ongoing, uniform process to manage the credentials of medical staff members.
2. Medical staff members permitted by laws and regulations and the hospital to provide patient care without supervision are identified.
3. Ⓓ Education, licensure/registration, and other credentials required by laws and regulations are copied by the hospital and maintained for each medical staff member in their personnel record or in a separate credential record.
4. All credentials required by hospital policy are copied by the hospital and maintained for each medical staff member in their personnel record or in a separate credential record.

Standard SQE.05.01

Medical staff members' education, licensure/registration, and other credentials required by laws and regulations and the hospital are verified and kept current.

Intent of SQE.05.01

Maintaining current verifications of medical staff credentials helps minimize safety risk to patients by ensuring that medical staff members are credentialed and meet all the qualifications to direct and provide patient care.

Verification

Verification is the process of checking the validity and completeness of a credential from the source that issued the credential. This process can be accomplished in the following ways:

1. An inquiry to a secure online database of, for example, those individuals licensed in the hospital's city or country
2. Documenting a telephone conversation with the issuing source
3. Corresponding via e-mail or conventional postal letter inquiry with the source

Verification of credentials from outside the country may be more complex and, in some cases, not possible. There should, however, be evidence of a credible effort to verify the credential. A credible effort is characterized by multiple (at least two within 60 days) attempts by various methods (for example, phone, e-mail, letter) with documentation of the attempts and result(s).

The three following situations are acceptable substitutes for a hospital performing primary source verification of credentials:

1. **Applicable to hospitals overseen directly by governmental bodies,** the government's verification process, supported by the availability of published governmental regulations about primary source verification; plus, government licensure, or equivalent such as a registration; and the granting of specific status (for example, consultant, specialist) are acceptable. As with all third-party verification processes, it is important to verify that the third party (for example, a government agency) implements the verification process as described in policy or regulations and that the process meets the expectations described in these standards.
2. **Applicable to all hospitals,** an affiliated hospital that has already conducted primary source verification of the medical staff applicant is acceptable as long as the affiliated hospital has current Joint Commission International (JCI) accreditation with "full compliance" on its verification process found in SQE.05.01, MEs 1 and 2. *Full compliance* means the hospital's Official Survey Findings Report indicates that all measurable elements are met, or any measurable element(s) required to be addressed by Strategic Improvement Plan (SIP) actions have been addressed and are now in full compliance.
3. **Applicable to all hospitals,** the credentials have been verified by an independent third party, such as a designated, official, governmental, or nongovernmental agency, as long as the following conditions apply: Any hospital that bases its decisions in part on information from a designated, official, governmental, or nongovernmental agency should have confidence in the completeness, accuracy, and timeliness of that information. To achieve this level of confidence in the information, the hospital should evaluate the agency providing the information initially and then periodically thereafter to ensure that JCI standards continue to be met.

The hospital has a process that ensures that the credentials of each contract medical staff have also been collected, verified, and reviewed to ensure current medical competence prior to assignment. Various methods can be used to conduct primary source verification. Examples include secure websites, documented phone confirmation from the source, written confirmation, and third parties, such as a designated, official, governmental, or nongovernmental agency. The hospital collects and maintains a record of each medical staff member's credentials. The records contain current licenses when regulations require periodic renewal. There is documentation of training related to any additional competencies.

It is important to understand the process for issuing select credentials. Information to consider when determining the issuance of credentials includes the following:

- Does the government agency that issues the license to practice base its decision on any or all of the following?
  - Verification of education
  - An examination of competence
  - Training by a medical specialty association, or membership
  - Payment of fees

- If admission to a specialty education program is based on verification of education and experience to date, the hospital does not need to verify education again.
- The process used by the government agency is documented by the hospital.
- The hospital must perform its own verification if the hospital does not have direct knowledge of the process used by the agency to verify education or has never had an opportunity to verify that the agency carries out the process as described.

Exception for SQE.05.01, ME 1, for initial surveys only. At the time of the initial JCI accreditation survey, hospitals are required to have completed primary source verification for new medical staff members who joined the medical staff within the twelve (12) months leading up to the initial survey. During the twelve (12) months following the initial survey, hospitals are required to complete primary source verification for all other medical staff members. This process is accomplished over the 12-month postsurvey period according to a plan that places priority on the verification of the credentials of active medical staff providing high-risk services.

Note: This exception refers only to the verification of credentials. All medical staff members must have their credentials collected and reviewed, and their privileges granted. A "phasing in" of this process is not acceptable.

Measurable Elements of SQE.05.01

1. Education, licensure/registration, and other credentials required by laws and regulations or issued by recognized education or professional entities as the basis for clinical privileges are verified from the original source that issued the credential.
2. Additional credentials required by hospital policy are verified from the source that issued the credential when required by hospital policy.
3. When third-party verification is used, the hospital verifies that the third party (for example, a government agency) implements the verification process as described in hospital policy and/or laws and regulations and that the process meets the following expectations:
   - The hospital verifies that the third party implements the verification process as described in hospital policy or regulations and that the process meets the expectations described in these standards.
   - The affiliated hospital that has already conducted primary source verification of the medical staff applicant is acceptable if the affiliated hospital has current Joint Commission International (JCI) accreditation with "full compliance" on its verification process found in SQE.05.01, MEs 1 and 2.
   - The hospital that bases its decisions in part on information from a designated, official, governmental, or nongovernmental agency must evaluate the agency providing the information initially and then periodically thereafter to ensure that JCI standards continue to be met.

Standard SQE.05.02

There is a uniform decision process for the initial appointment of medical staff members and others permitted to practice independently.

Intent of SQE.05.02

Established processes and select criteria ensure validation in the granting of appointments for medical staff.

Appointment is the process of reviewing an initial applicant's credentials to decide if the individual is qualified to provide patient care services that the hospital's patients need, and the hospital can support with qualified staff and technical capabilities. For initial applicants, the information reviewed is primarily from outside sources. Hospital policy identifies the individuals or mechanism accountable for this review, any criteria used to make decisions, and how decisions will be documented. Hospital policy identifies the process of appointment of medical staff for emergency needs or a temporary period. Emergency or temporary appointments and identification of privileges are not made until, at minimum, licensure has been verified.

Medical staff membership may not be granted if the hospital does not have the appropriate resources (that is, special medical equipment or staff) to support the professional practice of the individual. For example, a nephrologist seeking to provide dialysis services at the hospital may not be granted medical staff membership if the hospital does not provide such services.

Finally, when an applicant's licensure/registration has been verified from the issuing source, but other documents—such as education and training—have yet to be verified, the individual may be granted medical staff membership, and privileges may be identified for the applicant for a period not to exceed 90 days. Under such circumstances, these individuals may not practice independently and require supervision until all credentials have been verified. Supervision is clearly defined in hospital policy as to level and conditions and is not to exceed 90 days.

Measurable Elements of SQE.05.02

1. Medical staff appointments are made consistent with hospital policy and are consistent with the hospital's patient population, mission, and the care, treatment, and services provided.
2. Appointments are not made until at least licensure/registration has been verified from the primary source, and the medical staff member then provides patient care services under supervision until all credentials required by laws and regulations have been verified from the original source, up to a maximum of 90 days.
3. Ⓓ The method of supervision, frequency of supervision, and accountable supervisors are documented in the credential record of the individual.

Medical Staff Appointment and Privileges

Standard SQE.06.00

The hospital has a standardized, objective, evidence-based process to grant or deny privileges for medical staff members and others permitted to practice independently.

Intent of SQE.06.00

Privileging is the validation of a medical staff member's current clinical competence by the health care organization for the determination of what scope of clinical services the medical staff member will be authorized to perform. Privileging is a critical process that protects the safety of patients and advances the quality of the hospital's clinical services. The hospital establishes a uniform process to manage the applications for the granting, renewal, or revision of medical staff clinical privileges to ensure that the expectations for the appointment of medical staff membership are consistently followed. Considerations for clinical privilege delineation at initial appointment include the following:

Decisions regarding a medical staff member's clinical competence and clinical privileges are based primarily on information and documentation received from sources outside the hospital. The sources may include the following:

- Specialty education programs
- Letters of recommendation from previous medical staff appointments and/or close colleagues
- Any quality data that may be released to the hospital

Sources of information, other than those from educational institutions such as medical specialty programs, are not verified from the source unless required by hospital policy. These sources are used to identify the areas of presumed competence. Ongoing professional practice evaluation validates the areas of presumed competence.

There is no one best way to delineate which clinical activities the new medical staff member is privileged to perform. Specialty training programs may identify and list the general competencies of that specialty in areas of

diagnosis and treatment—with the hospital assigning privileges to diagnose and treat patients in those specialty competency areas. Other organizations may choose to list out in detail each type of patient and treatment procedure. Within each specialty area the process of privilege delineation is uniform; however, this process may not be the same in all specialty areas. For example, the privileges will be different for general surgeons, pediatricians, dentists, or radiologists. The process for privilege delineation will be standardized within each specialty group. The privilege delineation identifies which "specialty" services can be provided by family practitioners, primary care practitioners, and others who provide a variety of general medicine, obstetrics, pediatrics, and other services.

The decision as to how clinical privileges are delineated in a specialty area is linked with other processes, including the following:

- Selection by the department/service leaders of what processes are to be monitored through data collection
- Use of those data in the ongoing professional practice evaluation process of the medical staff in the department/service
- Use of the monitoring data in the process of reappointment and the renewal of privileges

In addition to the privileges granted in relation to the individual's education and training, the hospital identifies high-risk areas for which the medical staff member is explicitly granted such privileges or denied such privileges, including the following examples:

- Administration of chemotherapeutic agents
- Other classes of high-risk drugs
- High-risk procedures

The high-risk procedures, drugs, or other services are identified by each specialty area and evident in the privilege delineation process. Finally, some procedures may be high risk due to the instrumentation used, such as robotic and other computerized or remotely operated surgical or therapeutic equipment. Also, implantable medical devices require skills in implantation, calibration, and monitoring for which privileges should be specifically granted. Privileges are not granted if the hospital does not have the special medical equipment or staff to support the exercise of a privilege. For example, a nephrologist competent to do dialysis, or a cardiologist competent to insert stents, are not privileged for these procedures if the hospital does not provide such services. Finally, when an applicant's licensure/registration has been verified from the issuing source, but other documents—such as education and training—have yet to be verified, privileges are identified for the applicant. However, these applicants may not practice independently until all credentials have been verified by the processes described above. Such supervision is clearly defined in hospital policy as to level, conditions, and duration.

Hospital policy, laws and regulations, and/or other documents may stipulate that, in an emergency, any medical staff member with clinical privileges is permitted to provide any type of patient care, treatment, and services necessary as a lifesaving measure or to prevent serious harm—regardless of their medical staff status or clinical privileges—provided that the care, treatment, and services provided are within the scope of the individual's license.

The clinical privileges of all medical staff members are made available by printed copy, electronic copy, or other means to individuals or locations (for example, operating room, emergency department) in the hospital where the medical staff member will provide services. The medical staff member is provided a copy of their clinical privileges. Updated information is communicated when the clinical privileges of a medical staff member change.

Measurable Elements of SQE.06.00

1. Ⓓ The privilege delineation process used by the hospital meets the following criteria:
   - Standardized, objective, and evidence-based
   - Documented in hospital policies
   - Active and ongoing as the credentials of medical staff members change
   - Followed for all classes of medical staff membership
   - Effectiveness of the process can be demonstrated.
2. Ⓓ The hospital establishes criteria that determine a medical staff member's ability to provide patient care, treatment, and services within the scope of the privilege(s) requested, including evaluation of the following:
   - Current licensure and/or certification, as indicated, verified with the primary source
   - The applicant's specific relevant training, verified with the primary source
   - Evidence of physical ability to perform the requested privilege
   - Data from professional practice review by an organization(s) that currently privileges the applicant (if available)
   - Peer and/or faculty recommendation
   - When renewing privileges, review of the medical staff member's performance within the hospital
3. The clinical privileges of all medical staff members are made available to those individuals or locations in the hospital in which the medical staff member will provide services.
4. Each medical staff member provides only those services that have been specifically granted by the hospital.
5. The hospital implements a process to respond to a patient's request for additional information about the medical staff member responsible for their care.

Standard SQE.06.01

Hospital leaders grant temporary clinical privileges to medical staff for a limited period of time and for circumstances as defined by hospital policy.

Intent of SQE.06.01

Temporary clinical privileges to a medical staff member may be granted by hospital leaders for specified reasons. These temporary privileges are for a limited time for circumstances defined by hospital policy and consistent with laws and regulations. There are two circumstances in which temporary privileges may be granted. Each circumstance has different criteria for granting privileges. The circumstances for which the granting of temporary privileges is acceptable are as follows:

- To fulfill a specific patient care, treatment, and service need
- When an applicant for new privileges with a complete application that raises no concerns is awaiting review and approval by the medical staff executive committee and the governing body

An applicant for new privileges is defined as an individual who meets the following criteria:

- Is applying for clinical privileges at the hospital for the first time
- Currently holds clinical privileges and is requesting one or more additional privileges
- Is in the reappointment/reprivileging process and is requesting one or more additional privileges

Hospital policy, laws and regulations, and/or other documents may stipulate that, in an emergency, any medical staff member with clinical privileges is permitted to provide any type of patient care, treatment, and services necessary as a lifesaving measure or to prevent serious harm—regardless of their medical staff status or clinical privileges—provided that the care, treatment, and services provided are within the scope of the individual's license.

Measurable Elements of SQE.06.01

1. Ⓓ Temporary privileges are granted to meet a specific patient care need for the time period defined in hospital policy.
2. When temporary privileges are granted to meet a specific need, the organized medical staff verifies current licensure and current competence.
3. Ⓓ Temporary privileges of applicants for new privileges may be granted while awaiting review and approval by the organized medical staff upon verification of the following:
   - Current licensure
   - Relevant training or experience
   - Current competence
   - Ability to perform the privileges requested
   - Other criteria required by applicable laws and regulations
   - A query and evaluation of any relevant medical staff data bank or platform information, if applicable
   - A complete application
   - No current or previously successful challenge to licensure or registration
   - No subjection to involuntary termination of medical staff membership at another organization
   - No subjection to involuntary limitation, reduction, denial, or loss of clinical privileges
4. Ⓓ All temporary privileges are granted by the designated hospital leader per hospital policy.
5. Ⓓ All temporary privileges are granted on the recommendation of the medical staff leader or authorized designee per hospital policy.
6. Temporary privileges for applicants applying for new privileges are granted for a maximum of 120 days.

Standard SQE.06.02

At minimum every three years, the hospital decides to grant, deny, and/or modify requested medical staff membership and clinical privileges.

Intent of SQE.06.02

The hospital determines if medical staff membership and clinical privileges are to continue with or without modification. Explanations of terms and expectations found in these standards are as follows:

Reappointment

Reappointment is the process of reviewing, at least every three years, the medical staff member's record to verify the following:

- Active licensure
- Medical staff member is not compromised by disciplinary actions of licensing and certification agencies.
- Record contains sufficient documentation for seeking new or expanded privileges or duties in the hospital.
- Medical staff member is physically and mentally able to provide patient care and treatment without supervision.

The information for this review is collected from the internal, ongoing professional practice evaluation of the medical staff members, as well as from external sources such as regulatory or professional organizations or agencies. Hospital policy identifies the individual (such as the leader of a specialty service) or mechanism (such as a medical staff or department office when a department/service leader is not present or accountable for this review), any criteria used to make decisions, and how decisions will be documented. The information in the credential record of a medical staff member should be reviewed on an ongoing basis.

For example, when a medical staff member presents a certificate of achievement related to an advanced degree or advanced specialty training, the new credential should be immediately verified from the issuing source. Similarly, when an outside agency investigates a sentinel event related to a medical staff member and issues sanctions, this information should be used promptly to reevaluate the clinical privileges of the medical staff member. To ensure that medical staff records are complete and accurate, the records are reviewed at least every three years, and a note in the record indicates any actions taken or that no action is necessary and the appointment to the medical staff continues.

Considerations for clinical privilege delineation at reappointment include the following:

- Medical staff members may be granted additional privileges based on advanced education and training. The education and training are verified from the source providing the education or training or issuing the credential. The full exercise of the added privilege may be delayed until the verification process is complete or when there is a required period of supervised practice prior to granting an unrestricted new privilege; for example, a required number of supervised cases of robotic surgery.
- Medical staff members may have their privileges continued, limited, reduced, or terminated based on the following:
  - Results of the ongoing professional practice review process
  - Limitations placed on the individual's privileges by an outside professional, governmental, or regulatory agency
  - Hospital's findings from an evaluation of a sentinel or other event
  - Health of the medical staff member
  - Request of the medical staff member

Measurable Elements of SQE.06.02

1. The hospital determines if medical staff membership and clinical privileges are to continue with or without modification based on the ongoing professional practice evaluation of the medical staff member at least every three years.
2. Ⓓ Each medical staff member's personnel file contains evidence that all credentials are current.
3. Ⓓ Medical staff member personnel files contain any credentials obtained subsequent to initial appointment and include evidence of primary source verification prior to use in modifying or adding to clinical privileges.
4. Medical staff members and other clinical staff requesting privileges are notified regarding the granting decision. In the case of privilege denial, the applicant is informed of the reason for denial.
5. The hospital has implemented a process to disseminate all granting, modification, or restriction decisions to all appropriate internal and external persons or entities, as defined by hospital policy and applicable laws and regulations.
6. Ⓓ The renewal decision is documented in the medical staff member's credential record and includes the identification of the reviewer and any special conditions identified during the review.

Medical Staff Evaluations

Standard SQE.07.00

The hospital uses an ongoing standardized process to evaluate the quality and safety of the patient care provided by each medical staff member.

Intent of SQE.07.00

The information collected during the ongoing professional practice evaluation process is factored into decisions to maintain, revise, or revoke an existing privilege(s) prior to or at the end of the three-year renewal decision.

Definitions and further explanations of terms and expectations found in these standards are as follows:

Ongoing Professional Practice Evaluation

The process of ongoing data collection for the purpose of assessing a medical staff member's clinical competence and professional behavior. The department/service leader is responsible for the integration of the data and information on medical staff and taking appropriate actions at different stages in the process. Examples of actions include the following:

- Immediate: to counsel the staff member, place the staff member under supervision, limit privileges, or other measures intended to limit risks to patients and improve quality of care and patient safety
- Longer-term: synthesizing the data and information into a recommendation for continued medical staff membership and clinical privileges
- Other: note to other medical staff members the benchmark behaviors and clinical results evident in the data and information of the medical staff member

The ongoing professional practice evaluation (OPPE) of medical staff members provides critical information to the processes of maintaining medical staff membership and granting clinical privileges. Although three-year cycles are required for renewing medical staff membership and clinical privileges, the process is intended to be ongoing, and data are reviewed at least annually. Critical quality and patient safety incidents can arise if a medical staff member's clinical performance issues are not communicated and acted on when they arise.

The process of ongoing professional practice evaluation is intended to accomplish the following:

- Improve individual practices as they relate to high-quality, safe patient care.
- Provide the basis for reducing variation within a department/service through comparisons among colleagues and the development of practice guidelines and clinical protocols.
- Provide the basis for improving the results of the entire department/service through comparisons with external benchmark practices and published research and clinical results.

The ongoing professional practice evaluation of medical staff members encompasses three general areas—behaviors, professional growth, and clinical results.

Behaviors

Medical staff members are models and mentors in creating a culture of safety in a hospital. A safe culture is characterized by full participation by all staff, without fear of reprisal or marginalization. Safe cultures also include high respect between professional groups in which disruptive and other behaviors do not occur. Staff members are able to report concerns about safety or quality of care without fear of retaliation or marginalization from health care organization staff or leaders. Staff feedback through surveys and other mechanisms can shape desired behaviors and can support medical staff role models.

An evaluation of behaviors can include the following:

- Evaluation of whether a medical staff member understands and supports the hospital's code of conduct and the identification of acceptable and unacceptable behaviors
- Absence of reported unacceptable behaviors by the medical staff member
- Collection, analysis, and utilization of data from staff surveys and other sources regarding the safety culture in the hospital

The ongoing professional practice evaluation process should indicate the relevant achievements and challenges of the medical staff member in efforts to be a full participant in a safety culture.

Professional Growth

Medical staff members grow and mature as the organizations in which they practice evolve and introduce new patient groups, technologies, and clinical science. Each medical staff member will reflect growth and improvement in the following seven important dimensions of health care and professional practice:

- **Patient care:** including provision of patient care that is compassionate, appropriate, and effective for health promotion, disease prevention, treatment of disease, and care at the end of life
  - Examples of potential measures: frequency of preventive services and reports/complaints from patients and families
- **Medical/clinical knowledge:** including knowledge of established and evolving biomedical, clinical, epidemiologic, and social-behavioral sciences, as well as the application of knowledge to patient care and the education of others
  - Examples of potential measures: application of clinical practice guidelines, including the adaptation and revision of guidelines; participation in professional conferences; and publications
- **Practice-based learning and improvement:** including use of scientific evidence and methods to investigate, evaluate, and continuously improve patient care based on self-evaluation and lifelong learning
  - Examples of potential measures: self-motivated clinical inquiry/research, acquiring new clinical privileges based on study and acquiring new skills, and full participation in meeting professional specialty requirements or continuing education requirements of licensure
- **Interpersonal and communication skills:** including establishment and maintenance of effective exchange of information and collaboration with patients, their families, and other members of health care teams
  - Examples of potential measures: participation in teaching rounds, team consultations, team leadership, and patient and family feedback
- **Professionalism:** including commitment to continuous professional development, ethical practice, an understanding and sensitivity to diversity, and a responsible attitude toward patients, their profession, and society
  - Examples of potential measures: an opinion leader within the medical staff on clinical and professional issues, service on an ethics panel or discussions of ethical issues, keeping appointed schedules, and community participation
- **System-based practices:** including awareness of and responsiveness to the larger contexts and systems of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care
  - Examples of potential measures: understanding the meaning of frequently used hospitalwide systems, such as the medication system; and awareness of the implications of the overuse, underuse, and misuse of systems
- **Stewardship of resources:** including understanding the need for stewardship of resources, and practicing cost-conscious care, including avoiding the overuse and misuse of diagnostic tests and therapies that do not benefit patient care but add to health care costs
  - Examples of potential measures: participation in key purchasing decisions within the medical staff member's practice area, participating in efforts to understand appropriate use of resources, and being aware of the cost to patients and payers of the services provided

The ongoing professional practice evaluation process should recognize the relevant areas of achievement and potential improvement of the medical staff member in these professional growth areas.

Clinical Results

The ongoing professional practice evaluation process for a medical staff member reviews information common to all medical staff members as well as specific information related to the clinical privileges of the member and the services provided by their specialty. This evaluation is supported by a variety of data sources, including electronic and paper records, observations, and peer interactions.

Hospitalwide Data Sources

Hospitals collect a variety of data for use in management; for example, reporting to health authorities to support allocation of resources or payment of services. Examples of potential sources of data include length of stay, frequency of diagnostic testing, blood usage, and usage of certain drugs.

Department-Specific Data Sources

Data are also collected at the level of each department/service. The department/service leader sets the priorities for measurement in the department for purposes of monitoring as well as improvement. The measures are specific to the services provided and the clinical privileges of the individual medical staff members within the department. Examples of potential department/service data include frequency of clinical procedures performed, complications, outcomes, and use of resources such as consultants, among others.

It is likely that organizations collect data on key services on the department level for which all or most department/service staff members have privileges. Thus, there is no one set of data that will suffice to monitor and evaluate all medical staff members. The choice of data, the frequency of monitoring and analysis, and the actual use of the data and documentation in the personnel record of the medical staff member are very specific to the department/service, to the relevant profession, and to the privileges of the medical staff member.

The medical staff member ongoing professional practice evaluation process achieves the following:

- Is standardized by type of medical staff member and/or department or clinical services unit.
- At least one review is conducted during a 12-month period, according to hospital policy, with the monitoring and evaluation of medical staff members intended as an ongoing process.
- Is conducted by the individual's department or service head, senior medical manager, or a medical staff review body.
- Results of reviews, actions taken, and the impact of those actions on privileges (if any) will be documented in the medical staff member's record.

Measurable Elements of SQE.07.00

1. Ⓓ All medical staff members are included in an ongoing professional practice evaluation process and standardized evaluation at the department/service level as defined by hospital policy.
2. Ⓓ The ongoing professional practice evaluation process identifies areas of achievement and potential improvement related to the behaviors, professional growth, and clinical results of the medical staff member, and the results are reviewed with objective and evidence-based information as available. These results are compared to other department/service medical staff members. (*See also* GLD.07.01, ME 3)
3. Ⓓ The data and information from the monitoring are reviewed at least every 12 months by the individual's department or service head, senior medical manager, or medical staff body, and the results, conclusions, and any actions taken are documented in the medical staff member's credential record and other relevant records.
4. Hospitalwide and department/service data sources are used in ongoing evaluations of individual medical staff members. These data meet the following criteria:
   - Are collected in a manner that readily identifies the individual medical staff member.
   - Relates to the clinical practice of the individual medical staff member.
5. When the findings affect the appointment or privileges of the medical staff member, there is a process to act on the findings, and such "for cause" actions are documented in the medical staff member's record and are reflected in the list of clinical privileges. Notification is sent to those sites in which the medical staff member provides services.

Standard SQE.07.01

Hospital leaders define the circumstances requiring monitoring and evaluation of a medical staff member's professional performance.

Intent for SQE.07.01

Focused professional practice evaluation (FPPE) is defined as a process that evaluates the privilege-specific competence of the medical staff member who does not have documented evidence of competently performing the requested privilege(s) at the hospital. This process may also be used when a question arises regarding a currently privileged medical staff member's ability to provide safe, high-quality patient care. The focused evaluation process is defined by hospital policy and includes the time period of the evaluation and other criteria as indicated. The criteria that indicate the need for performance monitoring are clearly defined. These criteria can be single incidents or evidence of a clinical practice trend, and other existing privileges in good standing should not be affected by this decision.

A period of FPPE is required for all new privileges, including privileges requested by new applicants and all newly requested privileges for existing medical staff. Exemptions based on board certification, documented experience, or reputation are prohibited. The focused professional practice evaluation accomplishes the following:

- Evaluates the medical staff member and other clinical staff without current performance documentation at the organization.
- Evaluates the medical staff member and other clinical staff in response to concerns regarding the provision of safe, high-quality patient care.
- Develops criteria for extending the evaluation period.
- Communicates to the appropriate parties the evaluation results and recommendations based on results
- Implements changes to improve performance.

FPPE begins at the time privileges are granted, regardless of which process was followed (for example, temporary, expedited, full privileges). Both qualitative and quantitative data are considered when designing the process.

Qualitative or "categorical" data are nonnumerical data often collected through methods such as observations, discussions, record review, monitoring of diagnostic and treatment techniques, and so on. Examples may include the following:

- Description of procedures performed
- Periodic record review:
  - Quality/accuracy of documentation
  - Appropriateness of tests ordered / procedures performed
  - Patient outcomes
- Types of patient complaints
- Code of conduct breaches
- Peer recommendations
- Discussion with individuals involved in patient care, treatment, or services (for example, consultants, surgical assistants, nursing, administration)

Quantitative data often represent a certain quantity, amount, or range and are generally expressed as a unit of measure. Contrasted with qualitative data, quantitative data are generally in the form of numerical quantities such as measurements, counts, percentage compliant, ratios, thresholds, intervals, time frames, and the like. Examples may include the following:

- Length of stay trends
- Postprocedure infection rates
- Periodic record review

  - Date/time/signature entries
  - Telephone orders/verbal orders authenticated within defined time frame
  - Presence/absence of required information (for example, history and physical assessments elements)
- Number of history and physical assessments/updates completed within 24 hours after patient admission/registration
- Compliance with medical staff laws, regulations, policies, and the like
- Documenting the minimum required elements of a history and physical assessments/update
- Compliance with measures

Data could represent either (or both) qualitative and quantitative information, depending on how the data are used. Relevant information resulting from the focused evaluation process is integrated into performance improvement activities, consistent with the hospital's policies and procedures that are intended to preserve confidentiality and privilege of information. The data source used for the FPPE process must include medical staff member activities performed at the organization where privileges have been requested and may include activities performed at any location under the hospital's accreditation. In a multihospital system, where each hospital operates independently under separate accreditations, data from those hospitals may be used to supplement local data. In addition, when medical staff activity at the medical staff member's main hospital is low or limited, supplemental data may be used from another JCI organization where the medical staff member holds the same privileges. The use of supplemental data may NOT be used in lieu of a process to capture local data. Organizations choosing to use supplemental data should assess and determine the supplemental data's relevance, timeliness, and accuracy.

Measurable Elements of SQE.07.01

1. A period of focused professional practice evaluation is implemented for all initially requested privileges.
2. Criteria are developed for evaluating the performance of the medical staff member or other medical staff when issues affecting the provision of safe, high-quality patient care are identified.
3. The performance monitoring process is clearly defined and includes each of the following elements:
   - Criteria for conducting performance monitoring
   - Method for establishing a monitoring plan specific to the requested privilege
   - Method for determining the duration of performance monitoring
   - Circumstances under which monitoring by an external source is required
4. Ⓓ Focused professional practice evaluation is consistently implemented in accordance with the criteria and process defined by hospital policy.
5. Ⓓ The measures employed to resolve performance issues are defined in writing and implemented.

Section IV: Global Health Impact Standards

Global Health Impact (GHI)

Overview

The increasing severity of climate-based events directly affects health care organizations' operations as they react to these events and face disruptions in care and challenges in patient safety, the actual quality of care, and managing unexpected costs. The repercussions of extreme heat, poor water quality, flooding, wildfires, air pollution, and other unexpected environmental events are making people sicker and escalating the cost of providing care.

The "Global Health Impact" chapter, which was developed in collaboration with the International Hospital Federation's Geneva Sustainability Centre, provides an independent evaluation of health care organizations' efforts to improve their environmental footprint. The chapter aims to advance decarbonization in health care by helping organizations set and maintain goals to reduce their greenhouse gas emissions. It is understood that health care organizations vary in their efforts to establish environmental sustainability strategies.

The documentation icon—Ⓓ—is used to identify data collection and documentation requirements that are required during the survey.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Governance, Tracking, and Reporting

GHI.01.00 Hospital leaders ensure that environmental strategies are formally included and acted on as part of the organization's operations and governance.

Employee Engagement and Empowerment

GHI.02.00 Hospital leaders establish mechanisms to raise awareness and to engage and train employees on climate change and health across the organization.

Use of Environmental Resources, Green Operations, and Process

GHI.03.00 Hospital leaders develop and start to implement a plan to measure and reduce the use of materials and environmental resources, including energy, water, and emissions.

Procurement and Supply Chain

GHI.04.00 Hospital leaders implement actions to reduce the environmental impact of the supply chain across all operations and identify areas to reduce the unnecessary use of supplies within the hospital.

Infrastructure and Service Resilience

GHI.05.00 Hospital leaders assess the environmental risks and scenarios that may affect service delivery, hospital operations, and patient populations, with plans to comply with local emergency preparedness recommendations and rules, including those required by property insurance coverage.

Standards, Intents, and Measurable Elements

Governance, Tracking, and Reporting

Standard GHI.01.00

Hospital leaders ensure that environmental strategies are formally included and acted on as part of the organization's operations and governance.

Intent of GHI.01.00

To decarbonize and increase the resilience of a hospital, actions must be taken at all levels of the organization. This requires an effective strategy, stewardship, accountability, and leadership at the hospital leaders and board levels. This will allow the organization to do the following:

- Respond to country legislation and regulation in relation to climate and environmental issues.
- Identify the priorities for the organization.
- Inspire and support an organizational culture that takes environmental sustainability into account and creates a sense of ownership and shared goal by regularly communicating about it across the hospital.
- Engage all stakeholders in the process and clearly communicate what their specific role is, how it impacts their daily work and practices, and which positive outcomes are expected.
- Involve hospital governing bodies to ensure reporting, monitoring, and improvement of the strategies.

Growing evidence demonstrates the impact of climate change and disruptive climate events on health and delivery of health care. Therefore, it is part of hospitals' mission to fight adverse effects of climate change, and work toward more sustainable services by addressing it as an integral part of health care delivery. In addition to decarbonizing the sector and making it more resilient, many co-benefits have been identified, including positive impacts on health, patient experience, and operational performance. An increasing set of evidence also demonstrates the relevance of sustainability initiatives with quality of care, and adequacy for patient safety. In addition, environmental sustainability initiatives provide opportunities for financial savings and have been identified as an efficient way to support long-term financial sustainability of hospitals. The type of interventions, impacts, and benefits will depend on the hospital's size, setting, and interventions already in place.

A large scope of actions and processes can be implemented at the hospital leaders and board levels to drive this process forward. Examples of such actions include the following:

- Formally respond to country-specific legislation and regulation in relation to climate and environmental issues.
- Formally include environmental-sustainability goals in official and publicly available documents, including the organization's mission statement, values, charters, and other governance documents (this reinforces accountability and creates a sense of a shared goal throughout the organization).
- Adopt indicators to measure, track, and report on progress through existing frameworks to monitor and adjust over time.
- Increase the efficiency and active accountability and engagement of top management through the appointment of a dedicated person or group of people to oversee the process.

Beyond designating these people, it is essential to support them in their work and set targets incorporating environmental regulations to ensure an effective strategy. Their role is to develop a plan of action including short-, medium-, and long-term objectives; to identify the required resources; to oversee the development, implementation, and evaluation of the strategy; and to work and communicate with relevant stakeholders. This person should have relevant educational and/or professional experience to assume such a role.

Measurable Elements of GHI.01.00

1. Ⓓ Hospital leaders include environmental sustainability and low-carbon and resilient care on their board agenda to discuss at least once a year, with reporting of progress, declaration of resources allocated, and assessment of the implementation of the strategies. Minutes reflect actions taken and any follow-up on those actions.
2. Ⓓ Progress on environmental strategies is included in the organization's annual report for wider public visibility and accountability to the community and other stakeholders.
3. Hospital leaders appoint or designate, and annually evaluate the performance of, a person in the lead role who reports to the board (for example, Chief Sustainability Officer) to ensure that environmental strategies are part of the organization's priorities and are effectively implemented in tracking and governance processes. (*See also* GLD.06.00, ME 1)
4. The person appointed or designated as having the lead role is responsible for the following:
   - Defining the hospital's sustainability plan, strategies, and goals, in consultation with relevant stakeholders
   - Overseeing the implementation of processes related to environmental sustainability
   - Reporting to the hospital's leaders and board to present the progress made and take action on resulting discussion points
   - Producing reports and communications pieces for relevant stakeholders

Employee Engagement and Empowerment

Standard GHI.02.00

Hospital leaders establish mechanisms to raise awareness and to engage and train employees on climate change and health across the organization.

Intent of GHI.02.00

Employees have a role to play in the transition to low-carbon, resilient, and sustainable health care. In order to support their staff in implementing new or different practices and regulations, hospital leaders must provide the knowledge and tools to facilitate ownership and make staff agents of change.

Two key mechanisms can be used for engaging organization staff on climate change initiatives:

- A favorable and engaging organizational culture: An *organization culture* represents the "mindsets, beliefs and values that members of the organization share in common, and which shape the behaviours [and] practices . . . of the organization" (Prajogo and McDermott, 2005). Good leadership and focus on the customer (patient) are essential components to engage employees and rally them toward a common objective. Therefore, hospital leaders should emphasize that the strategy toward environmentally sustainable health care is a collective effort and that it can contribute to improved health outcomes and patient experience. This can be achieved through relevant and regular communications from hospital leaders to the staff, and mechanisms to allow the staff to share ideas and actively contribute to the sustainability strategy. The hospital setting being a complex and unpredictable environment, flexibility and a focus on relationships are key competencies to maintain a fruitful organizational culture.
- Training and education are key to providing the knowledge, tools, competencies, and guidance to the employees. Some content will be the same for all staff, such as basic knowledge about climate and health, and how this is included in hospital objectives. Those training courses should include content related to the hospital's setting, including the local or regional climate impacts and related health outcomes, potential environmental scenarios for the hospital, and vulnerabilities identified in the hospital's patient population. Some training courses may be more targeted to focus on specific roles and practices to adjust or implement, as in the following examples:

- Clinical staff will learn about alternatives to products generating a lot of waste (for example, nonsurgical gloves) or to anesthetic gases with high carbon emission intensity (for example, desflurane).
- Department managers will learn specific leadership competencies to support them and their teams to reduce waste and include sustainable behaviors in their daily practice.
- Cleaning employees will learn about the health and environmental impact of chemicals used in cleaning products and about the efficacy of alternatives.

"Green training" and engagement can have other beneficial outcomes for the organization, including the following:

- Providing a sense of challenge, which motivates employees to engage
- Greater satisfaction in jobs, when supported by the employer
- Satisfying professional experience for employees
- Responding to younger professionals' need to know their organization is positively engaged in these issues and help with workforce retention

Therefore, they can boost company morale, lower turnover rates, and increase the organization's overall performance and quality of service.

Measurable Elements of GHI.02.00

1. All medical and nonmedical staff across the hospital undergo specific yearly training sessions, aimed at providing basic knowledge about climate change, its impact on human health, and good practices they can implement for environmentally sustainable and resilient health care.
2. Hospital leaders communicate to employees about environmental sustainability and the organization's low-carbon and resilient care goals and activities.
3. A process is implemented for collecting staff ideas, which are reviewed by the lead person for sustainability to identify potential new initiatives and priorities.
4. Ⓓ A module on climate change, environmental sustainability, and low-carbon and resilient care is included in new employee orientation/onboarding. (*See also* SQE.01.06, ME 1)

Use of Environmental Resources, Green Operations, and Processes

Standard GHI.03.00

Hospital leaders develop and start to implement a plan to measure and reduce the use of materials and environmental resources, including energy, water, and emissions.

Intent of GHI.03.00

Hospitals must work across all emission scopes to address decarbonization and increased resilience and environmental sustainability. It is also essential to consider the use of natural resources as well as of materials. To this end, one of the primary tasks of the designated lead person for environmental sustainability should be to define a plan. This can be achieved through the following steps:

- Establishing and understanding the baseline for the scope of assessment and action
- Defining and prioritizing short- and long-term interventions
- Developing a plan for action and improvement
- Measuring, tracking, evaluating, and reporting the improvements toward the defined targets

For any hospital, the origins of carbon dioxide emissions, or greenhouse gas (GHG) emissions, can be classified into three scopes:

- Scope 1 emissions are from sources directly owned or controlled by an organization (for example, on-site fuel combustion in boilers, furnaces, vehicles).
- Scope 2 are from purchases and use of electricity, steam, heating, and cooling generated elsewhere. By using the energy, an organization is indirectly responsible for the release of these GHG emissions.
- Scope 3 emissions include indirect emissions caused by an organization's value chain, in the upstream and downstream activities of an organization. Among others, this includes purchased goods and services, transportation, and distribution (upstream and downstream) as well as waste disposal.

Hospitals can conduct a carbon footprint assessment to identify emission "hotspots" that require deeper decarbonization actions. Several carbon footprint calculation tools exist for the health care sector, for hospitals in low- to high-income countries. Collecting the data and completing the full process may take several months. Therefore, it is highly recommended to implement measures that will accelerate engagement and decarbonization before finalizing the carbon footprint assessment.

Key areas of resource management are presented below:

Power generation and electricity are essential to run any health care facilities and to provide safe and high-quality care. However, climate change (including through disruptive climate events) will negatively impact access to electricity, and forces organizations to consider the way energy is being produced and used. Good planning and interventions can make hospitals more resilient to such events while reducing their carbon emissions:

- Some facilities invest in on-site power generation, rather than purchasing that energy through the grid. Common benefits of on-site power generation are the reduction of energy cost, reduction of greenhouse gas emissions (particularly in the case of renewable energy generation), and improved reliability of supply.
- All organizations should aim to consume and produce energy from renewable energy sources. Renewable energy is derived from natural sources that are replenished at a higher rate than they are consumed. Common sources of renewable energy are sunlight, wind, geothermal energy, hydropower, ocean energy, and bioenergy. On the other hand, fossil fuels (coal, oil, and gas) are nonrenewable resources that take hundreds of millions of years to form and that can cause harmful greenhouse gas emissions, such as carbon dioxide.
- Rethinking buildings and infrastructure, including architecture, service designs, and space utilization, will also highly contribute to optimizing the use of energy while making the hospital more resilient and sustainable.

Climate change is accelerating water-related hazards and scarcity. Although some areas may be more impacted than others, organizations around the globe must implement solutions to conserve it. Health care facilities are directly concerned by water-safety issues as they will impact health care delivery, hygiene, and sanitation within the organization. Therefore, hospitals are recommended to measure their water consumption and implement solutions to optimize its supply and conservation. Good sewerage infrastructure and safe use of wastewater must also be managed, as they can increase the hospital's resilience while contributing to water, sanitation, and hygiene (WASH) targets.

Carbon emission reduction can also occur during health care delivery. A *low-carbon model* of care is a form of care delivery that generates less carbon emissions than alternatives available. It means that the carbon emissions impact of care delivery has been estimated to explicitly favor services or interventions that generate less carbon emissions and reduce energy use. A low-carbon model of care provision will be better at preventing illness, be leaner in service design and delivery, and promote the use of lower-carbon technologies (for example, telehealth, app-based). This carbon emission reduction also applies to pharmaceuticals, inhalers, and anesthetic gases. For example, Scotland has banned the use of desflurane due to the increased threat it poses to the environment. In addition, greening operating theatre practices can reduce energy use, supply usage, and waste generation which will lead to financial savings.

Supplies, and therefore, waste and emissions from pharmaceuticals and other chemicals used for treatments should also decrease through prescribing practices. It involves giving information to patients and clinical staff on the best treatment, with the use of the lowest effective dose for the shortest period of time, including drugs that have the smallest carbon footprint. Optimizing medications also involves addressing unnecessary prescribing, which reduces errors. Low-carbon prescriptions also include the use of alternatives such as psychotherapy, green prescribing, social prescribing, and lifestyle prescriptions.

Soft facility management, including cleaning practices, linen and laundry services, and waste management, also present many opportunities to reduce the use and waste of materials, energy, and chemicals. For example, cleaning can become chemical-free by using innovative microfiber mops and an adapted cleaning technique. This method can be fully applied or partially applied depending on the area of the hospital and safety-related issues. Benefits include cost savings, carbon reduction, decreased toxicity of wastewater, and improved health and well-being of patients and employees due to the reduction of respiratory diseases caused by chemical products.

For all of the above, alternatives keep emerging, and innovative approaches will be necessary to continue this effort.

Measurable Elements of GHI.03.00

1. Ⓓ Hospital leaders and managers develop a written measurable plan including targets and the monitoring thereof to reduce waste, carbon emissions, and the use of environmental resources.
2. Ⓓ The percentage of renewable energy (bought or self-produced) compared to the total energy consumption is identified and reported to the board on a yearly basis.
3. Hospital leaders implement actions to optimize water conservation and report the amount of water conserved to the board on a yearly basis.
4. Hospital leaders and managers can demonstrate yearly progress regarding the reduction of carbon emissions or negative environmental impacts of operations in at least one of the following soft facilities management areas:
   - Waste management
   - Cleaning practices
   - Linen and laundry services
5. Hospital leaders and managers contribute to reducing the carbon intensity of food and catering supplies; for example, by sourcing at least 50% of locally produced food whenever practicable and by providing vegetarian options on a daily basis.
6. Clinical practices are evaluated to reduce the environmental impact.

Procurement and Supply Chain

Standard GHI.04.00

Hospital leaders implement actions to reduce the environmental impact of the supply chain across all operations and identify areas to reduce the unnecessary use of supplies within the hospital.

Intent of GHI.04.00

It is estimated that medicines, medical equipment, and other supply chains can represent between 60% and 80% of a hospital's carbon footprint. This includes production, transport, and use and disposal of goods and services. However, despite those emissions being indirect, hospitals can play an active role in decreasing them. For example, this can be achieved by enhancing the way resources are used (for example, reduce, reuse, or even avoid), substituting for low-carbon and/or reusable initiatives, sourcing locally, working with suppliers to set targets, and leveraging their purchasing power to demand more sustainable products.

A growing number of international initiatives aim to promote sustainable procurement in the health care sector and guide hospitals to adopt sustainable practices and processes. These initiatives, illustrated by various examples and case studies, identify areas to do the following:

- Reduce their use of avoidable resources (for example, reducing the use of nonsurgical gloves where these are not necessary for infection control purposes).
- Improve and optimize the use of their current equipment (for example, conducting life cycle assessment or analysis to optimize the long-term use of imaging systems and other treatment devices). Life cycle assessments can also support decision-making when comparing the environmental impact of single-use items and reusable items, as well as associated cost savings.

The identification of unnecessary and avoidable supplies can take various forms and should demonstrate credible efforts. For example, identification efforts can be demonstrated through related audits and assessment, discussions as noted in minutes of meetings, and research on similar initiatives in other hospitals or organizations. Identification should lead to prioritization and translated into actions for implementation.

In addition to decarbonization, this can lead to improved patient experience and financial savings.

Measurable Elements of GHI.04.00

1. Ⓓ Climate- and environmental sustainability–criteria are included in the hospital procurement guidelines. (*See also* GLD.05.02, ME 3)
2. For any new contract with suppliers or vendors, department managers prioritize suppliers and vendors that have sustainability and carbon emission reduction objectives in place. (*See also* GLD.05.02, ME 3)
3. Hospital leaders and department managers identify opportunities to optimize processes within the hospital by identifying unnecessary and/or avoidable supplies in at least three of the following areas:
   - Pharmaceuticals and other chemicals used for treatments
   - Chemicals used for sterilizing, disinfecting, and cleaning purposes
   - Food and agricultural products
   - Medical devices
   - Hospital equipment and instruments
4. Hospital leaders and department managers implement actions to assess the benefits of reusable items instead of single-use materials in clinical and nonclinical areas. (*See also* PCI.03.01, ME 1)

Infrastructure and Service Resilience

Standard GHI.05.00

Hospital leaders assess the environmental risks and scenarios that may affect service delivery, hospital operations, and patient populations, with plans to comply with local emergency preparedness recommendations and rules, including those required by property insurance coverage.

Intent of GHI.05.00

The climate crisis has been recognized as the greatest threat to human health in the twenty-first century. It causes an increase in noncommunicable and infectious diseases, negatively impacts social and environmental determinants of health, and causes disruptive climate events (for example, floods, wildfires, landslides, strong winds), which can directly impact the health care delivery when and where they occur. For example, consequences may include the following:

- A sudden increase in the demand for health care services if the surrounding community is directly affected
- Damages to the infrastructure and facilities of the hospital

- Power cuts
- Disruption in the supply chain

Hospitals play a unique and essential role for their communities when facing those hazards and need to be able to provide uninterrupted care in those emergency situations.

Based on existing frameworks, hospitals should consider the following five areas to plan for all scenarios, adapt their infrastructures and services, and strengthen their resilience:

- Climate risks and community vulnerability assessment
- Land use, building design, and regulatory context
- Infrastructure protection and resilience planning
- Essential clinical care service delivery planning
- Environmental protection and ecosystem adaptations

A hospital's risk register, or equivalent document, records all risks that threaten the organization and its objectives. They may include or need to comply with local emergency preparedness guidelines or property insurance coverage. Due to the global nature of climate change impacts, environmental disruptive events should be included in all hospitals' risk registers.

These disruptive climate events are foreseen to become more frequent, and in locations where they didn't occur previously. Therefore, the risks and scenarios should be reassessed every three years to adjust and plan accordingly.

Measurable Elements of GHI.05.00

1. Ⓓ Climate change impacts are included in the hospital's risk register or equivalent document.
2. Ⓓ Hospital leaders develop a written plan of adaptive actions to mitigate current and future climate-related hazards and risks based on recent (that is, within the last three years) information, and progresses toward the organization's agreed targets. (*See also* FMS.09.00, MEs 1 and 2)
3. Ⓓ An assessment of the environmental risks, scenarios, and vulnerabilities within the communities is conducted every three years. The results are presented in a report and inform the plan of adaptive actions, which is updated accordingly. (*See also* FMS.09.00, ME 3)
4. Ⓓ Hospital leaders develop preparedness programs for adverse weather scenarios and disruptive events. The preparedness plan is tested and updated annually and includes measures taken to train the employees to respond to these scenarios. (*See also* FMS.02.00, ME 1; FMS.09.00, ME 1)

Section V: Academic Medical Center Standards

Academic Medical Center Standards

The Human Subjects Research Programs (HRP) and Medical Professional Education (MPE) standards for academic medical centers were developed and first published in 2012 to recognize the unique resource such centers represent for health professional education and human subjects research in their community and country. These standards also present a framework for including medical education and human subjects research into the quality and patient safety activities of academic medical centers. Unless deliberately included in the quality framework, education and research activities often are the unnoticed partners in patient care quality monitoring and improvement.

The standards are divided into two chapters, as medical education and clinical research are most frequently organized and administered separately within academic medical centers. For all hospitals meeting the eligibility criteria in the "Summary of Key Accreditation Policies" section of this publication, compliance with the requirements in these two chapters, in addition to the other requirements detailed in this 8th edition manual, will result in an organization being deemed accredited under the Joint Commission International (JCI) standards for academic medical centers.

Organizations with questions about their eligibility for academic medical center accreditation should contact JCI Accreditation's Central Office at jciaccreditation@jcrinc.com.

Human Subjects Research Programs (HRP)

Overview

Human subjects research is defined as research involving living individuals about whom an investigator obtains data through intervention or interaction with individuals and/or identifiable personal information. This type of research is a major commitment for hospitals that is integrated with the commitment to provide safe, high-quality care. The HRP standards require the governing entity and leaders in academic medical centers with research programs that conduct human subjects research to protect all participating subjects in accordance with international and national principles that govern clinical research. Research protocols involving human subjects are reviewed by an Institutional Review Board (IRB) or other research ethics review mechanism and receive ongoing oversight as necessary. Processes are established to oversee research involving hospital staff conducting the research and all research subjects, regardless of who or what entity sponsors the research. Hospital leaders establish program policies and processes that protect the rights of the human subject participants, identify the program scopes, specify sponsor responsibilities, and describe how the review process is conducted. The program policies also detail how any conflicts of interest applicable to the research and hospital will be managed. Those who conduct research in the organization meet the hospital's qualifications to do so and report all adverse events to the hospital's risk management/quality system in a timely manner. Vulnerable populations are considered when providing information on access to clinical research, clinical investigations, and clinical trials. Hospitals have the opportunity to integrate the research into their overall quality and patient safety program.

Standards

The following is a list of all standards for human subjects research for academic medical centers. The standards in this chapter are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Note: The requirements for Standard GLD.09.00 apply to all hospitals that conduct clinical research, regardless of whether the hospital is an academic medical center.

Leadership Accountabilities

HRP.01.00 Hospital leaders are accountable for the protection of human research subjects.

HRP.01.01 Hospital leaders establish the scope of the research program.

HRP.01.02 Hospital leaders establish a policy for sponsors of research to ensure their commitment to the conduct of ethical research.

HRP.01.03 When one or more of the research-related duties and functions of the sponsor are provided through an outside commercial or academic contract research organization, the accountabilities of the outside contract research organization are clearly defined.

HRP.01.04 Hospital leaders implement a process to provide the initial and ongoing review of all human subjects research.

Program Safety

HRP.02.00 The hospital manages conflicts of interest with research conducted at the hospital.

HRP.02.01 The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

HRP.02.02 The hospital informs patients and families about how to gain access to clinical research, clinical investigations, or clinical trials and includes protections for vulnerable populations to minimize potential coercion or undue influence.

Standards, Intents, and Measurable Elements

Leadership Accountabilities

Standard HRP.01.00

Hospital leaders are accountable for the protection of human research subjects.

Intent of HRP.01.00

Hospital leaders recognize their responsibility to protect the rights of human research subjects and are committed to promoting a safe environment for these patients.

Human subjects research is a complex and significant endeavor for a hospital. Department/service leaders' commitment to human subjects research is not separate from their commitment to patient care—commitment is integrated at all levels. Hospital leaders recognize the required level of commitment and personal involvement required to advance scientific inquiry. Thus, ethical considerations, good communication, responsible leaders of departments and services, regulatory compliance, and financial and nonfinancial resources are components of this commitment. With differing local regulations, hospital leaders must protect the patient and respect their rights during research, investigation, and clinical trials.

Protecting the rights of human research subjects and promoting a safe environment for these patients requires hospitals to be knowledgeable about and comply with those sources of regulation and professional standards specific for clinical research, such as those from the International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards.

Measurable Elements of HRP.01.00

1. Hospital leaders establish and promote a code of ethical professional behavior.
2. Ⓓ Hospital leaders, verbally and in writing, communicate within the hospital its commitment to protect human subjects research participants and support the code of ethical professional behavior.
3. Hospital leaders assume responsibility for patient protection irrespective of the sponsor of the research.
4. Ⓓ Hospital leaders have a process for budgeting to provide adequate resources for effective operation of the research program.

Standard HRP.01.01

Hospital leaders establish the scope of the research program.

Intent of HRP.01.01

To ensure that adequate control and resources support all the research within the hospital, hospital leaders must make decisions regarding the scope of research activities, including types and locations. Medical research conducted at the hospital represents varied medical areas and/or specialties within the organization and includes basic, clinical, and health services research. Such research may include clinical trials, therapeutic interventions, development of new medical technologies, and outcomes research, among others. Leaders must set parameters for when a staff member of the hospital may participate as a research subject. Also, leaders are responsible for ensuring that an adequate number of trained staff are available to serve as principal investigators and other members of research teams. The documentation of the required qualifications of staff must include these parameters.

Measurable Elements of HRP.01.01

1. Ⓓ Hospital leaders determine the scope of the research program.
2. Hospital leaders identify the facilities and resources that support the research program.
3. Hospital leaders identify the qualifications of staff permitted to participate in the research program as principal investigators or other members of the research team.
4. Ⓓ There is documentation of the qualifications of staff permitted to participate in the research program.
5. Hospital leaders identify those circumstances in which hospital employees and staff can serve as research subjects.

Standard HRP.01.02

Hospital leaders establish a policy for sponsors of research to ensure their commitment to the conduct of ethical research.

Intent of HRP.01.02

Hospital leaders and sponsors are accountable for all elements of the specific research, therefore establishing clear expectations and accountabilities ensures understanding of the commitment to ethically sound research. Hospital leaders and sponsors must share responsibility in the safety of the human subjects and in the protection of their rights. The policies, procedures, and contract agreements established and implemented by the hospital and sponsors must reflect the commitment to the preservation of the rights of the human subject participants, ethical and safe research practices, quality-focused initiatives, and compliance with laws and regulations. Research protocols must reflect that sponsors meet all the requirements, and hospital leaders verify this. Responsibilities of the research sponsor include the initiation, management, and financial commitment of a clinical trial, in addition to ensuring that the research is conducted in accordance with applicable policies and protocols, laws and regulations, and guidelines. Research sponsors must be qualified for the role. Qualifications of a research sponsor may include sponsor, investigator, and/or good clinical practice (GCP) training; and a background, certification, or training in clinical research and proposal preparation.

Measurable Elements of HRP.01.02

1. Ⓓ Hospital leaders establish a written policy for sponsors of research with requirements of accountability for the research, including the following:
   - Compliance with the hospital's policies and processes for monitoring and evaluating the quality, safety, and ethics of the research (*See also* GLD.07.00, ME 1)
   - Research teams must be trained and qualified to conduct the research.
   - Process to protect the privacy and confidentiality of subject data
   - Process to ensure that the research data are reliable and valid, and the results and reporting are statistically accurate, ethical, and unbiased
   - Patient or researcher incentives must not compromise the integrity of the research.
2. Hospital leaders verify that the sponsor of a research protocol must have qualifications for the role.
3. Ⓓ There is documentation confirming that the sponsor understands their responsibility and accountability for the research.

Standard HRP.01.03

When one or more of the research-related duties and functions of the sponsor are provided through an outside commercial or academic contract research organization, the accountabilities of the outside contract research organization are clearly defined.

Intent of HRP.01.03

The sponsor is responsible for the careful selection of a contract research organization, the clear delineation of accountability, and the monitoring of compliance under the contract. When regulations relate to the duties transferred by the sponsor to the contract research organization, the sponsor monitors compliance with those regulations as a part of contract review. The hospital approves the proposed contract with the contract research organization selected by the sponsor.

Human subjects research has many components, some of which a sponsor may choose to contract to an outside person or organization, usually termed a contract research organization. Such components may include recruiting subjects, conducting the research, providing data management, or serving as the research review mechanism.

Measurable Elements of HRP.01.03

1. Ⓓ The hospital establishes and implements a written process to determine the activities and responsibilities of a contract research organization.
2. Ⓓ The duties and functions transferred by the sponsor to the contract research organization are contained in a written contract.
3. Ⓓ The contract specifies that the contract research organization or sponsor is responsible for monitoring and evaluating the quality, safety, and ethics of the research. (*See also* GLD.07.00, ME 1)
4. The sponsor is responsible for monitoring the contract.

Standard HRP.01.04

Hospital leaders implement a process to provide the initial and ongoing review of all human subjects research.

Intent of HRP.01.04

One of the most important processes related to human subjects research is review and monitoring by an independent group of individuals, commonly referred to as an Institutional Review Board (IRB), an ethics committee, or similar designation that monitors all aspects of the research protocol to ensure patient protection and safe research. The composition, scope of responsibilities, and other factors may be described in laws or

regulations. The research review process may be contracted to an outside organization such as a regional or national IRB. The policies, procedures, and structure of the research review process are specified by hospital leaders, as well as which functions may or may not be transferred to a contract research organization. Also, hospital leaders are responsible for identifying the types of research that are exempt from this review function and the documentation of the activities of the review group. Documentation of this process is an important component of leaders' responsibility to review, at least on an annual basis, and determine how well the research review process is operating.

Measurable Elements of HRP.01.04

1. Hospital leaders identify and support the structure and operational requirements of the research review process.
2. The research review process complies with applicable laws and regulations.
3. Hospital leaders specify the requirements of entities outside of the hospital that provide all or a portion of the research review process, such as a contract research organization.
4. Hospital leaders ensure that research that is exempt from the research review process is identified.
5. Ⓓ Hospital leaders specify the requirements for documentation of the activities of the research review process.
6. Ⓓ Hospital leaders provide for a review of all research review processes at least annually.

Program Safety

Standard HRP.02.00

The hospital manages conflicts of interest with research conducted at the hospital.

Intent of HRP.02.00

Conflicts of interest can arise from many sources and in many forms for those sponsoring or participating in human subjects research. The conflicts may be financial (such as payment for recruitment of certain types of subjects) or nonfinancial (such as trips to speak at conferences). The research review process can identify and mitigate such conflicts, or the hospital can use or develop another type of mechanism to monitor and mitigate conflicts. The mechanism includes education about what constitutes a conflict and how conflicts can be successfully managed.

Measurable Elements of HRP.02.00

1. Ⓓ The hospital has a written policy to identity and manage conflicts of interest with research conducted at the hospital.
2. Ⓓ The hospital's conflict of interest policy includes a process for managing conflicts of interest, both financial and nonfinancial.
3. The hospital specifies the individuals, committees, and others for whom the requirements apply.
4. The hospital has an ongoing education and monitoring process to ensure compliance with the requirements.

Standard HRP.02.01

The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

Intent of HRP.02.01

Reporting events related to research protocols can provide vital information toward understanding the overall quality and safety of patient care in the hospital. For example, a significant adverse event when a drug is used for an off-label purpose is important patient safety information that should be part of the hospital's ongoing medication monitoring process.

Human subjects research may involve new types of surgical procedures, the use of new pharmaceuticals or the off-label use of current formulary drugs, the use of adult treatment modalities on pediatric populations, and many other research topics and methodologies. Of primary importance is the inclusion of research activities in the routine processes of the hospital; for example, the ordering, dispensing, and administration process for medications under study. Routine processes also include the reporting of adverse events through the quality and patient safety monitoring processes. Thus, reporting an adverse event related to a hospital patient on a research protocol should be to the quality monitoring mechanism of the hospital as well as to the sponsor of the research or the contract research organization.

All elements of the human subjects research program should be evaluated to determine which of the hospital's quality and safety programs are applicable. Furthermore, any reporting and monitoring processes that are ongoing within the hospital should be included in the research program. Examples include the following:

- Handling and disposal of certain experimental research pharmaceuticals, which should be a component of the management of hazardous materials
- Monitoring and maintenance of medical equipment used in experimental procedures

This should also be the case when some research activities are provided by a contract research organization.

Measurable Elements of HRP.02.01

1. The research program is a component of the hospital's processes to report and act on sentinel events and other adverse events, as well as the processes to learn from near misses (or close calls). (*See also* Sentinel Event Policy and APR.09.00, ME 1)
2. The research program is included in the hospital's programs for hazardous materials management, medical equipment management, and medication management. (*See also* FMS.05.00, ME 1; FMS.07.00, ME 1; MMU.01.00, ME 1)
3. The evaluation of staff participating in the research program is incorporated into the ongoing monitoring processes of professional performance. (*See also* SQE.01.03, ME 2)

Standard HRP.02.02

The hospital informs patients and families about how to gain access to clinical research, clinical investigations, or clinical trials and includes protections for vulnerable populations to minimize potential coercion or undue influence.

Intent of HRP.02.02

Safeguards are put into place through the hospital's research review function to protect vulnerable patients who may be at risk for coercion or undue influence to participate in research projects. Vulnerable patients include children, prisoners, pregnant women, persons with mental disabilities, persons who are economically or educationally disadvantaged, and others who have diminished or no capacity to make informed or voluntary decisions to participate in research. Another group that can be considered a vulnerable population is the hospital staff. Staff may feel pressure to participate; for example, when the principal investigator is their supervisor.

When patients decide to participate in research and grant consent, the individual providing the information and obtaining the consent is noted in the medical record. At times, a research protocol may be altered based on early findings; for example, a drug dose may be changed. Patient consent is obtained again under these

and similar circumstances. Risks to patient and/or family safety, rights, and well-being, or risks for coercion or undue influence are reported as adverse, unplanned events. In these circumstances, the IRB process includes the hospital and sponsor's process to prevent further risk when a research trial continues.

Measurable Elements of HRP.02.02

1. The hospital establishes and implements an informed consent process that enables patients to make informed and voluntary decisions about participating in clinical research, clinical investigations, or clinical trials, including the following:
   - How consent for participation will be obtained and documented
   - Under what circumstances consent will be obtained again during the research

   Note: This is accomplished through the research review process.
2. Patients and families are identified and informed about how to gain access to clinical research, clinical investigations, or clinical trials relevant to their treatment needs.
3. Through the research review process, the hospital implements safeguards to protect the safety, rights, and well-being of vulnerable patients, as identified by the hospital, who may be at risk for coercion or undue influence. (*See also* PCC.01.04, ME 4)
4. Through the research review process, the hospital implements safeguards to protect the safety, rights, and well-being of hospital staff who may be at risk for coercion or undue influence.

Medical Professional Education (MPE)

Overview

Integrating education of medical students and trainees into a hospital's operations needs to be consistent with the hospital's mission, strategic plans, resource allocation, and quality and patient safety program. The MPE standards emphasize the safety and quality of care provided to patients cared for by trainees and students as part of the hospital's services. For the professional education programs, both graduate and undergraduate, the hospital's governing entity and leaders are responsible to ensure that there is appropriate supervision of patient care, treatment, and services delivered in all teaching settings. Ensuring a rich and meaningful experience for medical students and trainees requires many factors in addition to the commitment of the governing entity and hospital leaders.

Trainees and students meet the following criteria:

- Are oriented to the organization and relevant departments.
- Understand and participate in quality improvement activities.
- Actively engage in the hospital's culture of safety.

The hospital's governing entity and leaders do the following:

- Create processes for the direction and accountability of the hospital teaching program medical staff members and other involved staff.
- Are knowledgeable about the teaching programs based on timely data-driven information.
- Require improvement processes in the teaching programs related to patient care when opportunities for improvement emerge.

For the standards language in this chapter and in the SQE chapter, the following terminology and associated definitions apply:

Medical Staff

All physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services. All classifications of appointments, all types, and levels of staff (employed, honorary, contract, visiting, and private community staff members), are included. Visiting staff include those who are teachers/tutors, and others allowed to provide patient care services temporarily. A hospital must define those other clinical staff, such as "house officers," "hospitalists," "fellows," and "junior doctors," who are no longer in training, but may or may not be permitted by the hospital to practice independently.

The term *medical staff* is thus inclusive of all physicians and other professionals permitted to treat patients with partial or full independence, regardless of their relationship to the hospital (for example, employed staff or independent consultants). In some cultures, traditional medicine practitioners, acupuncturists, chiropractors, and others, may be permitted by law and the hospital to practice independently. Thus, they are considered medical staff members, and these standards apply in full.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Scope of Medical Professional Education

MPE.01.00 The hospital's governing body and leaders approve and monitor the hospital's participation in providing medical education.

MPE.01.01 The hospital's teaching staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

MPE.01.02 Teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

Quality Oversight and Coordination

MPE.02.00 The hospital has a process for supervision of each type and level of medical student and trainee by a qualified physician.

MPE.02.01 Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

MPE.02.02 Medical students and trainees comply with all hospital policies and procedures, and all care is provided within the quality and patient safety parameters of the hospital.

MPE.02.03 Medical trainees who provide care or services within the hospital—outside of the parameters of their academic program—are granted permission to provide those services.

Standards, Intents, and Measurable Elements

Scope of Medical Professional Education

Standard MPE.01.00

The hospital's governing body and leaders approve and monitor the hospital's participation in providing medical education.

Intent of MPE.01.00

The governing body and leaders of the hospital are responsible to ensure that the hospital's medical staff program is in alignment with the hospital's mission, strategic plans, resource allocation initiatives, and quality and patient safety program. Integrating education of medical students and trainees (interns, residents, and fellows) into a hospital's operations requires a significant commitment of time, energy, and resources. When the decision to provide medical education involves a network of organizations, the governing entity is fully informed of all the relationships and accountabilities.

The governing entity and leaders of the hospital are also responsible for obtaining, reviewing, and agreeing to the education program parameters of the sponsoring academic program. Parameters include metrics for evaluating the ongoing program operations and patient experience, including patient satisfaction and patient engagement, and also how these might impact the quality of patient care. A set of metrics is selected and reported to the governing entity and hospital leaders on an annual basis. These metrics are relevant to the education programs within the hospitals and allow the governing entity and leaders to review the following:

- Scope and activities of the program
- Achievement of program goals
- Any relevant regulatory compliance issues
- Patient and staff satisfaction with the program, including the overall patient experience and the impact the program has on the quality of patient care

The reviews completed by the governing entity and leaders are documented.

Measurable Elements of MPE.01.00

1. Ⓓ The decision to provide medical education is made by the governing entity and leaders of the hospital, is consistent with the hospital's mission, and is documented.
2. Ⓓ The hospital's governing entity and leaders obtain, review, and accept the parameters of the participating medical school, and this action is documented.
3. Ⓓ The hospital's governing entity and leaders endorse a set of metrics to monitor and evaluate the ongoing operation of medical education programs, and there is documented review of the monitoring data.
4. Ⓓ The hospital's governing entity and leaders review the medical education programs within the hospital at least annually, and the review is documented.
5. The review includes the satisfaction of patients and staff with the clinical care provided under the program.

Standard MPE.01.01

The hospital's teaching staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

Intent of MPE.01.01

The teaching staff of the hospital must be adequate in number and expertise to advance medical student and trainee education. Providing a rich and meaningful learning experience for medical students and trainees requires many factors, such as support from the governing entity and hospital leaders to provide the resources necessary for program operations and advancement. For example, nursing staff members support the education program, and nursing staff understand their relationship to the education program.

Examples of resources for program operations and advancement include the following:

- The hospital's patient population is sufficient in number to support the education and clinical learning experience.
- Adequate classroom space, off-duty study, and rest facilities
- Print and online resources to support an effective learning environment
- Adequate opportunities and time for learning and interactions with teaching staff
- Availability of contemporary technology to teach evidence-based health care practices

Measurable Elements of MPE.01.01

1. Ⓓ There is documented evidence that the teaching staff of the hospital are adequate in number and have the education, training, and competence to support and advance the education of medical students and trainees.
2. Ⓓ There is documented evidence that the hospital's patient population is adequate in number and clinical needs to support the education of medical students and trainees.
3. Ⓓ There is documented evidence that the hospital's facilities, technology, and other resources support the education of medical students and trainees.

Standard MPE.01.02

Teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

Intent of MPE.01.02

All teaching staff who are responsible for medical student and trainee education and supervision are clearly identified so that the medical students, trainees, and other hospital staff understand educational accountabilities and authority. The hospital identifies the roles, responsibilities, and relationship of each teaching staff member to the academic institution. Hospital staff are educated on the educational roles, accountabilities, and authority of the teaching staff. For example, when any hospital staff member has a comment, concern, or other matter related to the education program or medical students and trainees, they will understand who is accountable for receiving and acting on that information.

The hospital has implemented a process to monitor and maintain current records of applicable academic titles and requirements, including renewal and redesignation. The relationship of the teaching staff of the hospital to the sponsoring academic institution(s) is clear. For example, when academic titles are conferred on teaching staff members, it is clear if titles are earned or honorary, how those titles are to be used, and what the titles mean to the public. Teaching staff who are not affiliated with the academic institution must also be defined by the hospital as such and how their teaching responsibility relates to the training program. The hospital has a recent complete listing of teaching staff, including applicable medical and academic titles. Any requirements for the renewal or redesignation of academic titles are monitored for compliance.

Measurable Elements of MPE.01.02

1. Ⓓ Teaching staff are identified to hospital staff, and there is a complete list of teaching staff, including both professional and academic titles, as applicable.
2. Staff are educated about these individuals, their roles, accountabilities, and authority.
3. Ⓓ The hospital implements a process to monitor and maintain current records of applicable academic titles and requirements for renewal or redesignation.

Quality Oversight and Coordination

Standard MPE.02.00

The hospital has a process for supervision of each type and level of medical student and trainee by a qualified physician.

Intent of MPE.02.00

Supervision is required to ensure safe patient care and ensure that the training program is a learning experience for the medical student or trainee. The hospital establishes a defined process for supervision by a medical staff member with appropriate clinical privileges to ensure that the process results in uniform medical student trainee experiences. The process includes the following:

- Required level of supervision is consistent with the level of training within the specialty and level of competence of the medical student and trainee, and adjusted accordingly during the course of the training.
- Medical student and trainee competence must be identified early in the training program and evaluated regularly during the course of the training.
- Written descriptions of the roles, responsibilities, and patient care activities of all participants of the professional education programs are provided.

Providing written descriptions of the roles, responsibilities, and patient care activities of the participants of professional education programs to the medical staff and hospital staff helps to keep uniformity in the process.

Each medical student and trainee can assess the level of supervision provided by teaching staff by doing the following:

- Understanding the clinical supervision process, including who is to provide the supervision and the frequency of the supervision (for example, a medical student understands whether supervision is provided by a resident, the patient's primary physician, a medical school faculty member, and/or teaching staff).
- Understanding whether the supervision includes daily signing of all notes and orders, signing of the care plan and progress notes every other day, or making a separate entry in the patient's medical record
- Identifying how the evidence of that supervision is documented, including the frequency and location of documentation

In addition, the hospital identifies and monitors the expectations for the mentoring/supervision process to ensure a uniform learning experience.

Measurable Elements of MPE.02.00

1. The hospital has a process for supervision of each medical student and trainee by a medical staff member with appropriate privileges to provide uniform medical student and trainee experiences.
2. Ⓓ The hospital establishes written descriptions of the roles, responsibilities, and patient care activities of the participants of professional education programs. The descriptions are as follows:
   - Include the process by which the supervisor(s) and professional education program director make decisions about each participant's progressive involvement and independence in specific patient care activities.
   - Are provided to the medical staff providing supervision.
   - Are provided to each medical student and trainee of the program.
   - Are provided to the hospital staff.
   - Identify policies and/or processes that delineate the participants in professional education programs who may write patient care orders, the circumstances under which they may do so, and what entries, if any, must be countersigned by a supervising physician.
   - Identify policies and/or processes that delineate the participants in professional education programs to perform part or all of a patient's medical history, physical examination, assessment, and plan of care under the supervision of, or through appropriate delegation by, a specific qualified doctor of medicine or doctor of osteopathy who is accountable for these tasks.
   - Identify policies and/or processes for when a medical history, physical examination, assessment, and plan of care performed by the participants in professional education programs must be validated and countersigned by a physician with appropriate privileges.
3. The level of supervision to be provided is based on the demonstrated competency of the medical student and trainee.
4. Ⓓ There is evidence that each medical student and trainee understands the level, frequency, and documentation of their supervision.
5. Ⓓ Medical records are reviewed for compliance with the documentation requirements and frequency.

Standard MPE.02.01

Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

Intent of MPE.02.01

Medical education programs in hospitals require an effective management structure and a commitment of staff time for their coordination and daily operation. The agreements between the hospital and the medical school are established and monitored. There is a current, accurate list of all medical students and trainees in the hospital. The hospital identifies the minimum documentation requirements for each medical student and trainee. Documentation for a medical student may be limited depending on their enrollment status and current level of training. Accommodations may be necessary to meet specific needs of the training program (for example, medical student scheduling conflicts, family obligations, imbalanced competencies and specialties between teaching staff and medical students and trainees). When an academic program is sponsored by the hospital, it is determined how and where these activities are conducted.

Measurable Elements of MPE.02.01

1. The operational structure for medical education in the hospital has been established and is fully operational.
2. The management structure for medical education in the hospital has been determined and implemented.
3. Ⓓ There is a complete and current list of all medical students and trainees in the hospital.
4. Ⓓ For each medical student and trainee, there is documentation of at least the following:
   - Enrollment status
   - Academic classification
   - Any required licensure or certification
   - Reports of medical student and trainee achievements
   - Identification of medical student and trainee competencies
   - Any known factors that will require accommodation
   - Any known factors that may influence the level of supervision required

Standard MPE.02.02

Medical students and trainees comply with all hospital policies and procedures, and all care is provided within the quality and patient safety parameters of the hospital.

Intent of MPE.02.02

Training programs and their students are a critical factor in the overall quality of care and patient safety. Individuals providing medical student and trainee supervision must ensure that all medical students and trainees can demonstrate knowledge of these quality and safety programs and are included in the evaluation process.

Each medical student and trainee receives basic education on quality and patient safety in their respective academic program. To achieve this, the hospital must do the following:

- Have a planned and deliberate program to introduce quality and patient safety concepts.
- Support the medical students and trainees in complying with relevant policies and guidelines.
- Include medical students and trainees in all quality and safety monitoring programs.

Examples of quality and patient safety education for the medical students' and trainees' initial orientation and ongoing training and evaluation would include the following:

- Compliance with the International Patient Safety Goals
- Required clinical practice guidelines
- Surgical time-out procedures
- Medication-ordering policies
- Other mechanisms to reduce variation in care processes, and thus reduce the risk in those processes

Measurable Elements of MPE.02.02

1. All medical students and trainees are provided an orientation that includes at least the following:
   - Hospital quality and patient safety program
   - Infection prevention and control program
   - Medication safety program
   - International Patient Safety Goals
   - Other required hospital orientation, including at the department and unit level
   - Ongoing required education
2. Medical students and trainees are included in the data collection for the hospital's quality monitoring programs.
3. Those supervising medical students and trainees ensure that the medical students and trainees are knowledgeable of the programs and participate in the programs.
4. Medical students and trainees can demonstrate knowledge of these programs.
5. Those supervising medical students and trainees consider compliance with these programs in their evaluation of medical student and trainee performance.

Standard MPE.02.03

Medical trainees who provide care or services within the hospital—outside of the parameters of their academic program—are granted permission to provide those services.

Intent of MPE.02.03

The laws and regulations in many countries permit trainees, as they advance in their program, to provide services to the hospital outside of their academic program. For example, a trainee may provide medical care in the hospital's emergency department in evenings or on weekends or may function as the "house doctor" during the night shift. If a medical trainee is granted permission to provide services outside of their academic program, the individual trainee must be evaluated and given permission to provide those services through the normal established processes for such professionals as described in the Staff Qualifications and Education (SQE) standards. Any approved services provided by a medical trainee outside their academic programs are then evaluated as required by the SQE standards.

Measurable Elements of MPE.02.03

1. The hospital determines what types of trainees and under which circumstances trainees can be hired or otherwise engaged by the hospital to provide patient care or other services.
2. Trainees providing such services are granted permission through credentialing and privileging, a job description, or other relevant processes for the services being provided.
3. Trainees providing such services are evaluated for the services being provided.

Appendix

Interim Measures

Interim Measures

Interim measures are actions taken to ensure the safety of the building's occupants during times when features and systems for fire safety are defective, compromised, or inoperable due to construction, maintenance, a breakdown, or repair, or due to an emergency situation such as civil unrest. When fire safety risks cannot be immediately addressed and corrected, the hospital plans for improvements to address the risks. Interim measures may need to be implemented to ensure the safety of occupants until improvements or repairs can be completed. The hospital determines when and to what extent interim measures will be implemented.

The following are examples of interim measures:

1. The hospital initiates a fire watch, which involves a trained individual(s) patrolling the areas of the building affected by the impairment/fire safety risk to look for evidence of smoke, fire, or other abnormal conditions. For example, a fire watch is initiated when a fire alarm system is out of service for more than 4 hours in a 24-hour period, or a sprinkler system is out of service for more than 10 hours in a 24-hour period.
2. The hospital posts signs identifying the location of alternative exits to everyone in the affected area of the hospital (for example, when normal exit pathways and/or exit doors are not accessible or not functional due to construction or maintenance activities).
3. The hospital inspects exits in affected areas on a daily basis.
4. The hospital provides temporary but equivalent fire alarm and detection systems for use when a fire alarm system is impaired.
5. The hospital provides additional firefighting equipment.
6. The hospital uses temporary construction partitions that are smoke-tight or made of noncombustible or limited-combustible material that will not contribute to the development or spread of fire.
7. The hospital increases surveillance of buildings, grounds, and equipment, giving special attention to construction and storage areas.
8. The hospital enforces storage, housekeeping, and debris-removal practices that reduce the building's flammable and combustible fire load to the lowest feasible level.
9. The hospital provides additional training to staff on the use of firefighting equipment.
10. The hospital conducts additional fire safety exercises with staff.
11. The hospital inspects and tests temporary fire systems monthly.
12. The hospital conducts education to promote awareness of fire safety–related building deficiencies, impairments, construction hazards, and temporary measures implemented to maintain fire safety.
13. The hospital provides additional training to staff to compensate for increased risks due to impaired structural or compartmental fire safety features.
14. Any other interim measure, as determined by the hospital, that is appropriate to the fire safety risk.

Patient Safety Systems (PS)

Quality and Patient Safety in Health Care

The quality of care and the safety of patients are core values of the Joint Commission International (JCI) accreditation process. This is a commitment JCI has made to patients, families, health care practitioners, staff, and health care organization leaders. The ultimate purpose of the JCI accreditation process is to enhance quality of care and patient safety.

Each accreditation requirement, the survey process, the Sentinel Event Policy (https://www.jointcommissioninternational.org/contact-us/sentinel-event-policy/) and other JCI policies and initiatives are designed to help organizations reduce variation, reduce risk, and improve quality. Hospitals should have an integrated approach to patient safety so that safe patient care can be provided for every patient in every care setting and service. Hospitals are complex environments that depend on strong leadership to support an integrated patient safety system that includes the following:

- Safety culture
- Validated methods to improve processes and systems
- Standardized ways for interdisciplinary teams to communicate and collaborate
- Safely integrated technologies

In an integrated patient safety system, staff and leaders work together to eliminate complacency, promote collective mindfulness, treat each other with respect and compassion, and learn from patient safety events, including close calls and other system failures that have not yet resulted in patient harm. The definition of these and other key terms are as follows:

- **Patient Safety Event** – an event, incident, or condition that could have resulted, or did result, in harm to a patient
- **Adverse Event** – a patient safety event that resulted in harm to a patient. Adverse events should prompt notification of hospital leaders, investigation, and corrective actions. An adverse event may or may not be the result of an error.
- **Sentinel Event** – a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and:
  - results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm). Sentinel events are a subcategory of adverse events (*See* Sentinel Event Policy https://www.jointcommissioninternational.org/contact-us/sentinel-event-policy/)
- **Close Call** – a patient safety event that did not cause harm but posed a risk of harm. Also called *near miss* or *good catch*.
- **Hazardous Condition** – a circumstance, other than a patient's own disease process or medical condition that increases the probability of a patient safety event, adverse event, or sentinel event

Quality and safety in health care are closely linked. *Quality*, as defined by the Institute of Medicine, is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[1] It is achieved when processes and results meet or exceed the needs and desires of the people it serves.[2,3] Those needs and desires include safety—meaning protection from harm. The components of a quality management system should include the following:

- Ensuring reliable processes
- Decreasing variation and defects (waste)
- Focusing on achieving positive measurable outcomes
- Using evidence to ensure that a service is satisfactory

Patient safety emerges as a central aim of quality. *Patient safety*, as defined by the World Health Organization, is the prevention of errors and adverse effects to patients that are associated with health care. Safety (protection from harm) is what patients, families, staff, and the public expect from Joint Commission International–accredited organizations. Although patient safety events may not be eliminated, the goal is always zero harm. Joint Commission International–accredited organizations should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families, and staff.

Goals of This Chapter

This "Patient Safety Systems" (PS) chapter provides health care organizations with a proactive approach to maintaining or redesigning a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with Joint Commission International's mission and its standards.

JCI partners with accredited organizations to improve the ability of health care systems to protect patients. The first obligation of health care is to "do no harm." Therefore, this chapter focuses on the following three guiding principles:

1. Aligning existing JCI standards with daily work to engage patients and staff throughout the health care system on reducing harm
2. Assisting health care organizations to become learning organizations by advancing knowledge, skills, and competence of staff and patients by recommending methods that will improve quality and safety processes
3. Encouraging and recommending proactive quality and patient safety methods that will increase accountability, trust, and knowledge while reducing the impact of fear and blame

It informs and educates hospitals about the importance and structure of an integrated patient safety system and helps staff understand the relationship between JCI accreditation and patient safety. It offers approaches and methods that may be adapted by any organization that aims to increase the reliability and transparency of its complex systems while removing the risk of patient harm.

The "Patient Safety" (PS) chapter cross-references specific Joint Commission International standards, describing how existing requirements can be applied to achieve improved patient safety. It does not contain any new requirements for accreditation, and the PS chapter is not intended as a stand-alone chapter for accreditation survey purposes. Standards referenced in this chapter are formatted with the standard number in boldface type (for example, "**Standard PCC.01.00**") and are accompanied by language that summarizes the standard. For the full text of a standard and its measurable elements (MEs), please refer to the *Joint Commission International Accreditation Standards for Hospitals,* 8th Edition.

Throughout this chapter, we will do the following:

- Discuss how hospitals can develop into learning organizations.
- Identify the role of leaders to establish a safety culture and ensure staff accountability.
- Explain how hospitals can continually evaluate the status and progress of their patient safety systems.
- Describe how hospitals can work to prevent patient safety events with proactive risk assessments.
- Highlight the critical component of patient activation and engagement in a patient safety system.
- Provide a framework to guide hospital leaders as they work to improve patient safety in their hospitals.

Becoming a Learning Organization

The need for sustainable improvement in patient safety and the quality of care has never been greater. One of the fundamental steps to achieving and sustaining this improvement is to become a learning organization. A *learning organization* is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.[4] Learning organizations uphold five principles:

1. Team learning
2. Shared visions and goals
3. A shared mental model (that is, similar ways of thinking)
4. Individual commitment to lifelong learning
5. Systems thinking

In a learning organization, patient safety events are seen as opportunities for learning and improvement.[5] Therefore, leaders in learning organizations should adopt a transparent, nonpunitive approach to reporting so that the organization can *report to learn* and can collectively learn from patient safety events. In order to become a learning organization, a hospital must have a fair and just safety culture, a strong reporting system, and a commitment to put those data to work by driving improvement. Each of these requires the support and encouragement of hospital leaders.

Leaders, staff, and patients in a learning organization realize that *every* patient safety event (from close calls to events that cause major harm to patients) must be reported and investigated.[5–9] It is impossible to determine if there are practical prevention or mitigation countermeasures available for a patient safety event without first doing an event analysis. An event analysis will identify systems-level vulnerabilities and weaknesses and the possible remedial or corrective actions that can be implemented.

When patient safety events are continuously reported, experts within the hospital can define the problem, complete a comprehensive systematic analysis, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the hospital.[5–9] In a learning organization, the hospital provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting. (*See* the "Sentinel Event Policy" [SE] chapter for more about comprehensive systematic analyses)

The Role of Leaders in Patient Safety

Hospital leaders provide the foundation for an effective patient safety system by doing the following[10]:

- Promoting learning
- Motivating staff to uphold a fair and just safety culture
- Providing a transparent environment in which quality measures and learnings about patient harm events are freely shared with staff
- Modeling professional behavior
- Addressing intimidating behavior that might undermine the safety culture
- Providing the support, resources, and training necessary to take on and complete improvement initiatives

For these reasons, many of the standards that are focused on the hospital's patient safety system appear in the Joint Commission International **Governance, Leadership, and Direction (GLD) standards**, including Standards **GLD.04.00** and **GLD.07.01** (which focuses on creating a culture of safety), and the **Quality and Patient Safety (QPS) standards**.

Without the support of hospital leaders, hospitalwide changes and improvement initiatives are difficult to achieve. Leadership engagement in patient safety and quality initiatives is imperative because 75% to 80% of all initiatives that require people to change their behaviors fail in the absence of leaders managing the change.[5] Thus, leaders should take on a long-term commitment to transform the hospital.[11]

Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for hospitals striving to become learning organizations. In a strong safety culture, the hospital has an unrelenting commitment to safety and to do no harm. *Among the most critical responsibilities of hospital leaders is to establish and maintain a strong safety culture within their hospital*. Joint Commission International's standards address safety culture in **Standard GLD.07.01**, which requires leaders to create and maintain a culture of safety and quality throughout the hospital.

The *safety culture* of a hospital is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety. Hospitals that have a robust safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.[12] Organizations will have varying levels of safety culture, but all should be working toward a safety culture that has the following qualities:

- Staff and leaders value transparency, accountability, and mutual respect.[5]
- Safety is everyone's first priority.[5]
- Behaviors that undermine a culture of safety are not acceptable and thus are reported to organization leaders by staff, patients, and families for the purpose of fostering risk reduction.[5,11,13]
- Collective mindfulness is present, wherein staff realize that systems always have the potential to fail, and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed.[11] Staff do not view close calls as evidence that the system prevented an error but rather as evidence that the system needs to be further improved to prevent any defects.[11,14]
- Staff do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events.[7] Staff know that their leaders will focus not on blaming staff involved in errors but on the systems issues that contributed to or enabled the patient safety event.[7,15]
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the hospital fosters a cycle of trust, reporting, and improvement.[11,16] In hospitals that have a strong safety culture, health care staff trust their coworkers and leaders to support them when they identify and report a patient safety event.[11] When trust is established, staff are more likely to report patient safety events, and hospitals can use these reports to inform their improvement efforts. In the trust-report-improve cycle, leaders foster trust, which enables staff to report, which enables the hospital to improve. In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself.[11] (*See* Figure 1.)

Figure 1. *The Trust-Report-Improve Cycle. In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.*

Leaders and staff must address intimidating or unprofessional behaviors within the hospital, so as not to inhibit others from reporting safety concerns.[17] Leaders should both educate staff and hold them accountable for professional behavior. This includes the adoption and promotion of a code of conduct that defines acceptable behavior and undermines a culture of safety. Joint Commission International's **Standard GLD.07.01, ME 2** requires that leaders develop such a code (*see also* **Standard QPS.03.04, ME 6**). Intimidating and disrespectful behaviors disrupt the culture of safety and prevent collaboration, communication, and teamwork, which is required for safe and highly reliable patient care.[18] Disrespect is not limited to outbursts of anger that humiliate a member of the health care team; it can manifest in many forms, including the following[5,13,18]:

- Inappropriate words (profane, insulting, intimidating, demeaning, humiliating, or abusive language)
- Shaming others for negative outcomes or mistakes, or for asking questions or for assistance
- Unjustified negative comments or complaints about another licensed practitioner's care
- Refusal to comply with known and generally accepted practice standards, which may prevent other licensed practitioners from delivering high-quality care
- Not working collaboratively or cooperatively with other members of the interdisciplinary team
- Creating rigid or inflexible barriers to requests for assistance or cooperation
- Not returning pages or calls promptly, or directing anger or impatience toward staff when paged or called

These issues are still occurring regularly in hospitals worldwide. Of 4,884 respondents to a 2013 survey by the Institute for Safe Medication Practices (ISMP), 73% reported encountering negative comments about colleagues or leaders during the previous year. In addition, 68% reported condescending language or demeaning comments or insults, and 77% of respondents said they had encountered reluctance or refusal to answer questions or return calls.[19]

Further, 69% report that they had encountered impatience with questions or the hanging up of the phone.

Nearly 50% of the respondents indicated that intimidating behaviors had affected the way they handle medication order clarifications or questions, including assuming that an order was correct in order to avoid interaction with an intimidating coworker.[19] Moreover, 11% said they were aware of a medication error during the previous year in which behavior that undermines a culture of safety was a contributing factor. The respondents included nurses, physicians, pharmacists, and quality/risk management personnel.

Only 50% of respondents indicated that their organizations had clearly defined an effective process for handling disagreements with the safety of an order.

This is down from 60% of respondents to a similar ISMP survey conducted in 2003, which suggests that this problem is worsening.[19] Although these data are specific to medication safety, their lessons are broadly applicable: Behaviors that undermine a culture of safety have an adverse effect on quality and patient safety.

A Fair and Just Safety Culture

A fair and just safety culture is needed for staff to trust that they can report patient safety events without being treated punitively.[3,9] In order to accomplish this, hospitals should provide and encourage the use of a standardized reporting process for staff to report patient safety events, and implement efforts designed to encourage reporting as required by JCI's **Standard QPS.03.04, ME 6**.

This is also built into the JCI standards at **Standard GLD.07.01**, which requires leaders to provide and encourage the use of systems for blame-free reporting of a system or process failure or the results of proactive risk assessments (*see also* **Standard QPS.03.04**). Reporting enables both proactive and reactive risk reduction. *Proactive risk reduction* identifies and solves problems before patients are harmed, and *reactive risk reduction* attempts to prevent the recurrence of problems that have already caused patient harm.[11,16]

A fair and just culture considers that individuals are human, fallible, and capable of mistakes and that they work in systems that are often flawed. In the most basic terms, a fair and just culture holds individuals accountable for their actions but does not punish individuals for issues attributed to flawed systems or processes.[15,19,20] **Standard GLD.02.00** requires that leaders hold staff accountable for their responsibilities, in accordance with hospital policies, and laws and regulations, but assumes hospital leaders will use a process to discern whether a flawed system or process was primarily a root cause of the error rather than the fault of an individual.

A fair and just culture does hold staff individually accountable for intentionally disregarding policies and procedures or laws and regulations, while making a distinction between willful disregard of these versus errors related to flawed systems or processes. For some actions for which an individual is accountable, the individual should be held culpable, and some disciplinary action may then be necessary. (*See* Sidebar 1, below, for a discussion of tools that can help leaders determine a fair and just response to a patient safety event.) However, staff should never be disciplined or ostracized for *reporting* the event, close call, hazardous condition, or concern.

Sidebar 1. Assessing Staff Accountability

The aim of a safety culture is not a "blame-free" culture but one that balances organizational learning with individual accountability. To achieve this, it is essential that leaders assess errors and patterns of behavior in a consistent manner, with the goal of eliminating behaviors that undermine a culture of safety. There has to exist within the hospital a clear, equitable, and transparent process for recognizing and separating the blameless errors that fallible humans make daily from the unsafe or reckless acts that are blameworthy.[15,18,23,35,38–43]

Numerous resources are available to assist an organization in creating a formal decision process to determine what events should be considered blameworthy and require individual disciplinary action in addition to systems-level corrective actions, such as the Incident Decision Tree (adapted by the United Kingdom's National Patient Safety Agency from James Reason's culpability matrix)[37] or the Just Culture Algorithm (Just Culture Company).[35,36] The use of a formal process reinforces the culture of safety and demonstrates the organization's commitment to transparency and fairness.

Reaching a determination of staff accountability requires an initial investigation into the patient safety event to identify contributing factors. The use of formal decision-making tools or processes can help make determinations of culpability more transparent and fair.[5]

(*See also* references 13, 16, 22, 23–29)

Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of data to improve. When hospitals adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the hospital begins reporting to learn and to learn collectively from adverse events, close calls, and hazardous conditions. Although this section focuses on data from reported patient safety events, it is but one type of data among many that should be collected and used to drive improvement.

When there is continuous reporting for adverse events, close calls, and hazardous conditions, the hospital can analyze the events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the organization.[21–24]

A number of standards relate to the reporting of safety information, including but not limited to **Standard GLD.04.01**, the **QPS standards**, and the **Medication Management and Use (MMU) standards**, which require hospitals to collect data to monitor their performance; to use data and information to guide decisions; and to understand variation in the performance of processes supporting safety and quality. Hospitals can engage frontline staff in internal reporting in a number of ways, including the following:

- Create a nonpunitive approach to patient safety event reporting as explained in the previous paragraphs.
- Implement measures to encourage increased reporting (**Standard QPS.03.04, ME 6**).
- Educate staff on and encourage them to identify patient safety events that should be reported.
- Provide timely feedback regarding actions taken on reported patient safety events.

Effective Use of Data

The meaningful use of data is a critical component of a patient safety program. Data to be collected should be selected with care in order to ensure that they are relevant and in accordance with laws and regulations,

applicable accreditation standards, internal and external reporting requirements, and health care industry standards; and the data should be validated, analyzed, and reported in accordance with **Standards QPS.03.00, QPS.03.01, QPS.03.02, QPS.03.03,** and **QPS.03.04**.

Collecting Data

When hospitals collect data to measure staff compliance with evidence-based care processes or patient outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient safety. Collecting data and monitoring for compliance with evidence-based care processes, such as central line care bundles or hand hygiene, represents a focus on leading indicators of harm and an opportunity to intervene prior to harm occurring.

For example, development of central line–associated bloodstream infections (CLABSIs) in patients with central lines represents a lagging indicator of harm, as harm has already occurred, and there is a likelihood that a gap in one or more care processes was a factor in its occurrence, such as failure to adhere to site dressing change procedures. Effective and meaningful use of data enables hospitals to identify problems, prioritize issues, develop solutions, and track performance to determine success.[10] Objective data can be used to support decisions as well as to influence people to change their behaviors and to comply with evidence-based care guidelines.[10,23]

JCI requires hospitals to collect and use data related to certain patient care outcomes and patient harm events. Some key Joint Commission International standards related to data collection and use require hospitals to do the following:

- Collect information to monitor conditions and safety risks for all departments and services, and the environment, throughout the hospital (**Standards QPS.02.00** and **QPS.04.01**).
- Identify risks for acquiring and transmitting infections (**Standard PCI.02.00**).
- Use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality (**Standard GLD.04.00**).
- Have an organizationwide, integrated patient safety program within their performance improvement activities (**Standards GLD.04.00** and **QPS.02.00**).
- Evaluate the effectiveness of their medication management system (**Standards MMU.01.00**, **MMU.07.00**, and **MMU.07.01**).
- Collect data to monitor their performance (**Standard QPS.03.00**).
- Improve performance on an ongoing basis (**Standard QPS.04.00**).

Analyzing Data

Effective data analysis can enable a hospital to "diagnose" problems within its system similar to the way one would diagnose a patient's illness based on symptoms, health history, and other factors. Turning data into information is a critical competency of a learning organization and of effective management of change. When the right data are collected and appropriate analytic techniques are applied, it enables the hospital to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the hospital not only understand the current performance of hospital systems but also can help it predict its performance going forward.[24]

Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps a hospital determine what has occurred in a system and provides clues as to why the system responded as it did.[24] Table 1, following, describes and compares examples of these tools.

Table 1. Defining and Comparing Analytical Tools

Tool	What It Is	When to Use It
Run Chart	A data chart, plotting in time order, used to show the performance of a process over time. It shows both positive and negative patterns, trends, and variation in process.	• When the hospital needs to identify changes and variation within a process • When the hospital needs a simple and straightforward analysis of a process • As a precursor to an SPC chart
Statistical Process Control Chart (SPC)	An advanced data chart, plotted in time order, used to show the performance and stability of a process over time. The chart includes a center line (process mean) and upper and lower control limits (process variation) based on the data plotted, that show both positive and negative patterns, trends, and variation in a process. Action is taken when a data point goes beyond a control limit or data points form a pattern or trend.	• When the hospital needs to determine if a process is stable, to identify variation within a process, or find indicators of why the variation occurred • When the hospital needs a more detailed and in-depth analysis of a process
Capability Chart	A chart used to assess the capability of a process to meet specifications based on the voice of the customer. The chart shows upper and/or lower specifications (that is, customer requirements or targets).	• When the hospital needs to determine whether a process will function as expected, according to specifications (requirements or targets) • When the hospital needs to determine how capable their process is for meeting customer specifications (requirements or target)

Using Data to Drive Improvement

After data have been turned into information, leaders should ensure the following (per the requirements shown)[25–27]:

- Information is presented and shared with the appropriate groups throughout the hospital, from frontline staff to the governing board in a clear manner (**Standards GLD.04.01** and **QPS.01.00**).
- Opportunities for improvement and actions to be taken are communicated (**Standard GLD.04.01**).
- Improvements are celebrated or recognized.

A Proactive Approach to Preventing Harm

Proactive risk reduction prevents harm before it reaches the patient. By engaging in proactive risk reduction, a hospital can correct process problems to reduce the likelihood of experiencing adverse events. Additional benefits of a proactive approach to patient safety include increased likelihood of the following:

- Identification of actionable common causes
- Avoidance of unintended consequences

- Identification of commonalities across departments/services/units
- Identification of system solutions

In a proactive risk assessment, the hospital evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. A proactive risk assessment increases understanding within the organization about the complexities of process design and management and what could happen if the process fails.

JCI addresses proactive risk assessments at **Standard QPS.04.01, ME 3**, which requires hospitals to select one high-risk process and conduct a proactive risk assessment at least annually. Hospitals should recognize that this standard represents a minimum requirement. Hospitals working to become learning organizations are encouraged to exceed this requirement by constantly identifying risks to proactively address these and reduce the risk of harm (for example, by identifying more than one process to perform a proactive risk assessment, such as low-volume but high-risk processes; or high-volume lower-risk processes, which may carry higher risks via statistical probability).

When conducting a proactive risk assessment, organizations should prioritize high-risk areas, or high-frequency areas. Areas of risk are identified from internal sources such as ongoing monitoring of the environment, results of previous proactive risk assessments, and results of data collection activities. Risk assessment tools should be accessed from credible external sources such as nationally recognized risk assessment tools and peer review literature.

Hazardous (or unsafe) conditions also provide an opportunity for a hospital to take a proactive approach to reduce harm. Hospitals benefit from identifying hazardous conditions while designing any new process that could impact patient safety. A *hazardous condition* is defined as any circumstance that increases the probability of a patient safety event. A hazardous condition may be the result of a human error or violation, may be a design flaw in a system or process, or may arise in a system or process in changing circumstances.

Human errors are typically skills based, decision based, or knowledge based, whereas violations could be either routine or exceptional (intentional or negligent). *Routine violations* tend to include habitual "bending of the rules," often enabled by management. A routine violation may break established rules or policies, and yet be a common practice within a hospital. An *exceptional violation* is a willful behavior outside the norm that is not condoned by management, engaged in by others, nor part of the individual's usual behavior[28] (*see* "A Fair and Just Safety Culture" section and Sidebar 1).

A proactive approach to such conditions should include an analysis of the systems and processes in which the hazardous condition is found, with a focus on the climate that preceded the hazardous condition. A proactive approach to hazardous conditions should include an analysis of the related systems and processes, including the following aspects[28]:

1. **Preconditions:** Examples include hazardous (or unsafe) conditions in the environment of care (such as noise, clutter, wet floors, and so forth), inadequate staffing levels (inability to effectively monitor, observe, and provide care, treatment, and services to patients).
2. **Supervisory influences:** Examples include inadequate supervision, unsafe operations, failure to address a known problem, and authorization of hazardous activities when alternatives exist.
3. **Organization influences:** Examples include inadequate staffing, organization culture, leadership, lack of strategic risk assessment.

Tools for Conducting a Proactive Risk Assessment

A number of tools are available to help organizations conduct a proactive risk assessment. One of the best known of these tools is the failure mode and effects analysis (FMEA). An FMEA is used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them. The FMEA asks "What if?" to explore what could happen if a failure occurs at particular steps in a process.[29] The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones. Failures should be prioritized according to how serious the potential consequences are, how frequently they may occur,

and how easily a failure can be detected.[30] Other tools to consider using for a proactive risk assessment include the following:

- Institute for Safe Medication Practices Medication Safety Self-Assessment®. Available for various health care settings, these tools are designed to help reduce medication errors. Visit https://www.ismp.org/selfassessments/default.asp for more information.
- Contingency diagram: The contingency diagram uses brainstorming to generate a list of problems that could arise from a process. Visit https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/contingency-diagram for more information.
- Potential problem analysis (PPA) is a systematic method for determining what could go wrong in a plan under development, rating problem causes according to their likelihood of occurrence and the severity of their consequences. Visit: https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/potential-problem-analysis and https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit
- Process decision program chart (PDPC) provides a systematic means of finding errors with a plan while it is being created. After potential issues are found, preventive measures are developed, allowing the problems to either be avoided or a contingency plan to be in place should the error occur. Visit https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/process-decision-program-chart for more information.

Strategies for conducting an effective proactive risk assessment, no matter the strategy chosen, should address the following:

- Promote a blame-free **reporting** culture (a blame-free **reporting** culture should be differentiated from the term *blame-free* in relation to *accountability* and *Just Culture* principles) (*see also* Sidebar 1).
- Describe the chosen process (for example, through use of a flowchart).
- Identify ways in which the process could break down or fail to perform its desired function, which are often referred to as "failure modes."
- Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- Prioritize the potential process breakdowns or failures.
- Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical comprehensive systematic analysis such as root cause analysis.
- Design or redesign the process and/or the underlying systems to minimize the risk of the effects on patients.
- Test and implement the newly designed or redesigned process.
- Monitor the effectiveness of the newly designed or redesigned process.

Encouraging Patient Activation

To achieve the best outcomes, patients and families must be more actively engaged in decisions about their health care and must have broader access to information and support. Patient activation is a critical component of patient safety. Activated patients are less likely to experience harm and unnecessary hospital readmissions.

Patients who are less activated suffer poorer health outcomes and are less likely to follow their physician's or other licensed practitioner's advice.[31,32] A patient-centered approach to care can help hospitals assess and enhance patient activation. Achieving this requires leadership engagement in establishing patient-centered care as a top priority throughout the hospital. This includes adopting the following principles[33]:

- Patient safety guides all decision-making.
- Patients and families are partners at every level of care.
- Patient- and family-centered care is verifiable, rewarded, and celebrated.

- The physician or other licensed practitioner responsible for the patient's care, or the physician's or other licensed practitioner's designee, discloses to the patient and family any unanticipated outcomes of care, treatment, and services in accordance with the organization's policy on disclosure (**Standard PCC.02.03**).
- Transparent communication when harm occurs. Although Joint Commission International standards do not require apologies or disclosure in all circumstances, evidence suggests that patients benefit psychologically and are less likely to pursue litigation when physicians disclose harm, express sympathy, and apologize.[34]
- Staffing levels are sufficient, and the staff has the necessary tools and skills.
- The hospital has a focus on measurement, learning, and improvement.
- Staff must be fully engaged in patient- and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Hospitals can adopt a number of strategies to support and improve patient activation, including promoting culture change, adopting transitional care models, and leveraging health information technology capabilities.[33]

Several JCI standards address patient rights and provide an excellent starting point for hospitals seeking to improve patient activation. These standards require that hospitals do the following:

- Respect, protect, and promote patient rights (**Standards PCC.01.00** and **PCC.01.01**).
- Respect the patient's right to receive information in a manner the patient understands (**Standard PCC.01.01**).
- Respect the patient's right to participate in decisions about their care, treatment, and services (**Standard PCC.02.00**).
- Honor the patient's right to give or withhold informed consent (**Standard PCC.03.00**).
- Address patient decisions about care, treatment, and services received at the end of life (**Standards PCC.02.01** and **COP.08.00**).
- Inform the patient about their responsibilities related to their care, treatment, and services (**Standard PCC.02.01**).

Beyond Accreditation: Joint Commission International Is Your Patient Safety Partner

To assist hospitals on their journey toward creating highly reliable patient safety systems, Joint Commission International (JCI) provides many resources, including the following:

- *JCI Quality and Patient Safety Department:* An internal Joint Commission department that offers hospitals guidance and support when an organization experiences a sentinel event or when a safety event is reported that may require analysis or improvement work JCIQuality@jcrinc.com.
- *Standards Interpretation Group*: An internal Joint Commission International department that helps organizations with their questions about Joint Commission International standards. Organizations can submit questions about standards to the Standards Interpretation Group by submitting a question to: https://www.jointcommissioninternational.org/standards/submit-a-jci-standards-interpretation-question/.
- *International Patient Safety Goals:* Joint Commission International gathers information about emerging patient safety issues from widely recognized experts and stakeholders to create the International Patient Safety Goals® (IPSG), which are tailored for each accreditation program. These goals focus on significant problems in health care safety and specific actions to prevent them. For a list of the current Goals, go to the IPSG chapter in the *Joint Commission International Accreditation Standards for Hospitals,* 8th Edition.
- *Joint Commission Resources:* A Joint Commission not-for-profit affiliate that produces books and periodicals, holds conferences, provides consulting services, and develops software products for accreditation and survey readiness. (For more information, visit http://www.jcrinc.com.)
- *Webinars and podcasts:* Joint Commission Resources offers free and fee-based webinars and podcasts on various accreditation and patient safety topics.

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Sentinel Event Policy (SE)

Careful identification, investigation, and analysis of serious patient safety events, and strong corrective actions that provide effective and sustained system improvement, are essential to reduce risk and prevent patient harm. The Sentinel Event Policy explains how Joint Commission International (JCI) partners with health care organizations that have experienced a serious patient safety event to protect future patients, improve systems, and prevent further harm.

Although health care organizations are not required to report sentinel events to JCI, accredited health care organizations must have a policy detailing how the organization addresses sentinel events. The specific requirements for that policy's content are included in the "Governance, Leadership, and Direction" (GLD) chapter (*see* **Standard GLD.04.00**) of the *Joint Commission International Accreditation Standards for Hospitals*, 8th Edition. The health care organization must complete a thorough comprehensive systematic analysis (most commonly a root cause analysis) to determine why the event occurred. The health care organization must then create a corrective action plan to prevent similar events from happening again, implement the plan, and monitor its effectiveness.

All accredited health care organizations are encouraged to voluntarily self-report potential sentinel events to Joint Commission International to allow collaboration with the Office of Quality and Patient Safety (OQPS). Timely reporting will promote early engagement with JCI to work with your organization. However, reporting a sentinel event to JCI does not take the place of reporting such events to other entities such as Ministries of Health when required by laws and regulations.

Contacting Joint Commission International after a sentinel event allows the health care organization to use the OQPS patient safety staff's expertise and experience. JCI can help analyze root causes, redesign processes, and monitor performance improvement practices and other aspects of the sentinel event process.

Voluntarily self-reporting sentinel events reinforces the health care organization's message to the public that it is doing everything it can to prevent a recurrence. Sharing information, particularly lessons learned, with Joint Commission International enhances Joint Commission International's Sentinel Event Database, which may help other organizations learn from them to prevent similar events. The more health care organizations report their own sentinel events, the better and more meaningful sentinel event statistics become. Joint Commission International sentinel event data identify not only the relative frequency of different categories of sentinel events reported each year, but they also provide information on trends in the occurrence of the most reported sentinel event categories.

Goals of the Sentinel Event Policy

The purpose of the JCI Sentinel Event Policy is to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. JCI's Sentinel Event Policy has the following four goals:

1. To positively impact care, treatment, and services by helping health care organizations identify opportunities to change their culture, systems, and processes to prevent unintended harm.

2. To help health care organizations that have experienced a sentinel event determine and understand contributing factors (including underlying causes, latent conditions, and active failures) and develop strategies to prevent or reduce such events in the future.
3. To increase the health care organization's resilience by becoming a learning organization.
4. To maintain the confidence of the public, clinical staff, and health care organizations in the priority of patient safety in JCI–accredited health care organizations.

Identifying Sentinel Events

Sentinel events are a subcategory of adverse events. A *sentinel event* is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and:

- results in death
  or
- severe harm (regardless of duration of harm)
  severe harm An event or condition that reaches the individual, resulting in life-threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring and/or surgery, invasive procedure, or treatment to resolve the condition.
  or
- permanent harm (regardless of severity of harm)
  permanent harm An event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline health.

Sentinel events are not only events that occur during the care and treatment of individuals. Physical and verbal violence, abductions, and power failures are all potential sentinel events that can affect the health care organization and its patients. Joint Commission International considers the following list of events, though not comprehensive, to be sentinel events if they occur in any Joint Commission International–accredited health care organization, although some of these events are unlikely to occur in certain health care settings:

- Death caused by self-inflicted injurious behavior if any of the following apply:
  - While in a health care setting
  - Within 7 days of discharge from inpatient services
  - Within 7 days of discharge from emergency department (ED)
  - While receiving or within 7 days of discharge following behavioral health care
- Unanticipated death of a full-term infant
- Homicide of any patient receiving care, treatment, and services while on site at the health care organization or while under the care or supervision of the organization
- Homicide of a staff member, visitor, or vendor while on site at the health care organization or while providing care or supervision to patients
- Any intrapartum maternal death
- Severe maternal morbidity (leading to *permanent harm* or *severe harm*)
  - *Severe maternal morbidity* is defined as a patient safety event that occurs from the intrapartum through the immediate postpartum period (24 hours), requiring the transfusion of 4 or more units of packed red blood cells (PRBC) and/or admission to the intensive care unit (ICU). *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and can provide mechanical ventilation or continuous vasoactive drug support. Sources: American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal-Fetal Medicine.
  - Ongoing vigilance to better identify patients at risk for severe maternal morbidity, and timely implementation of clinical interventions consistent with evidence-based guidelines, are important steps in the ongoing provision of safe and reliable care.

  - Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings.
- Sexual abuse/assault of any patient receiving care, treatment, and services while on site at the health care organization or while under the care or supervision of the organization
- Sexual abuse/assault of a staff member, visitor, or vendor while on site at the health care organization or while providing care or supervision to patients
  - *Sexual abuse/assault* is defined as nonconsensual sexual contact of any type with an individual. Sexual abuse includes but is not limited to the following:
    - Unwanted intimate touching of any kind, especially of the breasts, buttocks, or perineal area
    - All types of sexual assault or battery, such as rape, sodomy, and coerced nudity (partial or complete)
    - Forced observation of masturbation and/or sexually explicit images, including pornography, texts, or social media
    - Taking sexually explicit photographs and/or audio/video recordings of an individual and maintaining and/or distributing them (for example, posting on social media); this would include but is not limited to nudity, fondling, and/or intercourse involving an individual.
  - Generally, sexual contact is nonconsensual in the following situations:
    - When the individual lacks the cognitive or legal ability to consent even though appearing to want the contact to occur
    - When the individual does not want the contact to occur
    - Other examples of nonconsensual sexual contact may include but are not limited to situations in which an individual is sedated, is temporarily unconscious, or is in a coma. An individual's apparent consent to engage in sexual activity is not valid if it is obtained from the individual lacking the capacity to consent, or consent is obtained through intimidation, coercion, or fear, whether it is expressed by the individual or suspected by staff. Any forced, coerced, or extorted sexual activity with an individual, regardless of a preexisting or current sexual relationship, is considered sexual abuse.
    - Health care organizations are required to investigate and protect an individual(s) from nonconsensual sexual relations anytime the organization has reason to suspect that the individual(s) does not wish to engage in sexual activity or may not have the cognitive or legal ability to consent.
- Physical assault (leading to death, permanent harm, or severe harm) of any patient receiving care, treatment, and services while on site at the health care organization or while under the care or supervision of the organization
- Physical assault (leading to death, permanent harm, or severe harm) of a staff member, visitor, or vendor while on site at the health care organization or while providing care or supervision to patients
- Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome
  - *invasive procedure* is defined as a procedure in which skin or mucous membranes and/or connective tissue are incised or punctured, an instrument is introduced through a natural body orifice, or foreign material is inserted into the body for diagnostic or treatment-related purposes. Examples of invasive procedures include central line and chest tube insertions, biopsies and excisions, and all percutaneous procedures (for example, cardiac, electrophysiology, interventional radiology). Exclusions include venipuncture, defined as a collection of blood from a vein. **Note:** *This exclusion is still considered a patient safety event and should be reviewed by the appropriate local quality and safety teams.*
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services

- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe harm to the patient
- Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in death, permanent harm, or severe harm
  - If a clinical determination warrants the use of Rho(D) positive blood to a Rho(D) negative recipient or uncrossmatched blood for emergent or lifesaving interventions, it would not be considered a reviewable sentinel event.
  - Administration of blood or blood products where safety, potency, or purity has been compromised while the blood product in question was in the laboratory's control would be considered a sentinel event.
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
  - The time period after an invasive procedure encompasses any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. A failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a reviewable sentinel event. However, in such cases, the health care organization shall (1) disclose to the patient the unintended retention and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.
- Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)
- Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed
- Any delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or > 25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the health care organization. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present.
- Fall in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time when staff are present resulting in any of the following:
  - Any fracture
  - Surgery, casting, or traction
  - Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury
  - A patient with coagulopathy who receives blood products as a result of the fall
  - Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)

In cases in which the health care organization is uncertain if an event meets Joint Commission International's definition of a sentinel event, the event will be presumed to be a patient safety event, which still requires a comprehensive analysis (*see also* **Standard QPS.03.04**). In the spirit of collaboration and shared learning, it is requested that this analysis be shared with the Office of Quality and Patient Safety.

Accredited health care organizations are expected to identify and respond appropriately to all sentinel events (as defined by JCI) occurring in the health care organization or associated with services that the health care

organization provides, whether or not the event is voluntarily self-reported to JCI. An appropriate response includes all the following:

- A formalized team response that stabilizes the patient, discloses the event to the patient and family, and provides support for the family as well as staff involved in the event
- Notification of organization leaders
- Immediate investigation
- Completion of a comprehensive systematic analysis for identifying the causal and contributory factors
- Strong corrective actions derived from the identified causal and contributing factors that eliminate or control system hazards or vulnerabilities and result in sustainable improvement over time
- Timeline for implementation of corrective actions
- Systemic improvement with measurable outcomes

Determining That a Sentinel Event Is Subject to Review

When a hospital is unsure whether an event is a sentinel event, voluntary self-reporting by submitting the event to JCI allows the OQPS to determine whether it is indeed a sentinel event (*see* the "Reporting a Sentinel Event to Joint Commission International" section). Based on available information received about the event, JCI will determine whether an event meets the definition of *sentinel event* (as described in the "Identifying Sentinel Events" section). Any discrepancy in this determination will be resolved through discussions between Joint Commission International leaders and the health care organization's leaders.

Relationship to the Survey Process

When conducting an accreditation survey, the surveyor(s) evaluates the health care organization's compliance with the applicable standards, International Patient Safety Goals, and Accreditation Participation Requirements. Surveyors are instructed not to search for or investigate sentinel events during an accreditation survey or to inquire about whether there were any sentinel events reported to Joint Commission international.

During an accreditation survey, the surveyor(s) will assess the health care organization's compliance with the sentinel event–related standards (*see* **Standards GLD.04.00, QPS.03.04**, and **QPS.04.00**) in the following ways:

- Assess a health care organization's overall performance improvement practice, such as its processes for responding to safety events, adverse events, hazardous or unsafe conditions, close calls, and sentinel events *without inquiring about specific events* or asking for details of such events.
- Review the hospital's sentinel event policy and procedure for compliance with **GLD.04.00, ME 5** (patient safety events and sentinel events are defined).
- Review the health care organization's process and policy and procedure for responding to a sentinel event—a review of the process and relevant policy and procedure only, and *not a review of specific sentinel events* that may have occurred.
- Interview the health care organization's leaders and staff about their expectations and responsibilities for identifying, reporting on, and responding to sentinel events.

If a potential serious patient safety event or a sentinel event is newly identified during normal survey activities, the surveyor will take the following steps:

- Inform the health care organization's chief executive(s) that the event has been identified during the course of normal survey activities.
- Inform the chief executive(s) that the event will be reported to Joint Commission International for further review by the Office of Quality and Patient Safety, with follow-up under the provisions of this Sentinel Event Policy (*see* the "Joint Commission International's Response" section)

The surveyor(s) is not authorized to make a determination of whether the event is a sentinel event, or focus on or investigate the event further, nor is the surveyor(s) authorized to review comprehensive systematic analysis documents and determine the credibility, thoroughness, or acceptability of that analysis. Only the Office of Quality and Patient Safety may do this. However, the surveyor(s) is authorized to score a finding of noncompliance if the health care organization has not completed a comprehensive systematic analysis of the event (including a corrective action plan) within 45 days of the event. The surveyor(s) may score only to the time frame for completion of the comprehensive systematic analysis and not to the content of that analysis or the event itself. It is important to note that the hospital must also comply with all applicable laws and regulations regarding these time frames if these differ from the JCI requirements, but this is separate from the JCI process.

In this case, *after* the completion of the current on-site accreditation survey activities, OQPS will contact the health care organization to inquire about the event and determine whether submission of a comprehensive systematic analysis to JCI is required. If so, the health care organization will follow the steps described in the "Required Health Care Organization Response to a Sentinel Event" section of this policy.

Required Health Care Organization Response to a Sentinel Event

The health care organization must perform a comprehensive systematic analysis for all sentinel events, regardless of whether the events are voluntarily self-reported to JCI (*see* "Conducting a Comprehensive Systematic Analysis" for examples and resources). When a voluntarily self-reported sentinel event is determined to meet the criteria of this policy in a JCI–accredited organization, the health care organization is expected to do the following:

- Prepare a thorough and credible comprehensive systematic analysis and corrective action plan within 30 business days of the event or of becoming aware of the event.
- Submit its comprehensive systematic analysis and corrective action plan to Joint Commission International, or otherwise provide its response to the sentinel event using an approved methodology within 45 business days of the known occurrence of the event for Joint Commission International evaluation.

JCI will conduct a collaborative review with the health care organization's leaders or designee to determine whether the analysis and action plan are acceptable. JCI intends for the process to be collaborative and helpful rather than punitive, and the fact that a health care organization has experienced a sentinel event will not impact its accreditation decision. However, *purposeful* failure to respond appropriately to a sentinel event could have such an impact. In these instances, OQPS would recommend to the executive leaders of JCI and the JCI Accreditation Council to review the health care organization's accreditation status.

Reporting a Sentinel Event to Joint Commission International

Each health care organization is strongly encouraged, but not required, to voluntarily self-report to JCI any patient safety event that meets the definition of *sentinel event*. In fact, most sentinel events reported to JCI are self-reported by health care organizations. Health care organizations benefit from self-reporting in the following ways:

- Getting support and expertise during the review of a sentinel event
- An opportunity to collaborate directly with JCI
- Raising the level of transparency in the health care organization, which promotes a culture of safety
- Conveying the message to the health care organization's public that it is proactively working to prevent similar patient safety events in the future

A health care organization can report a sentinel event or ask to clarify whether an event meets the sentinel event definition at JCIQuality@jcrinc.com.

When a sentinel event is voluntarily self-reported to Joint Commission International, a clinician is assigned to review it and collaborate with the health care organization. This is the health care organization's main contact if there are questions about completing the process.

Conducting a Comprehensive Systematic Analysis

The health care organization must complete a comprehensive systematic analysis (*see also* **Standard QPS.03.04**) to identify the root cause(s) and contributory factors to any known sentinel event, regardless of whether the event is voluntarily self-reported to JCI.

A *comprehensive systematic analysis* is defined simply as a process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis (RCA), for example, is one common type of comprehensive systematic analysis. Examples of frameworks for conducting an RCA include the following:

- **The Joint Commission RCA framework:** https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/rca_framework_101017.pdf
- **The Institute for Healthcare Improvement RCA²:** https://www.ihi.org/resources/tools/rca2-improving-root-cause-analyses-and-actions-prevent-harm
- **SWARMing methodology:** https://www.jointcommissionjournal.com/article/S1553-7250(15)41065-7/pdf

The health care organization can determine its internal process, tools, and methodologies to conduct such an analysis. Any comprehensive systematic analysis should include a review of recent evidence-based literature to guide the health care organization in developing a strong corrective action plan (addressed in the next section) with the use of evidence-based practices or tools.

Joint Commission International staff review the analysis, which should focus on systems and processes, to verify that it is thorough and credible (*see* the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section). The health care organization's selected comprehensive systematic analysis method should address the questions from JCI's Framework for Root Cause Analysis and Corrective Actions. There are a number of mandatory fields within the form which must be completed by the health care organization. If the health care organization chooses to do so, it can upload supporting documents with its submission.

A health care organization's comprehensive systematic analysis should identify system vulnerabilities so that they can be eliminated or mitigated. It should not focus on individual health care worker performance but should seek out underlying systems-level causations that manifested in personnel-related performance issues. To help adhere to these characteristics it is recommended, but not required, that health care organizations consider the following guidelines when developing causative factor statements:

- Use specific and accurate descriptors for what occurred, rather than negative and vague words.
- Clearly show the cause-and-effect relationship.
- Include a preceding cause for any human errors or violations of procedure (that is, do not consider them as root causes or stand-alone causal factors).
- Classify a failure to act as a causal factor only when there is a preexisting duty to act.

See the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section for more detail on what is considered a thorough and credible analysis.

Developing a Corrective Action Plan

The end-product of the comprehensive systematic analysis is a corrective action plan. The corrective action plan identifies the strategies that the health care organization intends to implement to reduce the risk of similar events occurring in the future. When formulating a corrective action plan, the review team should analyze the strength of its proposed solutions. An evidence-based tool, such as the Action Hierarchy from the US Department of Veterans Affairs (VA) National Center for Patient Safety (https://www.patientsafety.va.gov/professionals/onthejob/rca.asp) or the Action Hierarchy from the Institute for Healthcare Improvement (IHI)

Patient Safety Essentials Toolkit (https://www.ihi.org/resources/tools/patient-safety-essentials-toolkit) can help the team identify strong actions that provide effective and sustained system improvement.

The health care organization should identify at least one intermediate or stronger action (as defined in the action hierarchy) to eliminate or mitigate system hazards or vulnerabilities identified in the comprehensive systematic analysis. The corrective action plan must address the following:

- Identifying corrective actions to eliminate or reduce system hazards or vulnerabilities directly related to causal and contributory factors
- Identifying who is responsible for implementing corrective actions
- Determining timelines to complete corrective actions
- Developing strategies to evaluate the effectiveness of the corrective actions
- Developing strategies to sustain the change

(*See* the "Review of Comprehensive Systematic Analyses and Corrective Action Plans" section for more detail on what is considered an acceptable corrective action plan.)

Submitting the Comprehensive Systematic Analysis and Corrective Action Plan

A health care organization that voluntarily self-reports a sentinel event must submit a comprehensive systematic analysis, including the resulting corrective action plan that describes the health care organization's risk reduction strategies as well as how the strategies will be evaluated and measured to determine effectiveness. This information is submitted electronically to JCI at JCIQuality@jcrinc.com and will be reviewed in a conference call involving JCI and the health care organization leaders or designee(s). These documents should not include the names of health care organization staff or patients involved in the sentinel event or other protected personal health information (PHI).

Joint Commission International's Response

JCI assesses the health care organization's response to the sentinel event against three criteria:

1. Thoroughness of the comprehensive systematic analysis
2. Credibility of the comprehensive systematic analysis
3. Acceptability of the health care organization's corrective action plan

JCI will provide collaborative consultation to the health care organization if the response lacks robust key elements and will allow an additional 20 calendar days beyond the original submission period for the health care organization to resubmit its response, including revised corrective actions if necessary.

Review of Comprehensive Systematic Analyses and Corrective Action Plans

JCI reviews the comprehensive systematic analysis and corrective action plans for thoroughness, credibility, and acceptability.

To be **thorough**, the analysis must do the following:

- Repeatedly ask "Why?" until the analysis identifies the systemic causal factors associated with each step in the sequence that led to the sentinel event.
- Focus on systems and processes, not solely on individual performance.
- Determine the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence.
- Use the analysis to help determine where redesign might reduce risk.
- Inquire into all areas appropriate to the specific type of event.
- Identify risk points and their potential contributions to this type of event.
- Determine potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future or determine, after analysis, that no such improvement opportunities exist.

To be **credible**, the analysis must do the following:

- Be clear (understandable information).
- Be accurate (validated information and data).
- Be precise (objective information and data without internal inconsistencies).
- Be relevant (focus on issues related or potentially related to the sentinel event).
- Be complete (cover all causes and potential causes).
- Be systematic (methodically conducted).
- Possess depth (ask and answer all the relevant "Why" questions and explain any "not applicable" finding).
- Possess breadth of scope (cover all possible systemic factors wherever they occur).
- Reflect diverse perspectives (include a process owner or designee, a patient or family member when appropriate, and individuals close to the process under review).

Joint Commission International does not require the active involvement of a senior leader in the day-to-day work of the comprehensive systematic analysis team. However, the team should report to the senior leader or designee, and the individual should be involved in deciding or approving the actions the health care organization will take as a result of the comprehensive systematic analysis.

To be considered **acceptable**, the corrective action plan must do the following:

- Identify changes that can be implemented to reduce risk, or formulate a rationale for not undertaking such changes.
- Identify, in situations in which improvement actions are planned, the following:
  - Who (by title) is responsible for implementation
  - When the action will be implemented (including any pilot testing)
  - How the effectiveness of the actions will be evaluated
  - How the actions will be sustained
  - The point at which alternative actions will be considered if improvement targets are not met
  - At least one stronger or intermediate-strength action

All comprehensive systematic analyses and corrective action plans will be considered and treated as confidential by JCI (*see* the "Handling Sentinel Event–Related Documents" section below).

If JCI finds the analysis and action plan thorough, credible, and acceptable, JCI will notify the health care organization and assign one or more follow-up activities.

Follow-Up Activities

After JCI has determined that a health care organization has conducted a thorough comprehensive systematic analysis (for example, root cause analysis) and developed a comprehensive corrective action plan, JCI will notify the health care organization whether the analysis and action plan have been accepted and will assign an appropriate follow-up activity. This will be a mutually agreed-upon documentation of sustained improvement and reduction of risk, which may include one or more Measures of Success (MOS).

Sentinel Event Measures of Success

The health care organization's follow-up activity may be conducted through the Sentinel Event Measure of Success (SE MOS) process. The health care organization will identify one or more SE MOS—that is, one or more numerical or quantifiable measures (ideally with a numerator and denominator), usually related to an audit, which determines if the health care organization effectively sustained the planned corrective action(s). The health care organization will track the measure for at least 90 days (or three months) and report its compliance to Joint Commission International. The health care organization's report, due on a mutually agreed-upon date, should demonstrate whether the health care organization reached its identified SE MOS and is sustaining compliance.

The health care organization's accreditation decision may be impacted under the following circumstances:

- An SE MOS submitted on time does not meet preestablished levels of compliance and JCI requests an additional 120 days (or four months) of data that still does not meet preestablished levels of compliance.
- Submission of an SE MOS more than 90 days (or three months) after the mutually agreed-upon date.

On-Site Review of a Sentinel Event

JCI will generally not conduct an on-site review of a self-reported sentinel event unless it determines that a potential ongoing *Immediate Threat to Health or Safety* exists. An *Immediate Threat to Health or Safety* is a threat that represents immediate risk and may have serious adverse effects on the health or safety of patients and/or others. All potential Immediate Threats to Health or Safety are referred to Joint Commission International's executive leaders for authorization to conduct an unannounced for-cause survey. If an on-site survey is conducted, the health care organization will be billed a sufficient charge, based on an established fee schedule, to cover the costs of conducting such a survey.

Disclosable Information

If Joint Commission International receives an inquiry about the accreditation decision of a health care organization that has experienced a sentinel event, the health care organization's current accreditation status will be reported in the usual manner without referring to the sentinel event. If the inquirer specifically references the sentinel event, Joint Commission International will acknowledge that it is aware of the event and currently is working or has worked with the health care organization through the sentinel event review process, without disclosing details of the event. All details and materials related to the sentinel event are and will remain confidential.

Handling Sentinel Event–Related Documents

Joint Commission International restricts access to any submitted comprehensive systematic analysis and corrective action plan to the Office of Quality and Patient Safety in accordance with procedures designed to protect the confidentiality of the documents. Joint Commission International will retain any corrective action plan(s) resulting from the analysis of the sentinel event long enough to serve as the basis for appropriate follow-up activities, such as the SE MOS or other mutually agreed-upon documentation of sustained improvement. After the health care organization implements the corrective action plan and Joint Commission International verifies that it meets the established levels of compliance, the information contained in any electronically submitted analysis will be de-identified after the OQPS completes its review.

The Sentinel Event Database

Joint Commission International collects and analyzes aggregate data from the comprehensive systematic analyses, corrective action plans, and follow-up activities in its Sentinel Event Database. Joint Commission International develops and maintains the database in a manner that excludes health care organization, caregiver, and patient identifiers.

Aggregate data relating to root causes and risk reduction strategies for sentinel events that occur with significant frequency may form the basis for future error-prevention advice to health care organizations.

Overseeing the Sentinel Event Policy

The executive leaders of Joint Commission International are responsible for approval of this policy and overseeing its implementation. For more information about Joint Commission International's Sentinel Event Policy, visit Joint Commission International's website (https://www.jointcommissioninternational.org/contact-us/sentinel-event-policy/).

Summary of Key Accreditation Policies

This section provides a high-level summary of Joint Commission International's (JCI's) accreditation policies for hospitals and academic medical centers. Full policies and procedures are posted on your organization's secure *JCI Direct Connect* extranet site. The policies can be grouped into the following categories:

1. Before Survey
   - Seeking JCI accreditation
   - Applying for accreditation
2. During Survey
   - The survey process
   - Cost of surveys
   - The on-site survey
3. After Survey
   - Accreditation decisions
   - Public disclosure and confidentiality
   - Maintaining accreditation
   - Accreditation renewal

Seeking JCI Accreditation

Basis of the Accreditation Process

Evaluation of compliance with the *Joint Commission International Accreditation Standards for Hospitals,* 8th Edition, is the basis of the hospital accreditation process. When accredited, hospitals are expected to demonstrate continuous compliance with current editions of the standards at all times of the accreditation cycle.

JCI publishes new standards and notifies health care organizations at least six months in advance of the effective date to provide time for hospitals to come into full compliance with the revised and new standards by the *effective date*. For hospitals seeking accreditation for the first time, the effective date indicates the date after which all surveys and accreditation decisions will be based on the new standards.

Any on-site or other accreditation-related activity (for example, videoconferences, extension surveys, for-cause surveys) or evidence of compliance submitted (for example, data, policies and procedures, root cause analyses and action plans, or self-assessments) after the effective date must be consistent with the current edition of the standards.

Accreditation Timeline

Every hospital prepares for its initial or triennial JCI on-site survey differently. A sample timeline followed by many hospitals appears below.

Before Survey:

- 24 months before survey—New initial applicants complete the initial registration process (IRP). When approved, then complete and submit the electronic application for accreditation (E-App) for survey, if ready. Obtain JCI standards and begin education on the standards and implementation of the expectations.
  Note: Many organizations begin this process by attending one of the many educational programs JCI offers around the world. For more on the process of getting started, see the guidance offered on JCI's website.
- 9–24 months before survey—Improve practices to ensure that they meet the requirements of the standards. Train staff on these new practices. Evaluate effectiveness and refine as necessary.
- 6–12 months before survey—Assess readiness; update the electronic profile, review the E-App, submit for the initial or triennial survey, and schedule dates.
- 4–6 months before survey—Receive, complete, and sign the JCI survey contract.
- 2 months before survey—JCI Survey Team Leader contacts the hospital to determine the survey logistics and agenda.

Survey:

- Scheduled survey conducted.

After Survey:

- Within 20 calendar days after the survey—Receive accreditation decision and Official Survey Findings Report from JCI.
- Within 10 calendar days of receiving the Official Survey Findings Report, the organization may submit a written request to JCI Accreditation for a revision of the report (*see* "General Postsurvey Policies" on the JCI website).
- 6–12 months before triennial survey date—Update and submit E-App for survey and schedule survey dates.
- The timeline may be accessed on the JCI website at https://www.jointcommissioninternational.org/pathway/.

Applying for Accreditation

The Application Process

A hospital applying for JCI accreditation for the first time (known as *initial applicants*) may begin their accreditation journey by completing a webform available at https://www.jointcommissioninternational.org/accreditation/jcia-contact-us/.

Following a review of the webform, the organization will be provided with a link to submit an initial registration. Upon approval of the initial registration, the organization will be sent a login and password to *JCI Direct Connect* (*see* below) to complete and submit an E-app for review by JCI Accreditation Central Office staff. The E-App provides detailed information and key statistics that create a hospital profile needed for JCI to manage its accreditation process, develop a contract for survey, and plan the survey agenda and on-site evaluation process. The E-app should be submitted approximately 6 to 12 months prior to the survey dates requested. The E-app provides the information needed to develop a contract specifying cost, number of surveyors, and number of survey days.

Hospitals already accredited or certified apply for continued accreditation or certification via the E-App on *JCI Direct Connect* 6 to 12 months prior to the survey dates requested. The hospital must notify JCI within 30 days—or at least 30 days before the scheduled survey date—of any change to the information reported in the survey application.

JCI Direct Connect

JCI provides each accredited and/or certified organization with access to *JCI Direct Connect*, JCI's secure, password-protected customer portal. *JCI Direct Connect* contains the following:

- E-App
- Important accreditation- or certification-related due dates
- Official reports, e-mails, and announcements including standard updates
- Continuous-compliance tools
- Current accreditation or certification manual and survey process guide
- A publicity guide for appropriate use of JCI Gold Seal of Approval® with advice on promoting the hospital's accreditation or certification

Organizations receive access to *JCI Direct Connect* when first applying for accreditation or certification and receive incremental access to more of the site's content and services as they proceed through the accreditation or certification process. Only fully accredited and certified organizations receive access to all of *JCI Direct Connect*s content and services.

Types of Surveys

Full Survey

Survey of all the hospital standards throughout an entire organization. This may be the initial survey or the triennial survey. Definitions of both follow:

- *Initial Survey*—The first full survey of a hospital
- *Triennial Survey*—The survey of a hospital after a three-year cycle of accreditation

Follow-up Survey

A survey that may be conducted as a required follow-up to a full survey (initial/triennial) when the documented findings do not meet one or more of the accreditation decision rules. A follow-up survey is limited in scope, content, and length and is designed to gather information on a specific issue(s) or limited number of standards or measurable elements (MEs), International Patient Safety Goals (IPSG), and/or Accreditation Participation Requirements (APR).

Follow-up surveys are scheduled at least 120 days, but no later than six months from the date the hospital received the Preliminary Survey Findings Report. JCI Accreditation may deny or withdraw an organization's accreditation/certification if the organization does not allow JCI Accreditation to conduct a follow-up survey.

Extension Survey

An extension survey is conducted to evaluate an organization's continued compliance with the appropriate accreditation/certification program standards following significant changes in the organization's services/programs, patient volume, facilities, governance, or ownership. When any of these factors change, Joint Commission International Accreditation (JCIA) must evaluate the change to determine if the change is within or outside of the scope of a planned initial survey or the scope of a current accreditation award.

JCI may conduct an extension survey when the hospital notifies JCI before the change or within 30 days of changes in such core information from the hospital's profile, including but not limited to the following (*See also* APR.03.00):

- A change in the organization's ownership
- Requesting to change hospital accreditation to academic medical center accreditation
- A merger or acquisition; the organization has merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable JCI standards.
- The revocation or restriction of operational licenses or permits, any limitations or closure of patient care services, any sanctions of professional or other staff, or other actions under laws and regulations brought by relevant health authorities

- New biomedical equipment for patient care that are used to expand the types and volume of patient care services 25% or more than was stated in the most recent E-App.
- Changes in use of patient care buildings, construction of new or expansion of patient care buildings, or the occupation of buildings that are used to expand the types and volume of patient care services 25% or more than was stated in the most recent E-App, or was not reported as a patient care location, or was not included in the scope of the previous accreditation survey
- Temporary cessation of services and/or significant reduction of patient care services/volume due to extenuating circumstances
- Intentional expansion of the organization's capacity to provide services in the absence of new, renovated, or expanded facilities by 25% or greater, as measured by patient volume, scope of services, or other relevant measures
- The addition of one or more types of health care services (for example, addition of a dialysis unit)
- Implementation of a higher level of service (for example, adding inpatient invasive diagnostic cardiology when originally providing only outpatient cardiac rehabilitation)

Extension surveys are surveys limited in scope, content, and length and designed to gather information relevant to the specific changes in the hospital. JCI will determine whether an extension survey or a full survey is required based on the changes in the scope of services being provided.

For-Cause Survey

A type of survey that is limited in scope, content and length and designed to gather information on a specific issue(s) related to a high-risk patient safety event, sentinel event, or a pattern of incidents that relate to JCI standards or Accreditation Participation Requirements (APRs). A for-cause survey may be conducted after the receipt of information regarding the occurrence of any situation, event, or series of events in an accredited/certified organization that may create a significant unsafe situation or threat to health and safety.

JCIA may conduct a for-cause survey for the following reasons:

- A concern of a potential ongoing and/or *Immediate Threat to Health or Safety* within the organization
- To confirm/investigate an applicable condition(s) that resulted in the organization being classified as Preliminary Denial of Accreditation
- To confirm accreditation eligibility status following sanctions, penalties, limitation in operations imposed by a regulatory, legal, or other authoritative body, or closure of services for a period of time
- When it becomes aware of potentially serious standards or noncompliance to APRs
- Verification of implemented adverse event, regulatory or "other" required corrective actions, effectiveness, and sustainability of those actions
- When it has other valid reasons for surveying an accredited/certified organization to determine accreditation status or capability for resuming services
- When the organization demonstrates the need for additional JCI surveillance to ensure that the organization's patients are not at risk and that the hospital's compliance with all relevant JCI standards has not been interrupted
- An initial review of a patient safety event or follow-up to an event, if it is determined that there is a potential ongoing *Immediate Threat to Health or Safety* or potentially significant noncompliance with JCI standards and/or APRs

The Survey Process

Purpose of a Survey

An accreditation survey is designed to assess a hospital's compliance with JCI standards based on the following:

- Interviews with staff and patients and other verbal information
- Observations of patient care processes

- Review of policies, procedures, clinical practice guidelines, medical records, staff records, governmental and/or regulatory compliance reports, and other documents requested from the hospital
- Review of quality and patient safety improvement data, performance measures, and outcomes
- Individual *patient tracers* (that is, evaluation of a patient's care experience through the hospital care process)
- *System tracers* of organizationwide processes (for example, medication management, infection prevention and control, hazardous materials, and waste, or other high-risk, high-/low-volume, problem-prone systems, and processes

Preparing for Survey

JCI assigns each hospital an account manager to serve as the primary contact between the hospital and JCI. This individual assists in the coordination of the presurvey activities and is available to answer questions about the following:

- Application submission and receipt, contracting, and scheduling
- Official Survey Findings Report processing and Strategic Improvement Plans
- Status of accreditation and certification certificates
- Notifying JCI of significant changes in your organization, including how to update information in *JCI Direct Connect* and the E-App
- General JCI policies and practices and the survey process
- Concerns regarding any of JCI's processes

Scheduling the Survey

JCI and the hospital select the survey date and prepare the survey agenda together to meet the hospital's needs and the requirements for an efficient survey. To reduce surveyor travel costs, JCI makes every effort to coordinate the scheduling of surveys of other hospitals in a specific country or region.

Planning the Survey Agenda

JCI assigns each hospital a Team Leader to assist in the coordination of the survey agenda planning. The Team Leader will contact the hospital approximately eight weeks in advance of the survey to coordinate logistics for the survey and prepare a survey agenda based on the size, type, and complexity of the hospital. The agenda specifies the sites JCI surveyors will visit, the types of interviews surveyors will conduct, the staff to be interviewed, and the documents that must be provided to the surveyors.

The Survey Team

Highly qualified and experienced international surveyors perform the survey. JCI conducts surveys in the English language; however, JCI makes every effort to use surveyors fluent in the language(s) used at the organization. If JCI surveyors with the appropriate language capabilities are not available, it is the responsibility of the surveyed organization to provide qualified translators who are free from conflict of interest. A typical hospital survey team consists of a physician, nurse, and hospital administrator.

Cancellation of a Survey

JCI or a hospital may cancel a survey without penalty or damages when events such as wars, terrorism, or other similar emergencies or circumstances make it impossible, illegal, or unreasonable to go forward with a survey. Cancellation due to any of the reasons cited above must be communicated in writing as soon as possible. If the hospital cancels the survey thirty (30) or fewer days prior to the start date of the survey for any reason or reasons other than those stated above, JCI will require payment of all associated direct costs plus a cancellation fee as outlined in the signed contract. If a hospital cancels the survey more than once after the survey dates are confirmed via e-mail by JCI, JCI will also require a rescheduling fee. This rescheduling fee will increase for

each cancellation request. In the event that JCI cancels the survey for any reason or reasons other than those previously stated, JCI does not charge the organization a fee.

Postponement of a Survey

A hospital may postpone a survey that has already been scheduled without penalty or damages when one or more of the following situations occur:

- A natural disaster or another major unforeseen event that substantially disrupts operations
- A major strike that causes the organization to stop accepting patients, cancel surgery and/or other elective procedures, and transfer patients to other hospitals
- Patients, the organization, or both are being moved to another building during the dates of the scheduled survey.

JCI reserves the right to conduct a survey if the organization continues to provide patient care services under any of the above circumstances. Hospital renovation projects do not prevent JCI from conducting the survey.

If a hospital postpones the survey thirty (30) or fewer days prior to the first date of the survey for reasons other than those previously stated, JCI will require payment of all associated direct costs plus a postponement fee as outlined in the signed contract. If a hospital postpones the survey more than once after the survey dates are confirmed via e-mail by JCI, JCI will charge a rescheduling fee. This rescheduling fee will increase for each postponement request. In the event that JCI postpones the survey for any reason or reasons other than those previously stated, JCI does not charge the organization a fee.

Cost of Surveys

Calculation of Costs

JCI bases its accreditation survey fee on several factors, including the volume, type, and complexity of services provided by the hospital; the number of locations or care settings included in the survey; and the number of surveyors and survey days required to conduct the evaluation of compliance with JCI standards. Surveyor time for report preparation is included in the calculated survey days. JCI charges the hospital for any required follow-up surveys and for some hospital-initiated survey postponements or cancellations. Inquiries related to estimates of survey fees should be sent via e-mail to JCIAccreditation@jcrinc.com.

Travel Costs

In addition to survey fees, the hospital is responsible for paying all travel costs for the surveyors. This includes transportation (airfare, train, and car) and reasonable hotel accommodations and meals, including a set daily rate for meals and incidental expenses.

Payment Schedule of Survey Fees

JCI bills organizations for accreditation fees using one of two options, noted below. JCI requests that organizations identify their preferred billing option by selecting and signing for the desired option on the last page of their accreditation contract.

Payment Option I

Upon the hospital's return of the signed contract and within 30 days of receipt of the confirmed survey dates, the hospital will receive an invoice for 100% of the survey fees, not including surveyor expenses and surveyor airfares, unless available. Payment is due upon receipt of the invoice. Within 30 days of the conclusion of the survey, JCI will bill the hospital for the remaining surveyor(s) travel and maintenance expenses.

Payment Option II

Upon the organization's return of the signed contract and within 30 days of receipt of the confirmed survey dates, the organization will receive an invoice for the first half of the accreditation survey fees (50%) and all surveyor airfares if available. Payment is due upon receipt of the invoice. At the conclusion of the survey, the second invoice for the remaining 50% of the survey fees and available surveyor travel and maintenance expenses will be billed to the organization. If required, a third invoice may be billed for the balance of expenses.

The Survey

Scope of the Survey

The scope of a JCI survey is determined by the information in the hospital's E-App. All patient care buildings/settings and all patient units identified on the application are included in the survey. All standards contained in the current edition of the *Joint Commission International Accreditation Standards for Hospitals* and updated standards communicated through *JCI Insight* and the organization's *JCI Direct Connect* extranet site are applicable unless the hospital does not provide that service (for example, does not provide laboratory services on-site).

The Survey Process

The *tracer methodology* is the foundation of the JCI survey process. In the tracer methodology, surveyors select representative patients from the hospital's patient population and trace each patient's care experience through the hospital; and will also trace several key clinical and managerial systems and processes. This exercise allows surveyors to identify standards compliance issues evident in one or more steps of the patient care and management processes or in the interfaces between processes.

In addition, surveyors interview staff individually and in groups, observe patient care, speak to patients and their families, review patient medical records, review staff personnel records, and review policies and procedures and other documents.

Hospitals should consult their *Joint Commission International Survey Process Guide for Hospitals Including Standards for Academic Medical Centers*, 8th Edition—which JCI provides to hospitals after they have returned a signed contract for survey to JCI—for detailed descriptions of what takes place during a typical initial or triennial survey, including detailed descriptions of all survey activities, required documentation, and other resources.

The surveyors confer with the organization's chief executive officer and other leaders at a leadership conference at the end of each survey. During this conference, the surveyors provide preliminary information about their findings. Any preliminary information is not final until the review by JCI Accreditation Central Office staff has been completed.

If, during the survey, the surveyors identify any condition they believe poses a serious threat to public or patient safety, they notify the JCI Accreditation Central Office staff. In those circumstances, JCI decides whether to issue an expedited Denial of Accreditation decision and if it should inform relevant public authorities.

The Survey Report

The survey team may provide a draft of the report of standards compliance at the exit interview and will, upon request of the hospital's leaders, report survey findings to the hospital staff at a closing conference. Surveyor findings are not considered final until reviewed by the JCI Accreditation Central Office staff. The Official Survey Findings Report will be complete and posted to *JCI Direct Connect* within 20 calendar days of the end of the survey unless a follow-up survey is required.

Revision of the Official Survey Findings Report

The hospital has ten (10) calendar days from receipt of the Official Survey Findings Report to request, in writing or by e-mail, revision of the report related to one or more survey findings. Appropriate data and supporting information must accompany the request. The JCI Accreditation Central Office staff will review the materials and contact the hospital and/or surveyors as needed in evaluating the information. When the request for revision of the report would change the survey outcome, the JCI Accreditation Council then considers the request for revision and makes the final accreditation decision.

Accreditation Decisions

JCI makes accreditation decisions by applying decision rules to the scored standards. Decision rules determine an accreditation decision that appropriately represents an organization's overall performance as measured by evidence of compliance with the applicable standards.

The JCI Accreditation Council may exercise reasonable discretion in individual cases to determine whether to vary from applicable decision rules in furtherance of JCI's mission to continuously improve the safety and quality of care in the international community. JCI Accreditation Council considers all information from the initial or triennial full survey and any required follow-up surveys in making its decision regarding accreditation. The outcome is that the organization meets the criteria for accreditation or does not meet the criteria and is denied accreditation.

Appeal of Decisions to Deny or Withdraw Accreditation

Hospitals have the right to appeal adverse accreditation decisions. If, based on a full or follow-up survey, or a threat-to-life health and safety situation, there is a decision to deny or to withdraw accreditation, an organization has 10 calendar days from receipt of its Official Survey Findings Report or notice of accreditation withdrawal to notify JCI, in writing or by e-mail, of its intent to appeal the decision. After submission of the intent to appeal, the organization has thirty (30) calendar days from the appeal request date to submit materials to support its appeal to JCI.

The appeals process affords the hospital an opportunity to present materials as outlined in the JCI Appeals Policy. JCI reserves the right to update its policies and procedures from time to time and recognizes the *JCI Direct Connect* website as the official location for the posting of all current policies and procedures regarding the JCI appeals process. In the event of any conflict between the JCI manual currently in effect and a JCI policy or procedure as posted on the *JCI Direct Connect* website, the policy or procedure on the *JCI Direct Connect* website shall govern.

Public Disclosure and Confidentiality

Confidentiality

JCI keeps confidential all matters having to do with the accreditation process except the following:

- An accredited hospital's status (that is, whether the organization is accredited, was denied accreditation, or if accreditation was withdrawn by JCI)
- The number of complaints submitted about an organization that meet the JCI criteria for review

The official accreditation status of a hospital is noted on the JCI website as either Accredited (including the date of the accreditation decision) or Accreditation Withdrawn (including the date the decision was made to withdraw accreditation). JCI posts the status of Accreditation Withdrawn on the JCI website for one year.

When an organization voluntarily withdraws from the accreditation process, JCI posts this and the date of the withdrawal on the JCI website. The accredited hospital may release more detailed information on its accreditation status, up to and including its Official Survey Findings Report, to whomever it wishes. However,

when a hospital disseminates inaccurate information about its accreditation status, JCI reserves the right to clarify information that would otherwise be considered confidential.

JCI provides to the individual submitting a complaint that meets the criteria for review the following:

- The applicable standards reviewed
- Any standards for which recommendations for improvement were issued and/or a Strategic Improvement Plan (SIP) was required as a result of the review
- When applicable, any change in the hospital's accreditation status

Accreditation Award Display and Use

JCI provides each hospital with three certificates of accreditation at the time of initial accreditation and at the time of each accreditation renewal. The certificates and all copies remain JCI's property. Certificates must be returned if the organization is issued a new certificate reflecting a name change or the organization's accreditation is withdrawn or denied for any reason.

A hospital accredited by JCI must be accurate in describing to the public the nature and meaning of its accreditation award and must not misrepresent its accreditation status or the facilities and services to which the accreditation award applies. JCI supplies each hospital receiving accreditation with appropriate publicity guidelines for announcing the accreditation award.

Maintaining Accreditation

Length of Accreditation Awards

An accreditation award is valid for three years unless revoked by JCI. The award is retroactively effective on the first day after JCI completes the hospital's survey or, when a follow-up survey is required, completes any follow-up survey(s). At the end of the hospital's three-year accreditation cycle, JCI reevaluates the hospital for renewal of its accreditation award.

Strategic Improvement Plan (SIP)

A Strategic Improvement Plan (SIP) is a comprehensive, strategic plan of actions an organization implements to achieve full compliance with the standards/measurable elements, with consideration of the finding's placement in the *Survey Analysis for Evaluating Risk*® (*SAFER*®) Matrix cited in an accreditation or certification Official Survey Findings report. The SIP explains the organization's process in defining the improvement plan strategy(ies) and/or approach, including specific actions to correct the cited findings and methodology to prevent reoccurrence and sustain improvements over time.

The SIP is expected to do the following:

- Establish the strategies/approach that the hospital will implement to address each identified finding.
- Describe specific actions the hospital will use to achieve compliance with the standards/MEs cited.
- Describe specific steps the hospital will use to communicate and educate its staff, physicians, and others in implementing actions to achieve compliance with the MEs cited.
- Describe methodology to prevent reoccurrence and to sustain improvement over time.
- Identify the measures that will be used to evaluate the effectiveness of the improvement plan.

The SIP must demonstrate that the hospital's actions will lead to full compliance with the standards and MEs. The SIP is reviewed and approved and accepted by the JCI Accreditation Central Office staff after the Accreditation or Certification Letter and Gold Seal have been awarded.

An organization that fails to submit an acceptable SIP within 120 days of the organization's survey is placed in Preliminary Denial of Accreditation and a follow-up survey is required to verify evidence of compliance. When this occurs, the client organization is notified and the follow-up survey protocol is implemented.

Reporting Requirements Between Surveys

JCI requires ongoing communication throughout the three-year accreditation cycle between the accredited hospital and JCI to ensure that the hospital continues to meet the accreditation requirements after becoming accredited. Accreditation is neither automatically transferred nor continued if significant changes occur within the accredited organization. Please *see* the "Accreditation Participation Requirements" (APR) section for the list of changes that must be reported.

Preliminary Denial of Accreditation

Preliminary Denial of Accreditation is type of temporary accreditation status that results when JCI determines that one or more of the following conditions may be present:

- An *Immediate Threat to Health or Safety* exists within the organization.
- An individual who does not possess a valid license, registration, or certification (for example, expired license) is providing or has provided health care services in the organization that would, under applicable laws and regulations, require such a license, registration, or certification and which placed the organization's patients at risk for a serious adverse outcome.
- JCI is reasonably persuaded that the organization submitted falsified documents or misrepresented information in seeking to achieve or retain accreditation.
- The organization has not met the policy for reporting requirements to JCI as outlined in the "Accreditation Participation Requirements" chapter.
- The organization fails required full survey(s).
- The organization fails to submit an acceptable Strategic Improvement Plan within 120 calendar days of the organization's survey.
- The provision of one or more clinical services has been suspended due to ongoing reconstruction, construction of new building, a mandate set forth by a governmental/regulatory authority, or the results of a natural disaster or another unforeseen event.

JCI Accreditation Central Office staff and surveyors may identify the conditions during a survey, during the review of a survey report or postsurvey follow-up activity, or from a complaint submitted against the hospital or after removal or restriction of its license/permit to operate by a national or other regulatory body or authority. When JCI finds that the condition is substantiated and not resolved, Denial of Accreditation is recommended to the JCI Accreditation Council. The organization has the right to appeal this decision as previously described.

Accreditation Renewal

The JCI Accreditation Central Office staff remind the hospital to update its E-App before the hospital's triennial accreditation due date and notify JCI of its intention to be reaccredited. JCI then schedules the survey, making every effort to synchronize the next survey date with the conclusion of the previous three-year accreditation cycle. JCI works with the hospital and others in the country or region that are also due for surveys to coordinate the survey dates in an effort to maximize resources and reduce travel expenses. A hospital's previous accreditation status may remain in effect up to two months after the subsequent full accreditation survey to accomplish any required follow-up.

Glossary

abnormal result A result that is outside of the expected range for the test but not immediately life-threatening. *See also* critical result.

accreditation Determination by an accrediting body that an eligible program, institution, or organization, such as a health care organization, complies with a required set of standards, indicating that a level of quality, performance, or similar attribute has been met. *See also* certification; standards-based evaluation.

accreditation decisions As it relates to Joint Commission International (JCI) accreditation, an organization can achieve the following categories of accreditation based on a JCI survey:

Accredited The organization demonstrates acceptable compliance with all JCI standards and International Patient Safety Goals (IPSGs).

Denial of Accreditation The organization does not demonstrate acceptable compliance with JCI standards and/or IPSGs, JCI withdraws accreditation for other reasons, or the organization voluntarily withdraws from the accreditation process.

accreditation process A continuous process whereby health care organizations demonstrate to JCI that they are providing safe, high-quality patient care, as determined by compliance with JCI standards and IPSG requirements. The key component of this process is an on-site survey of an organization by JCI surveyors.

accreditation survey An evaluation of an organization to assess compliance with applicable standards and IPSGs and to determine its accreditation status. The JCI accreditation survey includes the following:

- Evaluation of documents provided by the organization
- Verbal information about the implementation of standards or examples of their implementation that enables compliance to be determined
- On-site observations by surveyors
- Tracking of patients through the care process using tracer methodology
- Education about standards compliance and performance improvement

A survey of all standards throughout an entire organization is considered a full survey. An initial survey and triennial survey are full surveys:

initial survey The first on-site survey of an organization.

triennial survey The survey of an organization after a three-year cycle of accreditation.

Accredited *See* accreditation decisions.

acute care A level of health care in which a patient is treated for a brief but severe episode of illness; for conditions that are the result of disease or trauma; or during recovery from surgery. Many organizations are acute care facilities with the goal of discharging the patient as soon as the patient is deemed healthy and stable, with appropriate discharge instructions.

administrative/financial performance measures Measures that address the organizational structure for coordinating and integrating services, functions, or activities across operational components, including financial management (for example, utilization, credentialing).

adverse drug event An injury resulting from a medical intervention related to a medication, including harm from an adverse drug reaction or a medication error.

adverse drug reaction A response to a medicinal product that is noxious and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis, or treatment of disease or for the restoration, correction, or modification of physiological or psychological function.

adverse event A patient safety event that results in harm to a patient. *See also* near miss; no-harm event; patient safety event; sentinel event.

aggregate To combine standardized data and information.

air handling system A utility system consisting of fans, filters, humidifiers, dehumidifiers, heating and/or cooling elements, air mixers, and other necessary equipment to control the temperature, humidity, air movement, and air cleanliness of a space.

algorithm Set of rules followed by a computer for problem-solving or operations.

ambulatory care Care provided on an outpatient basis and includes the diagnosis, observation, treatment/interventions, and rehabilitation services. Ambulatory care includes a wide range of services and settings, including polyclinics, specialty services centers, freestanding day surgery centers, and others.

analyte The substance or constituent on which testing is conducted. *See also* calibration material.

analytic sensitivity The lowest concentration or amount of an analyte or other substance that can be measured.

analytic specificity The extent to which a method responds only to the analyte to be measured.

anatomic pathology Services related to surgical pathology, autopsy, and cytology.

anesthesia *(as it pertains to the ASC chapter)* Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. *See also* procedural sedation.

appeal A process through which a clinical care organization or program that has been denied accreditation or certification may exercise its right to a hearing.

applying redundancies Duplication of critical components, functions, or processes to increase reliability of a system and improve system performance. Examples include backups and fail-safes.

appointment Formal authorization of medical or dental staff to perform patient care, which is accompanied by a delineation of authorized clinical privileges. The authorization process includes a review of the health care practitioner's credentials and qualifications to determine if they align with the health care organization's needs to provide patient care. *See also* reappointment.

appropriateness review The process of conducting a review of each newly prescribed or ordered medication for appropriateness based on factors such as evaluation of appropriateness of the drug, dose, frequency, and route of administration; therapeutic duplication; allergies, or sensitivities, and interactions between the medication and other medications or food; variation from hospital criteria for use; patient's weight and other physiological information; current or potential impact as indicated by laboratory values; and other contraindications.

artificial intelligence (AI) The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages.

assay An analysis to determine the presence, absence, or quantity of one or more components.

assessment (patient) The process established by an organization or program for obtaining appropriate and necessary information (such as physiological, psychological, health history, spiritual/cultural, social, and/or economic information) about each individual seeking entry into a health care setting, service, or program. The information is used to aid diagnosis and/or care planning, identify conditions and their severity, and

inform treatment recommendations. Assessments incorporate information from multiple in-depth sources, including screenings, and match an individual's needs, preferences, and goals with the appropriate type and level of care, treatment, or services. *See also* reassessment; screening.

assessment (performance improvement) The systematic collection and review of patient-, process-, program-, or organization-specific data.

autocorrect A function that automatically replaces text.

autofill A function that prefills a field automatically with previously entered information or a predetermined value in an EHR.

automatic shutdown device for air handling system A device that automatically interrupts the electrical power to the air handling system when smoke is detected, in order to prevent the spread of smoke through the building.

automatic smoke management system A mechanical system that controls the movement of smoke during a fire automatically, without requiring manual controls.

behavior modification The targeted outcome of an organized patient education program wherein patients successfully integrate the theory and skills necessary to manage their disease(s) or condition(s).

best practice Clinical, scientific, or professional technique, method, or process, that is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice. These practices, also sometimes referred to as good practice or better practice, are typically evidence based and consensus driven.

beyond use date (BUD) The date and/or time after which a product should not be used.

beyond use date medication A medication that is opened, or used not in original form or conditions that the manufacturer provides, and is typically safe and effective to use for a short period of time after opening (shelf life). This would apply to a refrigerated medication—which has a usable time outside of the refrigerator—or an insulin vial that is opened and used for 28 days, or a sterile admixture that is compounded using other components. "Beyond use date" medications are marked with a date of expiration based on when they were opened.

bias An influence on results that causes them to routinely depart from their true value.

blood component A fraction of separated whole blood (for example, red blood cells, plasma, platelets, granulocytes).

blood transfusion services Services relating to transfusing and infusing individuals with blood, blood components, or blood derivatives.

brand-name medication A medication sold by a drug company under a specific name or trademark, and that is protected by a patent. Brand-name medications include prescription medications and over-the-counter medications. *See also* generic medication.

breach A gap or breakthrough in the technological defenses.

calibration material A solution that has a known amount of analyte weighed in or has a value determined by repetitive testing, using a reference or definitive testing method. Calibration material, also referred to as standard, may be traceable to a National Institute of Standards and Technology (NIST) standard. *See also* analyte.

calibration verification The process used to verify a laboratory's reportable range of patient test results, which includes calibration materials with at least a minimum value, a midpoint value, and a maximum value, performance of which is based on manufacturers' recommendations or instrument history, and whenever a major change in the reagents or equipment or instrument could affect the calibration.

capital cost The cost of investing in the development of new or improved facilities, services, or equipment. Does not include operational costs.

carbon footprint An indicator to measure the total amount of greenhouse gases emitted from a product, task, or company.

care management/case management A process to manage and to coordinate health care resource use in the provision of care and services.

care plan *See* plan of care.

certification 1. The procedure and action by which an authorized organization evaluates and certifies that an individual, institution, or program meets requirements, such as standards (including JCI certification standards). Certification differs from accreditation in that certification can also be applied to individuals (for example, a medical specialist). 2. The process by which a nongovernmental agency or association certifies that an individual has met predetermined qualifications specified by that agency or association. *See also* accreditation; standards-based evaluation.

certification decisions Categories of certification that an organization can achieve based on a JCI survey. The categories are as follows:

> **Certified** The organization demonstrates acceptable compliance with all standards and International Patient Safety Goals.
>
> **Denial of Certification** The organization is consistently not in compliance with JCI standards and International Patient Safety Goals, JCI withdraws its certification for other reasons, or the organization voluntarily withdraws from the certification process.

certification framework The structures and processes in an organization that are necessary for a certifying organization to do the following:

- Consistently and reliably evaluate applicant organizations against standards.
- Recruit and send out trained evaluators.
- Reach consistent and defensible certification decisions.
- Carry out related policies and procedures.

certification process A continuous process whereby health care organizations are required to demonstrate to JCI that they are providing safe, high-quality care, as determined by compliance with JCI standards and International Patient Safety Goal recommendations. The key component of this process is an on-site evaluation of an organization by JCI surveyors.

certification program *See* JCI Certification Program.

certification review An evaluation of a clinical care program to assess its level of compliance with applicable JCI standards and to make determinations about its certification status. The evaluation includes assessing documentation, reviewing performance measurement reports, collecting verbal information, making on-site observations, and educating and consulting with the program about standards compliance and performance improvement.

chain of custody A verifiable procedure that tracks, monitors, and documents the movement and location of a biologic specimen in order to maintain the integrity of the sample. The process includes patient identification, collection, processing, and testing. Chain of custody is also a factor in the safe and respectful handling/transfer of the deceased and human body parts from mortuaries to resting places.

chief executive/chief executive officer The most senior executive of the health care organization, occupied by one or more individuals selected by the governing entity to manage the organization on a day-to-day basis.

cleaning Removal of visible foreign material (for example, soil, organic material) from objects and surfaces, which is normally accomplished manually or mechanically using water with detergents or enzymatic products.

clinical alarm A component of some medical devices that is designed to notify caregivers of an important change in the patient's physiologic status. A clinical alarm typically provides audible and/or visible notification of the changed patient status.

clinical care management An interdisciplinary, continuum-based approach to health care delivery that prevents, minimizes, or delays exacerbations or complications of an illness or conditions by doing the following:

- Supporting the participant's self-management activities
- Supporting the ongoing patient/practitioner relationship
- Using a standardized method or process for delivering or facilitating the delivery of clinical care based on clinical practice guidelines or evidence-based practice
- Tailoring treatments and interventions to the participant's need
- Promoting the flow of patient information across settings and health care practitioners while protecting patient rights, security, and privacy

- Analyzing and using data to continually revise treatment plans
- Continuously evaluating ways to improve performance and clinical practice, thereby improving participant care

This definition is consistent with the Disease Management Association of America (DMAA) definition.

clinical care performance measures Measures designed to evaluate the processes or outcomes of care associated with the delivery of clinical services. They allow for internal and external comparisons to be used to continuously improve patient health outcomes; may focus on the appropriateness of clinical decision-making and implementation of these decisions; and must be condition or procedure specific or address important functions of patient care (for example, medication use, infection prevention and control, patient assessment, patient safety).

clinical decision support tool Technology or information systems used to enhance clinical decision-making for health care practitioners, staff members, or patients.

clinical information management The management of patient or clinical information to define, process, and sequence activities, thereby maximizing care coordination to improve care. The particular methodology of managing clinical information, whether paper based or electronic, is based on sound information management principles.

clinical pathway 1. A defined process, often evidence-based, that guides care management for a well-defined group of patients, decreases variance, and often uses a multidisciplinary team. 2. Services relating to solving clinical problems, particularly using laboratory methods in clinical diagnosis. Includes clinical chemistry, bacteriology and mycology, parasitology, virology, clinical microscopy, hematology, coagulation immunohematology, immunology, serology, and radiobioassay. *See also* pathway.

clinical practice guidelines Statements that include recommendations intended to optimize patient care, which are informed by a systematic review of scientific evidence and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines are used in making care decisions and developing clinical care processes for diagnoses and conditions and often require clinical pathways and clinical protocols.

clinical staff staff members who provide or have provided clinical services to the organization's patients, residents, or individuals served. *See also* medical staff; nonclinical staff; staff.

clinical trial Testing of drugs, devices, or techniques in three or sometimes four stages, depending on the purpose, size, and scope of the test. Phase I trials evaluate the safety of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques to determine the safe dosage range (if appropriate). They involve a small number of healthy subjects. The trial usually lasts about one year. Phase II trials are usually controlled to assess the effectiveness and dosage (if appropriate) of the drugs, devices, or techniques. These studies involve several hundred volunteers, including a limited number of patients with the target disease or disorder. The trial usually lasts about two years. Phase III trials verify the effectiveness of the drugs, devices, or techniques determined in Phase II. Phase III patients are monitored to identify any adverse reactions from long-term use. These studies involve groups of patients large enough to identify clinically significant responses. The trial usually lasts about three years. Phase IV trials study the drugs, devices, or techniques that have been approved for general sale. These studies are often conducted to obtain more data about a product's safety and efficacy.

close call *See* near miss.

cohort 1. A group of patients who share one or more characteristics or features (for example, age or clinical diagnosis). 2. To place a group of patients in the same space to receive treatment. For example, patients exposed to or infected with the same pathogen may be cohorted for infection control purposes.

community Related to primary care centers, a community refers to a group of people within certain geographic boundaries or who share common characteristics such as health risks or disease processes. *See also* population.

comparison group The group of health care organizations or programs to which an individual health care organization or program is compared.

competence A determination of an individual's skills, knowledge, and capability to meet defined expectations, as frequently described in a job description. *See also* credentials.

comprehensive systematic analysis A process for identifying the basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis is one type of comprehensive systematic analysis. *See also* root cause analysis; sentinel event.

confidentiality 1. The restriction of access to data and information to health care practitioners and clinical staff who have a need, a reason, and permission for such access. 2. An individual's right to personal and informational privacy, including for their medical record.

contamination The presence of an unwanted material or organism, such as an infectious agent, bacteria, parasite, or other contaminant, that is introduced to an environment, surface, object, or substance, such as water, food, or sterile medical supplies.

continuity of care The degree to which the care of individuals is coordinated among health care practitioners, among organizations, and over time. *See also* handover.

continuum of care Matching the individual's ongoing needs with the appropriate level and type of care, treatment, and services within an organization or across multiple organizations. *See also* levels of care.

contract research organization A person or an organization contracted by the sponsor of the research to perform duties and functions for one or more of a sponsor's research trials.

contracted services Services provided through a written agreement, either through another organization, agency, or individually. The agreement specifies the services or staff to be provided on behalf of the applicant organization, the duration of the agreement, and the fees to provide these services or staff.

controlled substance A drug or other substance that is tightly controlled by the government or regulatory agencies because it may cause physical and mental dependence and have restrictions on how they can be filled and refilled. The control applies to the way the substance is made, used, handled, stored, and distributed. Controlled substances include opioids, stimulants, depressants, hallucinogens, and anabolic steroids. Controlled substances with an approved medical use, such as morphine, Valium, and Ritalin, are available only by prescription from a licensed medical professional.

copy-and-paste Selecting text or data from an original or previous source to reuse in a different location.

corrective action Any activity or action taken to address an impairment, vulnerability, deficiency, or risk that is identified in response to an event or proactively (for example, through inspections, maintenance, risk assessment, or similar activity).

credentialing The process of obtaining, verifying, and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization. The process of periodically checking staff qualifications is called recredentialing. *See also* privileging; recredentialing.

credentials Documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, including education (such as a diploma from a medical school, specialty training [residency] completion letter or certificate), completion of the requirements of a medical professional organization, licensure, recognition of registration with a medical or dental council, training, and experience, which indicate the individual's sustainability to fulfill a role. Additional criteria may be added by a health care organization. *See also* competence.

criteria 1. Expected level(s) of achievement, or specifications against which performance or quality may be compared. 2. For purposes of eligibility for a JCI review, the conditions necessary for programs to be reviewed for certification by JCI.

critical result A variance from normal range that represents a pathophysiologic state that is high risk or life-threatening, is considered urgent or emergent in nature, and in which immediate medical action is likely necessary to preserve life or prevent a catastrophic occurrence. *See also* abnormal result.

culture of safety Also known as a safe culture, a collaborative environment in which skilled clinicians treat each other with respect; leaders drive effective teamwork and promote psychological safety; teams learn from errors and near misses; caregivers are aware of the inherent limitations of human performance in complex systems (stress recognition); and there is a visible process of learning and driving improvement through debriefings. Staff members are able to report concerns about safety or quality of care without fear of retaliation from health care organization leaders or other staff members.

curative services Services provided to overcome disease and to promote recovery. Curative services or therapy are different from palliative services, which give relief but not cure. *See also* palliative services.

cybersecurity Protection against unauthorized access and use of electronic data; actions taken to prevent unauthorized access and use of electronic data.

cyberattack An attempt to access a computer network, infrastructure, information systems, or personal devices (including cell phones) with a goal to disable, destroy, or steal data.

data Facts, clinical observations, or measurements collected during an assessment activity. Data before they are analyzed are called raw data.

Data includes the following:
- Patient medical records
- Data from medical equipment and devices
- Research data
- Quality data
- Billing data
- Human resources data

data element A discrete piece of data, such as patient birth date or principal diagnosis.

data integrity The accuracy, consistency, and completeness of data.

data point The representation of a value for a set of observations or measurements at a specific time interval (for example, perioperative mortality rate for June 2023).

data quality The accuracy and completeness of measure data on performance, in the context of the analytic purposes for which they will be used.

data sources The primary source document(s) used for data collection (for example, billing or administrative data, encounter form, enrollment form, medical record).

decentralized storage An electronic data storage method in which data are encrypted and stored across multiple locations. These locations may be run by individuals or organizations that lease data storage for a fee. The data remain the property of the data owner, not the storage site; storage providers cannot access the data.

deep sedation/analgesia A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. *See also* procedural sedation.

deficiency A state of being noncompliant or defective; lacking a necessary quality or element; or failing to meet expectations or standards. Health care organizations can have deficiencies in processes, procedures, policies, performance, and other areas.

defined measure A structured measure with defined populations that measures specific events or values; such measures may have numerators and denominators, take the form of a continuous variable, or result from review questions.

Denial of Accreditation *See* accreditation decisions.

denominator The lower part of a fraction used to calculate a rate, proportion, or ratio. A statement that depicts the primary or overall population of interest that the measure is interested in evaluating (for example, patients with a principal diagnosis and/or other diagnoses of insulin-dependent diabetes).

department/service leaders The individuals who manage and direct the varied services of the organization, commonly referred to as departments, services, and/or units.

disaster A sudden, unexpected event that causes widespread damage and disruptions, as well as injury and/or loss of life; may be naturally occurring or human-made. *See also* disaster preparedness; emergency.

disaster preparedness The ability of the health care organization to maintain operations, respond to the potentially increased volume and acuity of patients, and meet the needs of the community affected by the disaster. *See also* disaster; emergency.

discharge The point at which an individual's active involvement with an organization or program is terminated and the organization or program no longer maintains active responsibility for the care of the individual.

discharge summary A section of a patient's medical record that summarizes the reasons for admittance, the significant findings, the procedures performed, the treatment rendered, the patient's condition on discharge, and any specific instructions given to the patient or family (for example, follow-up, medications).

disease prevention Activities and strategies specifically aimed to decrease the risk of acquiring an acute or chronic disease, as well as to halt the progress and minimize the consequences of a disease if present. *See also* preventive services.

disinfection A process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects, usually by using liquid chemicals or wet pasteurization.

do-not-use list A written catalog of abbreviations, acronyms, and symbols that are not to be used throughout an organization—whether handwritten or entered as free text into a computer—due to their potentially confusing nature.

downtime Data system interruption.

efficiency The relationship between the outcomes (results of care) and the resources used to deliver care. For example, when two programs use the same amount of resources, the one that achieves a higher immunization coverage rate is more efficient. Increasing efficiency involves achieving the same outputs with fewer resources or more outputs with the same amount of resources.

elective procedure A procedure planned in advance by the patient. *See also* emergency procedure.

electronic health record (EHR) An electronic (digital) collection of health information about a person that is stored on a computer. An electronic health record includes information about a patient's health history, such as diagnoses, medications, tests, allergies, immunizations, and treatment plans. Generally thought to be more comprehensive than an electronic medical record due to the inclusion of the patient and all health care practitioners, not only medical health care practitioners, in its maintenance. *See also* patient medical record.

elope Intentionally leave a health care organization without notifying the organization and against medical advice.

emergency 1. An unanticipated, sudden, or life-threatening occurrence, such as events necessitating resuscitation or emergency surgery to prevent death or disability. 2. A natural or human-made event that significantly disrupts the environment of care (for example, damage to the organization's building[s] and grounds due to severe windstorms or earthquakes); that significantly disrupts care and treatment (for example, loss of utilities, such as power, water, or telephones, due to floods, civil disturbances, accidents, or emergencies in the organization or its community); or that results in sudden, significantly changed or increased demands for the organization's services (for example, bioterrorist attack, building collapse, or train crash in the organization's community). *See also* disaster, disaster preparedness.

emergency cart A self-contained, portable set of trays, drawers, and/or shelves used to contain and transport all equipment, medications, and supplies necessary to perform life-support protocols.

emergency procedure A procedure that is not planned in advance but takes place in response to an emergent or urgent health situation. *See also* elective procedure.

emergent A classification of acuity used in the triage systems to signify that the patient's condition is life-threatening and requires immediate intervention. *See also* urgent.

employment practices Analysis, screening, or other methods used to recruit, hire, select, transfer, promote, provide benefits for, or similarly affect employees or future employees.

encryption The act of converting information or data into a code to prevent unauthorized access, reading, or use.

equipment maintenance program, preventive *See* maintenance program, preventive.

equipment maintenance program, routine *See* maintenance program, routine.

error 1. A mistake that causes harm. 2. Failure to carry out a planned action as intended, or application of an incorrect plan.

evidence-based (or scientific-based) guidelines Guidelines that have been scientifically developed based on recent literature review and are consensus driven.

excluded population Detailed information describing the population(s) that should not be included in the numerator and denominator, or a continuous variable measure calculation (for example, specific age groups, diagnoses, procedures, enrollment periods, insurance, and health plan groups).

extension survey A survey that may be conducted when the health care organization has changes in core information, services, and/or other factors (for example, a change that results in a considerable increase in volume of patients served). The organization notifies JCI within 30 days of the effective date of the change(s).

external data source A repository for data that exists outside the organization's control.

facility management and safety program Program with specific plans for the following areas of operations: safety and security, hazardous materials, disaster preparedness, fire safety, medical equipment, and utility systems.

failure mode and effects analysis (FMEA) A systematic approach to examining a design prospectively for possible ways failure may occur. The ways failure may occur are then prioritized to help organizations create design improvements that will have the most benefit. This tool assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur.

falsification (of information) Fabrication, in whole or in part, of any information provided by an applicant or certified organization to JCI.

family The person(s) with a significant role in the patient's life. This may include a person(s) not legally related to the patient. This person(s) is often referred to as a surrogate decision-maker if authorized to make care decisions for a patient if the patient loses decision-making ability.

fellow *See* trainee, medical.

fire alarm A device or system of devices that gives audible and/or visible warning of an outbreak of fire in the building or area in which it is installed. Fire alarm systems can be automatic, semiautomatic, or manual.

fire door A type of door that has been built to withstand direct exposure to fire for an extended period of time, without allowing the fire to spread to the other side of the door.

fire door assembly A fire barrier that consists of any combination of a fire door, a frame, hardware, and other accessories that together provide a specific degree of fire protection to an opening.

fire extinguisher A portable device used to put out small fires, or to reduce the destruction caused by a fire before firefighters arrive. Different types of fire extinguishers are applicable to different types of fires. For example, foam extinguishers are used for solid and liquid fires; carbon dioxide extinguishers can be used for solid, liquid, gas, oil, fat, and electric fires.

fire hose A very high-pressure hose used to take water or fire retardant materials to a fire.

fire pump A device used to increase the water pressure in fire sprinkler systems and standpipe systems and deliver an appropriate amount of water, particularly when the system is fed by a nonpressurized water tank or other water supply that lacks adequate pressure. Fire pumps can be driven by an electric motor, diesel engine, or steam turbine.

fire separations A method of using fire-resisting walls, floors, doors, ducts, and other elements to

prevent fire from spreading to adjacent areas for designated time periods.

fire sprinkler system A device placed in ceilings facing toward the floor that are designed to extinguish an emerging fire using water piped through a high-pressure supply.

fire suppression system A set of components designed to extinguish a fire through application of an external substance, such as water or foam. Many fire suppression systems also include fire detection systems and fire alarms.

focused professional practice evaluation (FPPE) A process that evaluates the privilege-specific competence of the medical staff member who does not have documented evidence of competently performing the requested privilege(s) at the hospital. This process may also be used when a question arises regarding a currently privileged medical staff member's ability to provide safe, high-quality patient care.

follow-up survey A survey that may be conducted as a required follow-up to a full survey (initial/triennial) when the documented findings do not meet one or more of the decision rules. A follow-up survey is an on-site survey that is limited in scope, content, and length and designed to collect information on a specific issue(s) or limited number of standards or measurable elements, IPSGs, and/or Accreditation Participation Requirements (APRs). JCI conducts two types of follow-up surveys: for-cause surveys and extension surveys.

for-cause survey A survey conducted when JCI learns of potentially serious standards noncompliance, serious patient care or safety issues, regulatory issues or sanctions, or other serious issues within an accredited organization or certified program that may have placed the organization in Preliminary Denial of Accreditation.

framework An outline, overview, or "skeleton" of interconnected items that can be modified at any time by adding or deleting items.

full operation Criteria indicating the organization's readiness for comprehensive on-site evaluation against all relevant JCI standards, based on identification of the following in the organization's electronic application for survey (E-App): a list of all clinical services currently provided for patients; utilization statistics for clinical services showing consistent patient activity levels and types of services provided for at least four months or more prior to submission of the organization's E-App; and all inpatient and outpatient clinical services, units, and departments.

full survey The survey of all the applicable standards throughout an entire organization. This may be the initial survey, or triennial survey.

functional status The ability of individuals to take care of themselves physically and emotionally according to the expected norms of their age group. Functional status may be divided into social, physical, and psychological functions. Functional status may be assessed by asking questions during periodic health examinations or using formal screening instruments. *See also* measure.

generic medication A medication created to be the same as an existing approved brand-name medication in dosage form, safety, strength, route of administration, quality, and performance characteristics. Generic medications include prescription medications and over-the-counter medications. *See also* brand-name medication.

governance Level of leadership held by the governing entity of the health care organization, which can have various configurations.

governance structures The committees, task forces, and other groups formed by governance to provide assistance or advice.

governing entity The individual(s) or group that has ultimate authority and responsibility for establishing policy, maintaining quality of care, and providing for organization management and planning for the organization. Examples for the structure of a governing entity include a group of individuals (such as a board of directors) or one or more individual owners. In the case of public organizations, the governing entity is often the Ministry of Health (MOH).

green training The process of providing employees with methods that ensure adequate resource utilization, waste reduction, and energy conservation.

handover The transfer of responsibility for a patient and the patient's care that is achieved through effective communication (for example,

between health care practitioners; from one department, unit, or service of the organization to another; between the organization and other levels of health care; between staff and patients/families). Also called handoff. *See also* continuity of care.

harm Physical or psychological injury, including increased anxiety, inconvenience (such as prolonged treatment), monetary loss, social impact, and/or other negative effects suffered by a person.

harvesting (of organs) Removal of an organ for means of transplantation.

hazardous conditions Circumstances that have the potential to create future adverse events.

hazardous materials and waste Materials for which handling, use, storage, and disposal are guided or defined by local, national, or regional regulation. Types of hazardous materials and waste include pharmaceutical, chemical, cytotoxic, and infectious.

hazardous medication compounding The compounding of hazardous drugs that pose a risk of exposure to patients and health care workers (for example, drugs that are carcinogenic, are teratogenic, or have developmental toxicity, reproductive toxicity, or organ toxicity).

hazardous medications Medications that (as indicated by studies in animals or humans) have a potential for causing cancer, developmental or reproductive toxicity, genotoxicity, or harm to organs. Chemotherapy, antiviral drugs, hormones, and some bioengineered drugs are examples of hazardous medications.

hazard vulnerability analysis (HVA) A tool used for the identification of potential emergencies and the direct and indirect effects those emergencies may have on the organization's operations and demand for its services.

health care–associated infection(s) (HAI[s]) Any infection(s) acquired by an individual while receiving care or services in a health care organization. Common HAIs are urinary tract infections, surgical wound infections, pneumonia, and bloodstream infections.

health care organization management standards For purposes of JCI accreditation or certification, standards that are organized according to what is done directly or indirectly to provide for a safe, effective, and well-managed organization and facility (for example, prevention and control of infection, facility management, staff qualifications).

health care practitioner Any individual qualified by education and training and permitted by license and laws (when applicable) and the organization to provide care and services, within the scope of the individual's practice, without direction or supervision.

1. A physician who is authorized to practice medicine or surgery (as indicated) by a governing or licensing body for the country or region in which the physician practices.
2. Any other person determined by the Ministry of Health to be independently capable of providing health care services (for example, advanced practice registered nurses [nurse practitioners], nurse-midwives, physician assistants, podiatrists, dentists, optometrists).

See also licensed practitioner; practitioner.

health information exchange The act of sharing health information through electronic systems, allowing health care teams to quickly and securely access a patient's health information.

health information systems Electronic systems designed to collect, manage, store, and transmit health information, health care operational information, and health care policy decisions.

health information technology Technology used to analyze, store, share, and process information and data by health professionals and within health care settings. Health information technology can include electronic health records for documentation and information sharing, patient portals, systems for storing data, data security, platforms for communication and care coordination, interfaces with other systems to facilitate patient care and treatment, electronic prescribing tools, telehealth technology, electronic applications, and medical billing software.

health promotion Activities that increase an individual's control over their own health, thereby improving it. These activities may occur at the individual, family, community, and system levels; they promote healthy behaviors and other changes that decrease the risk for acute and chronic diseases and injury.

health status performance measures Measures that address the functional well-being of specific populations, both in general and in relation to specific conditions, demonstrating change over time (for example, physical functioning, bodily pain, social functioning, mental health).

heat detector A device that senses unusually high temperatures and/or sudden increases in temperature and activates the fire alarm system. They are typically used in places where smoke detectors may cause false alarms.

histogram A graphic display, using a bar graph, of the frequency distribution of a variable. Rectangles are drawn so that their bases lie on a linear scale representing different intervals, their heights are proportional to the frequencies of the values within each of the intervals.

holding bed A bed associated with or connected to an emergency department, an outpatient department, or an operating theatre in which a patient may wait for a decision about the need for another level of care or transfer to another clinical area, such as admission to an inpatient ward, transfer to another facility, or discharge from the hospital. These are considered separate from the actual unit/ward bed count.

home care The term that is generally used to refer to services provided in the home or in the community to recovering, disabled, or chronically ill persons and their families. These services may include some combination of professional health care services and personal care and supportive services. Professional health care services (also known as "skilled care") may include physical and/or psychological assessment, nursing and health care, medication teaching and administration, wound care, pain management, disease education and management, physical therapy, speech therapy, or occupational therapy. Home supportive care services (also known as "nonskilled care") may include such things as light housekeeping, meal preparation, medication reminders, dressing, laundry, shopping, transportation, and companionship. In addition, home care can provide palliative care, respite care, hospice care, and other related services, including provision of medical equipment and supplies to those in need.

hospital leader(s) A single or group of individuals who typically report to the chief executive(s) of the hospital and most frequently include a chief medical officer representing the medical staff, a chief nursing officer representing all levels of nursing in the hospital, senior administrators, and any other individuals the hospital selects, such as a chief quality officer, vice president of human resources, chief operating officer, and so on.

human subjects research Research involving living individuals about whom an investigator obtains data through intervention or interaction with individuals and/or identifiable personal information. Research protocols involving human subjects are reviewed by an Institutional Review Board (IRB) or other research ethics review mechanism and receive ongoing oversight as necessary.

Immediate Threat to Health or Safety A threat that represents immediate risk and has or may potentially have serious adverse effects on the health or safety of the patient, resident, or individual served. These threats are identified on-site by the surveyor. Also known as immediate threat to life (ITL).

immediately available When an item, individual, document, or other resource is available as soon as it is requested. *See also* readily available.

implantable medical device A device that is permanently placed into a surgically or naturally formed cavity of the body to continuously assist, restore, or replace a function or structure of the body throughout the useful life of the device. Examples include a prosthesis (such as a hip), a stent, a pacemaker, and an infusion pump.

included population Detailed information describing the population(s) that the numerator and denominator—or a continuous variable—intends to measure (for example, specific age groups, diagnoses, procedures, enrollment periods, insurance, and health plan groups).

independent business entities Independently owned businesses occupying space within a hospital; for example, coffee shops, gift shops, banks.

indicator A measure to determine, over time, an organization's or program's performance of functions, processes, and outcomes.

in extremis Near death.

infectious waste *See* hazardous materials and waste.

information management The creation, use, sharing, and disposal of data or information across an organization. This practice is critical to the effective and efficient operation of organization activities. It includes the role of management to produce and to control the use of data and information in work activities, information resources management, information technology, and information services.

information technology The use of computers to create, process, store, retrieve, and exchange data and information, including health care information.

information technology maintenance program, preventive *See* maintenance program, preventive.

information technology maintenance program, routine *See* maintenance program, routine.

informed consent The process of informing a patient about a procedure, treatment, or clinical trial/research study so that the patient can make a voluntary, informed decision to accept or refuse to have the procedure or treatment. The patient must be fully informed and understand the information that they are provided before giving consent. The elements of informed consent include but are not limited to information about, and potential benefits and risks of, the proposed procedure, treatment, or clinical trial/research study; and possible alternatives to the procedure/treatment.

inpatient Generally, persons who are admitted to and housed in a health care organization at least overnight. *See also* outpatient; patient.

in-service education Organized education, usually provided in the workplace, designed to enhance the skills of staff members or to teach them new skills relevant to their jobs and disciplines.

integrated provider (system) A health care practitioner organization that offers a broad corporate system for managing a diversified health care delivery system. The system typically includes one or more organizations, a large group practice, a health plan, and other health care operations. Health care practitioners are employees of the system or in a tightly affiliated practitioner group. The system can provide several levels of health care to patients in the same geographic areas.

intent A brief explanation of a standard's rationale, meaning, and significance. Intents may contain examples of compliance and detailed expectations of the standard that are evaluated in the on-site survey process.

interface The point at which various systems meet and interact with each other; a device or program that allows a user to interact with technology.

interim measures Actions taken to ensure the safety of the building's occupants during times when features and systems for fire safety are defective, compromised, or inoperable due to construction, maintenance, or a breakdown or repair. Interim measures may need to be implemented to ensure the safety of occupants until improvements or repairs can be completed. Some examples include initiating a fire watch, inspecting exits in affected areas on a daily basis, providing additional firefighting equipment, providing temporary but equivalent fire alarm and detection systems, and other appropriate activities.

intern *See* trainee, medical.

international normalized ratio A measurement of how long it takes blood to form a clot; performed in a laboratory and used to determine the effects of oral anticoagulant medications on a patient's clotting system.

invasive procedure The puncture or incision of the skin, insertion of an instrument, or insertion of a foreign material into the body for diagnostic or treatment-related purposes. Examples of invasive procedures include central line and chest tube insertions, and cardiac catheterization. Venipuncture is not categorized as an invasive procedure.

JCI Accreditation Program The division of JCI responsible for administration of all activities related to organizational health care accreditation or certification.

JCI Certification Program The division of JCI responsible for administration of all activities related to organizational health care certification.

job description Explanation of an employment position, including duties, responsibilities, and conditions required to perform the job.

laboratory A facility that is equipped to examine material derived from the human body to provide information for use in the diagnosis, prevention, or treatment of disease; also called clinical laboratory or medical laboratory.

laboratory-acquired infections (LAIs) Infections acquired through laboratory or laboratory-related activities. Laboratory-acquired infections can come from a wide variety of bacteria, viruses, fungi, and parasites.

laws and regulations Statements or directions specifying required decisions and actions issued by a local or national authority. Penalties, legal or otherwise, are normally assessed when laws and regulations are not followed.

leader An individual who sets expectations, develops plans, and implements procedures to assess and improve the quality of an organization's management, clinical, and support functions and processes.

levels of care A classification of health care service levels. They are divided by the kind of care given, the number of people served, and the people providing the care. The main levels of care are primary, secondary, and tertiary. Levels of care classified by the acuity of the patient or intensity of the services provided are emergency, intensive, and general. *See also* continuum of care.

licensed practitioner An individual who is licensed and qualified to direct or provide care, treatment, and services in accordance with laws and regulations, and organizational policy. *See also* health care practitioner; practitioner.

licensure A legal right that is granted by a government agency in compliance with a statute governing an occupation (such as physicians, dentists, nurses, psychiatry, or clinical social work, or the operation of a health care facility).

long-term care Care provided to individuals who require physical, supportive, rehabilitation, or palliative care. This care may include skilled nursing care, subacute care, complex medical or rehabilitative care, dementia-specific care, alternative levels of care, intermediate care, and/or other long-term care services. These services may be provided within the hospital confines, affiliated with a hospital, or in a freestanding long-term care organization (including long-term acute care hospitals).

low carbon A small amount of carbon dioxide released into the atmosphere.

maintenance program, preventive The planned, scheduled, visual, mechanical, engineering, and functional evaluation of equipment conducted before using new equipment and at specified intervals throughout the equipment's lifetime. The purpose is to maintain equipment performance within manufacturers' guidelines and specifications and to help ensure accurate diagnosis, treatment, or monitoring. It includes measuring performance specifications and evaluating specific safety factors.

maintenance program, routine The performance of basic safety checks—that is, the visual, technical, and functional evaluations of equipment—to identify obvious deficiencies before they have a negative impact. It normally includes inspections of the case, power cord, structural frame, enclosure, controls, indicators, and so on.

material safety data sheet (MSDS) *See* safety data sheet (SDS).

measurable elements (MEs) The specific requirements of a standard that identify what is reviewed and assigned a score during the on-site survey process.

measure 1. To collect quantifiable data about a function, system, or process (one "measures"). 2. A quantitative tool. *See also* functional status.

measurement Quantifiable data about a process outcome, or structure.

measure set A unique grouping of carefully selected measures that, when viewed together, provide a comprehensive understanding or assessment of a unit's, department's, organization's, or program's performance.

medical device An instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for health care

purposes. *See also* medical equipment; medical technology.

medical equipment Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury. Medical equipment requires calibration, maintenance, repair, user training, and decommissioning—activities that are usually managed by clinical engineers. *See also* medical device; medical technology.

medical record *See* electronic health record (EHR); patient medical record.

medical research Basic, clinical, and health services research that includes many types of research studies, such as clinical trials, therapeutic interventions, development of new medical technologies, and outcomes research, among others.

medical staff All physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services, regardless of the organization's classification of appointment, employment status, contract, or other arrangements with the individual to provide such patient care services. *See also* clinical staff; nonclinical staff; staff.

medical student An individual enrolled in a medical educational institution. *See also* student, medical.

medical technology Fixed and portable medical devices and equipment used for the direct diagnosis, treatment, monitoring, and care of individuals. *See also* medical device; medical equipment.

medical waste *See* hazardous materials and waste.

medication Any prescription medications; sample medications; herbal remedies; vitamins; nutraceuticals; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; and intravenous solutions (plain or with electrolytes and/or drugs), as well as solutions administered/used on the patient by the surgical team during surgical/invasive procedures.

medication, high-risk or high-alert Any drug that bears a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients.

medication error A preventable event that may cause or lead to inappropriate medication use or patient or resident harm while the medication is in the control of the health care professional, patient, resident, or consumer. Such events may be related to professional practice; health care products; procedures and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

medication reconciliation The process of identifying the medications currently being taken by an individual. These medications are compared to newly ordered medications, and discrepancies are identified and resolved.

medication side effect A pharmacological effect of a drug, normally adverse, other than the one(s) for which the drug is prescribed.

minimal sedation (anxiolysis) A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. *See also* procedural sedation.

mission statement A written expression that sets forth the purpose, or "mission," of an organization or one of its components. The generation of a mission statement usually precedes the formation of goals and objectives.

moderate sedation/analgesia (conscious sedation) A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. *See also* procedural sedation.

monitoring The tracking of information on a routine basis. The purpose of monitoring is to identify the changes in a situation, equipment, or patient condition, and/or effectiveness of an intervention.

multidisciplinary Including representatives of a range of professions, disciplines, or service areas. Also called interdisciplinary

multifactor authentication An electronic authentication method in which a user is granted access to a website or application only after successfully presenting two or more pieces of evidence (or factors) to an authentication mechanism: knowledge (something only the user knows), possession (something only the user has), and inherence (something only the user is).

near miss A patient safety event that did not reach the patient. Also called a close call. *See also* adverse event; no-harm event; patient safety event; sentinel event.

no-harm event A patient safety event that reaches the patient but does not cause harm. *See also* adverse event; near miss; patient safety event; sentinel event.

nonclinical staff Those whose roles and responsibilities in the organization indirectly support patient care (admissions, food service, housekeeping, among others). *See also* clinical staff; medical staff; staff.

nonstructural elements (of a building) Physical components of a building that do not provide necessary supporting structure and are not essential to the stability of the building. Nonstructural elements include architectural elements that are not load-bearing (roof, ceilings, windows, and doors); emergency access and exit routes; components of utility systems (such as electricity, plumbing, waste management, fire protection); and medical and laboratory equipment. *See also* structural elements (of a building).

nosocomial infection(s) *See* health care–associated infection(s) (HAI[s]).

numerator The upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator depicts the portion of the denominator population that satisfies the condition of the performance measure to be an indicator event (for example, the number of individuals with a specific disease who have had a procedure).

nursing staff Clinical nursing professionals within an organization who are accountable for the promotion of health, the prevention of illness, and the provision of quality and safe patient care within the parameters of the nursing profession. Such personnel include registered, licensed, and vocational nurses; advanced practice nurses; and may include others such as nursing assistants or other designated unlicensed assistive personnel.

nutritional care Interventions and counseling to promote appropriate nutrition intake. This activity is based on nutrition and information about food, other sources of nutrients, and meal preparation. It includes the patient's cultural background and socioeconomic status.

nutritional interventions Care and counseling to promote appropriate nutrition intake. This activity is based on nutrition and information about food, other sources of nutrients, and meal preparation. It includes the patient's spiritual/religious, cultural background, and socioeconomic status.

nutrition therapy Medical treatment that includes enteral and parenteral nutrition.

observation The time during which a patient is watched closely by a caregiver (or caregivers).

observation bed Bed used for providing patient care and observation for up to 24 hours, while determining whether the patient can be safely discharged or if they should be admitted for acute care. Other terms for this service may include but are not limited to the following: clinical decision unit/ward (CDU/CDW), short-stay unit/ward, or chest pain unit/ward.

ongoing professional practice evaluation The process of ongoing data collection for the purpose of assessing a practitioner's clinical competence, professional behavior, and professional growth. The information collected during this process is factored into decisions to maintain, revise, or revoke an existing privilege(s) prior to or at the end of the three-year renewal decision.

organizational chart A graphic representation of titles and reporting relationships in an organization, sometimes referred to as an organogram or organization table.

original source (of a measure) An individual, group of individuals, or organization who is initially responsible for developing the measure.

other clinical staff Clinical professionals who are not licensed to practice independently (without supervision) that are employed or permitted by the hospital to provide care and services to patients or to participate in patient care processes (for example, midwives, surgical assistants, emergency medical care specialists, pharmacists, pharmacy technicians). In some countries or cultures, this group also includes traditional healers or those who provide alternative services or services that complement traditional medical practice (for example, acupuncture, herbal medicine).

outcome The effect(s) that an intervention has on a specific symptom, condition, or problem. It reflects the result of the intervention.

outpatient Generally, persons who do not need the level of care associated with an inpatient or residential program. *See also* inpatient; patient.

palliative services Treatments and support services intended to alleviate pain and suffering rather than to cure illness. Palliative therapy may include surgery or radiotherapy undertaken to reduce or to shrink tumors compressing vital structures and thereby to improve quality of life. Palliative services include attending to the patient's psychological, personal, spiritual/religious, and cultural needs and supporting the dying patient and their family. *See also* curative services.

participant The patient or the person (often a family member) receiving services from the clinical care program to assist the patient (for example, a parent may receive services from the clinical care program to help their child with a chronic disease).

pathology and clinical laboratory services The services that provide information on diagnosis, prevention, or treatment of disease or the assessment of health, through the examination of the structural and functional changes in tissues and organs of the body that cause or are caused by disease. It also includes the biological, microbiological, serological, chemical, immunohematological, hematological, or other examination of materials derived from the human body.

pathway An agreed-upon treatment regimen that includes all elements of care. *See also* clinical pathway.

patient An individual who receives care, treatment, and services. *See also* inpatient; outpatient.

patient care process The act of providing accommodations, comfort, and treatment to an individual. This implies responsibility for safety, including treatment, services, habilitation, rehabilitation, or other programs requested by the organization or network for the individual.

patient-centered care Care that is respectful of, and responsive to, individual patient preferences, needs, and values. Ensures that patients are involved in their own clinical decisions.

patient-centered standards For purposes of JCI accreditation, standards that are organized according to what is done directly or indirectly for or to patients (for example, patient education, creation of patient records, patient assessment).

patient engagement When a patient is an active participant in their own care, according to the patient's knowledge, skills, ability, and willingness to manage their own health.

patient experience How a patient is affected (physically, emotionally, and psychologically) by their visit to or stay at a health care facility. Patient experience is affected by elements such as pain management; interactions with staff; the patient's preferences, needs, and values; and the physical environment.

patient medical record A written or electronic documentation of varied patient health information, such as assessment findings, treatment details, progress notes, and discharge summary. This record is created by health care professionals. *See also* electronic health record (EHR).

patient portal A secure online website that allows patients to access their personal health information over the Internet.

patient safety event An event, incident, or condition that could have resulted or did result in harm to a patient. A patient safety event can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment

failure, or human error. *See also* adverse event; near miss; no-harm event; sentinel event.

patient tracer These (*see* tracer methodology for a description of tracers) occur during the on-site survey and focus on evaluating an individual patient's total care experience within a health care organization. *See also* system tracer.

perception of care quality performance measures Satisfaction measures that focus on the delivery of clinical care from the patient's/participant's perspective, including but not limited to patient safety and education, medication use, pain management, communication about plans and outcomes of care, prevention and illness, and improvement in health status. A measure may address one or more aspects of care.

performance improvement The systematic process of detecting and analyzing performance problems, designing and developing interventions to address the problems, implementing the interventions, evaluating the results, and sustaining improvement.

performance measurement The use of quantitative tools (for example, rates, ratios, indices, percentages) to provide an indication of an organization's or program's performance in relation to a specified process or outcome.

phishing The fraudulent act of sending an e-mail under the guise of a fake identity to attempt to obtain personal information, such as passwords, financial information, and other identifying information, or organizational information, such as proprietary information or access to systems.

physiologic-based criteria Criteria centered on the branch of biology dealing with the functions of the living organism and its parts of the physical and chemical factors and processes involved.

plan A method for outlining detailed strategies and resource needs for meeting short- and long-term goals and objectives. Examples of plans include but are not limited to those addressed in the facility management and safety program (safety plan, security plan, hazardous materials plan, emergencies plan, fire safety plan, medical equipment plan, and utility systems plan).

planned downtime Scheduled data system interruption for the purpose of conducting maintenance, repairs, upgrades, and other changes to the system. *See also* unplanned downtime.

plan of care An individualized plan that identifies the patient's care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. It is based on data collected during patient assessment. The format of the plan in some organizations may be guided by specific policies and procedures, protocols, practice guidelines, clinical paths, or a combination of these. The plan of care may include prevention, care, treatment, habilitation, and rehabilitation.

plant-based food US Food and Drug Administration (FDA) definition: "food made from plants" and "vegetarian" (100% plant material containing no animal protein/meat).

point-of-care testing Analytical testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to individuals, such as at the bedside or procedure area.

policy A statement of expectations, usually written, meant to influence or determine decisions and actions. Policies are the rules and principles that guide and inform the organization's procedures and processes.

population As related to health care organizations, *population* refers to the patients served by the organization. It may also be defined by geographic area or characteristics of the individuals served by the organization, such as age, education level, income, health risks, disease process, treatment type, and other demographic information. *See also* community.

practitioner Any person who has completed a course of study and is skilled in a field of health care. This includes a physician, dentist, nurse, pharmacist, and respiratory therapist, among others. Practitioners are licensed by a government agency or certified by a professional organization. *See also* health care practitioner; licensed practitioner.

preoperative assessment A clinical risk assessment that assesses the health of a patient

to determine if the patient is safe to undergo the anesthesia and surgery.

preventive maintenance *See* maintenance program, preventive.

preventive services Interventions to promote health and prevent disease. These include identification of and counseling on risk factors (for example, smoking, lack of physical activity), screening to detect disease (for example, breast cancer, sexually transmitted diseases), immunizations, and chemoprophylaxis (for example, hormone replacement therapy). *See also* disease prevention.

primary care Basic, general, or essential health care at the point where a patient first seeks care. Primary care is the provision of health promotion and disease prevention services using integrated and accessible health care. It aims to use open communication and partnerships between patients and clinicians to improve the health and quality of life for the individual, family, and community.

primary care center A health care organization distinguished by the level of integration with the greater health community and involvement in improving the health of the immediate community served. Primary care centers strive for accessibility, comprehensiveness, care coordination, continuity of care, management of chronic diseases, and accountability on an individual patient level and community level. Primary care centers are also distinguished by their emphasis on health promotion and disease prevention.

primary source verification Verification of an individual health care practitioner's reported qualifications by the original source or an approved agent of that source. Methods of conducting primary source verification of credentials include direct correspondence, documented telephone verification, secure electronic verification from the original qualification source, or reports from credentials verification organizations that meet JCI requirements. *See also* verification.

principal site The location at which an organization provides the majority of medical specialty programs for postgraduate medical trainees (for example, residents or interns) and not just one specialty, as in a single-specialty organization (for example, an ophthalmologic hospital, dental hospital, or orthopedic hospital).

privileging The process whereby a specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization, based on evaluation of the individual's credentials and performance. *See also* credentialing; recredentialing.

procedural sedation *(as it pertains to the ASC chapter)* the technique of administering sedatives or dissociative agents with or without analgesics to an individual, in any setting, by any route, to induce an altered state of consciousness that allows the patient to tolerate painful or unpleasant procedures while maintaining cardiorespiratory function. *See also* anesthesia. The four levels of sedation and anesthesia are as follows:

minimal sedation (anxiolysis) indicates a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

moderate sedation/analgesia (conscious sedation) indicates a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

deep sedation/analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

general anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required

because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

procedure How a task is performed, usually including step-by-step instructions.

process A set of actions that produce or lead to a particular result.

process measure A measure used to assess a goal-directed, interrelated series of actions or steps (for example, the number of times a procedure was performed).

proficiency testing The testing of unknown samples sent to a laboratory by a proficiency testing program for the purpose of determining performance related to specific tests and measurements and to monitor continuing performance. A similar term includes external graded interlaboratory comparison testing.

profile An electronic or handwritten entry included in a patient's medical record that outlines key and up-to-date medical information about the patient (for example, current medications, diagnoses, laboratory results,). A profile may be developed for patients who are seen over time and who require complex care or have complex diagnoses.

program An organized, official system that guides action toward a specific goal. The program identifies needs, lists strategies to meet those needs, includes staff involved, and sets goals and objectives. The format of the program may include narratives, policies and procedures, plans, protocols, practice guidelines, clinical pathways, care maps, or a combination of these.

proportion A type of rate in which the numerator is expressed as a subset of the denominator (for example, 20%, or 1 out of 5 patients with a principal diagnosis of insulin dependent diabetes mellitus [denominator] demonstrate self–blood glucose monitoring [numerator]).

prospective A focus on the potential for something to happen in the future.

protocol A scientific medical treatment plan or study outline for a new or experimental procedure or treatment with the intent of measuring human applications (for example, management of diabetes mellitus type 2). Protocols frequently include such components as types of participants, scheduling, procedures used, and types of medications and dosages, among others.

qualified individual An individual who satisfies the requisite skill, experience, education, and other job-related requirements for the particular position the individual holds or desires and who is capable of performing the essential functions of that position, with or without reasonable accommodation for any disability.

quality control The performance of processes through which actual performance is measured and compared with goals, and the difference is acted on.

quality improvement An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of patients and others. Also called continuous quality improvement, continuous improvement, organizationwide continuous quality and performance improvement practices.

quality of care The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Dimensions of performance include the following: patient perspective issues; safety of the care environment; and accessibility, appropriateness, continuity, effectiveness, efficacy, efficiency, and timeliness of care.

radiobioassay The analysis of radioactive material in the human body by direct measurement or the evaluation of materials removed.

radiopharmaceutical The United States Pharmacopeia and the National Formulary (USP-NF) defines a radiopharmaceutical as a completed form of a medication that contains a radioactive substance and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any nonradioactive reagent kit or radionuclide generator that is intended for similar use. Also known as a radioactive drug.

rate-based measure An aggregate data measure in which the value of each measurement is expressed as a proportion or ratio.

ratio The relationship between two counted sets of data, which may have a value of zero or greater. In a ratio, the numerator is not necessarily a subset of the denominator (for example, the number of patients on fewer than three medications: number of patient-days).

readily available An item, individual, document, or other resource that is available for use a short time after it is requested. *See also* immediately available.

reagent A substance that is used to test for the presence of another substance by causing a chemical reaction in order to allow researchers to detect, measure, produce, or change other substances.

reappointment The process of reviewing the medical staff member's record to verify continued licensure; that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies; that the record contains sufficient documentation for seeking new or expanded privileges or duties in the organization; and that the medical staff member is physically and mentally able to provide patient care and treatment without supervision. *See also* appointment.

reassessment Ongoing data collection that begins on initial assessment, comparing the most recent data collected with the data collected at the previous assessment. *See also* assessment (patient); screening.

recall, medical equipment When a piece of medical equipment is removed from the market because it is found to be defective or potentially harmful. Equipment may be recalled by the manufacturer, supplier, or a regulatory agency.

recall, medication When a medication is removed from the market because it is found to be either defective or potentially harmful. Defects may be related to incorrect packaging, potential contamination, or poor manufacturing, resulting in impurities or errors in strength/potency. Medications may be recalled voluntarily by the manufacturer, or at the request of a government agency.

recredentialing The process of periodically checking staff qualifications to provide patient care services in or for a health care organization. *See also* credentialing; privileging.

recruitment Seeking—usually new—employees or other members of an organization.

reference (contract) laboratory A laboratory owned and operated by an organization other than a hospital or certified program, with which a hospital, certified program, or other health care organization contracts for testing.

referral The sending of an individual from one clinician to another clinician or specialist, or from one setting or service to another or other resource, either for consultation or care that the referring source is not prepared or qualified to provide.

rehabilitation services The use of medical, social, educational, and vocational measures together for training or retraining individuals disabled by disease or injury. The goal is to enable patients to achieve their highest possible level of functional ability.

reliability A characteristic of a measure that indicates how accurately and consistently the measure produces similar results. For example, a reliable measure or measurement tool yields accurate and consistent results when used by different individuals, across different settings, with different patients, and so on, as applicable.

renewable energy Energy that is supplied from naturally renewing resources, including the sun, wind, water, and geothermal heat.

representative sample As it relates to JCI standards, a representative sample of medical records is reviewed as part of an organization's monitoring and performance improvement activities. *Representative sample* means medical records from all departments and services of the organization and both active and discharged records. The number of medical records should make sense for the organization. For example, random sampling and selecting approximately 5% of medical records may achieve a representative sample.

research Investigational or exploratory studies that may or may not require oversight by an Institutional Review Board (IRB) or other research ethics review mechanism. Research studies may involve human subjects—such as patients—interactions with the individuals, and identifiable personal information. These types of research studies require IRB oversight. Such research

may include clinical trials, outcomes research, therapeutic interventions, and development of new medical technologies, among others. Research may also be non–human subjects research involving no direct interaction with individuals. Examples include medical record review studies, case studies, and research involving data/specimens. A research study that does not involve patients directly—such as a retrospective medical record review study—would still require IRB review if it includes identifiable patient information. In such a study, IRB review is necessary to ensure protection of human subjects.

resident A recipient of care in a nursing care center or assisted living community.

resident, medical *See* trainee, medical.

resident care process The act of providing accommodations, comfort, and treatment to a resident. This implies responsibility for safety, including treatment, services, habilitation, rehabilitation, or other programs requested by the organization or network for the individual.

resident-centered standards For purposes of JCI accreditation, standards that are organized according to what is done directly or indirectly for or to residents (for example, resident education, creation of resident records, resident assessment).

resident record/medical record A written account of a variety of resident health information, such as assessment findings, treatment details, progress notes, and discharge summary. This record is created by health care professionals.

resident tracer The process used by JCI to evaluate an individual resident's total care experience within a health care organization.

responsible physician The physician who has overall responsibility for the care and management of an individual patient at a specific point in time during the patient's hospital stay.

responsible surgeon In cases of surgical procedures, the person who performs the surgery. Different titles used for the responsible surgeon include attending surgeon and consultant surgeon, among other titles.

resuscitation services Services related to the provision of qualified staff and licensed practitioners, supplies, and processes used to revive an individual.

retrospective tracing As it relates to supply chain management, the process of identifying and tracking unstable, contaminated, defective, or counterfeit supplies after they have entered the organization. When applicable, the organization notifies the manufacturer and/or distributor about the unstable, contaminated, defective, or counterfeit supply.

risk 1. Combination of the probability of occurrence of harm and the severity of that harm. 2. The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.

risk assessment The identification and evaluation of potential failures and sources of errors in a process. This is followed by prioritizing areas for improvement based on the actual or potential impact on care, treatment, or services provided.

risk management program Clinical and administrative activities that organizations undertake to identify, to evaluate, and to reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

root cause analysis A process for identifying the basis or causal factor(s) that brings about variation in performance, including the occurrence, or possible occurrence, of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance. *See also* comprehensive systematic analysis; sentinel event.

routine maintenance *See* maintenance program, routine.

rules and regulations Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally assessed when rules and regulations are not followed.

safety The degree to which the organization's buildings, grounds, and equipment do not pose a hazard or risk to patients, staff, or visitors.

safety data sheet (SDS) A formal document with information about the characteristics and actual or potential hazards of a substance; includes instructions related to first aid, spills, and safe storage, among other information. Formerly known as material safety data sheet (MSDS).

sampling The process of selecting a group of units or observations from a larger collection of units or observations, which provides information that may be used to make a decision about the larger quantity.

scope of practice The range of activities performed by a health care practitioner in a health care organization. The scope is determined by training, tradition, licensure, laws and regulations, and the organization.

scope of services The range of activities, such as clinical care services, offered by the organization and performed by health care practitioners, support staff, managerial staff, the governing entity, and so on.

screening Simple, high-level evaluation that identifies patients at high risk for a condition. Screenings are generally brief, have a narrow scope, and are conducted by clinicians, support staff, and/or the patient, based on questions developed by qualified individuals. This process identifies the type and level of care, treatment, or services and may indicate a need for further evaluation; however, it is not definitive in diagnosis or indication of a specific condition. *See also* assessment (patient); reassessment.

scribe An individual qualified, trained, and competent to assist health care practitioners with documentation.

second victim A health care practitioner involved in an unanticipated adverse patient event, a medical error, and/or a patient-related injury who becomes victimized in the sense that the practitioner is traumatized by the event.

secure platform Platform security refers to the security architecture, tools, and processes that ensure the security of an entire computing platform. It uses bundled security software, systems, and processes to enable the security of a computing platform's hardware, software, network, storage, and other components.

security Protection from loss, destruction, tampering, or unauthorized access or use.

security measures Processes to manage and control access,

sedation *See* anesthesia; procedural sedation.

sentinel event A patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in any of the following: death, permanent harm, or severe temporary harm. The Sentinel Event Policy located on *JCI Direct Connect* includes detailed information on sentinel events. *See also* adverse event; comprehensive systematic analysis; near miss; no-harm event; patient safety event; root cause analysis.

single-use devices Medical devices that are intended by the manufacturer to be discarded after one use, regardless of its condition after use.

sites of service Locations offering the services of the clinical care program. For certification review purposes, a site of service is considered unique if it is responsible for at least two of the following three activities: program management (hiring, budget allocation, information systems), clinical leadership (selection of guidelines, management of training programs), or care coordination (monitoring and education for program participants).

smoke separations/compartments A space within a building enclosed by smoke barriers on all sides, including top and bottom.

souring A process in which chemicals are added to laundered materials during the final rinse cycle in order to lower the pH of the water and to assist with the removal of detergents and rust stains. Most souring chemicals are fluoride-based, including ammonium silicofluoride, ammonium bifluoride, and hydrofluosilicic acid; glycolic acid is also used.

specialty laboratory programs Programs that include laboratory disciplines, such as chemistry (including toxicology, therapeutic drug testing, and drugs of abuse testing), clinical cytogenetics, immunogenetics, diagnostic immunology, embryology, hematology (including coagulation testing), histocompatibility, immunohematology, microbiology (including bacteriology, mycobacteriology, mycology, virology, and parasitology), molecular biology, pathology (including surgical pathology, cytopathology, and necropsy), and radiobioassay.

specimen A sample of a substance to be used in testing, examination, or study.

staff According to their roles and responsibilities, all people who provide care, treatment, and services in the organization (for example, medical staff, nursing staff, housekeeping staff, registration clerks, engineers), including those receiving pay (permanent, temporary, and part-time staff, as well as contract staff), and trainees and students (for example, medical students, nursing students). *See also* clinical staff; medical staff; nonclinical staff.

stakeholder An individual or group that is involved in and affected by a policy or course of action. In health care, stakeholders may include patients and their families; physicians, nurses, and other clinicians and practitioners; nonclinical staff members; members of leadership and governance; vendors and contracted employees; members of the community; and others.

standard A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality patient care, treatment, and services.

standardized measure A performance measure that has precisely defined specifications, has standardized data collection protocols, meets established evaluation criteria, and can be uniformly adopted for use.

standards-based evaluation 1. An assessment process that determines a health care organization's or health care practitioner's compliance with preestablished standards. *See also* accreditation; certification. 2. A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe, high-quality care, treatment, and services.

standpipe system A series of pipes that connect a water supply to fire hose connections in strategic locations inside a building. They are common in multistory and other large buildings where much of the space is far from an outside entrance, as they prevent long lengths of fire hose in stairwells and on the ground.

sterile compounding The combining, admixing, mixing, diluting, pooling, reconstituting, repackaging, or altering of a drug or bulk drug substance to create a sterile medication.

sterilization The use of physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

structural elements (of a building) Internal and external load-bearing components of a building that are essential to its stability. Structural elements of a building include the foundation, columns, beams, walls, floor slabs, and so on. It also includes the location of the building. *See also* nonstructural elements (of a building)

structure measure A measure of whether organizational or program resources and arrangements are in place to deliver health care (for example, the number of facilities providing a service).

student, medical An individual enrolled in a medical educational institution.

supply chain The steps in moving a finished product (drug, medical equipment, medical device, or medical supply) from its source (a manufacturer) to its consumer (an organization). Key considerations in the supply chain are the risks to the product (for example, protection from losing stability, becoming contaminated, and becoming defective); the potential risk points in the steps of the supply chain (for example, quality of product, storage conditions, customs, delivery methods); and the selection of vendor, distributor, and so on, based on the risks in the supply chain.

surgery Those procedures that investigate and/or treat diseases and disorders of the human body through cutting, removing, altering, or insertion of diagnostic/therapeutic scopes.

survivor risk factors Chances for surviving family members or other loved ones to experience difficulties with the death of a loved one.

symptom, primary First or most prominent indication of an illness, disease, or other disorder.

symptom, secondary An indication of illness, disease, or other disorder that appears after or because of a primary symptom.

system tracer A tracer (*see* tracer methodology for a description of tracers) that occurs during the on-site survey and focuses on evaluating priority safety and quality-of-care issues on a systemwide basis throughout the organization. Examples of such

issues include infection prevention and control, medication management, facility management, and the use of data. *See also* patient tracer.

telecommunication Communication over a distance by cable, telegraph, telephone, or broadcasting.

telehealth The distribution of health-related services and information via electronic information and telecommunication technologies. It allows for long-distance clinician contact, care, advice, reminders, education, intervention, and monitoring, as well as remote admissions.

template Customizable forms and data fields that can be applied to the EHR.

temporary clinical privileges Clinical privileges granted to a medical staff member for a limited period of time and for circumstances as defined by hospital policy and consistent with laws and regulations.

texting The act of sending an electronic text message from one cell phone to another.

therapeutic duplication One person using two drugs, usually unnecessarily, from the same therapeutic category at the same time.

time-out A pause, just prior to performing a surgical or other procedure, during which any unanswered questions or confusion about patient, procedure, or site are resolved by the entire surgical or procedural team. Even when there is only one person doing the procedure, a brief pause to confirm the correct patient, procedure, and site is appropriate.

tracer methodology A process that JCI surveyors use during the on-site survey to analyze an organization's systems by following individual patients through the organization's health care process in the sequence experienced by the patients. Depending on the health care setting, this may require surveyors to visit multiple care units, departments, or areas within an organization or single care unit to "trace" the care rendered to a patient. *See also* patient tracer; system tracer.

trainee, medical An individual training in medical service after graduation from a medical educational institution. For the purpose of JCI accreditation and certification, trainees include interns, residents, and fellows.

transfer The formal shifting of responsibility for the care of a patient from one care unit to another, one clinical service to another, one qualified practitioner to another, or one organization to another.

unplanned downtime Unexpected data system interruption as a result of power or equipment failures, heating/cooling system failures, natural disasters, human error, or interruptions to Internet or intranet services, among other disruptions. Unplanned downtime can have a negative impact on data systems, such as data loss, hardware failures, and data corruption. *See also* planned downtime.

urgent A classification of acuity used in triage systems to signify that the patient's condition is potentially life-threatening and requires timely assessment and possible intervention. *See also* emergent.

utility systems Organizationwide systems and equipment that support the following: electrical distribution; emergency power; water; vertical and horizontal transport; heating, ventilation, and air-conditioning; plumbing, boiler, and steam; piped gases; vacuum systems; or communication systems, including data-exchange systems.

utilization The use, patterns of use, or rates of use of a specified health care service. Overuse occurs when a health care service is provided under circumstances in which its potential for harm exceeds the possible benefits for a patient. Underuse is the failure to use a health care service that may have been necessary for a patient and may have produced a favorable outcome for a patient. Misuse occurs when an appropriate service has been selected but a preventable complication occurs. All three reflect a problem in quality of health care. They can increase mortality risk and diminish quality of life. *See also* utilization management.

utilization management The planning, organization, direction, and control of resources. How this relates to patient care by a health care organization is significant. *See also* utilization.

validity A characteristic of a measure that indicates the degree to which the measure assesses what it is intended to measure. For example, the measure

or measurement tool is valid when it captures the intended clinical outcome, patient experience, and so on.

variation The differences in results obtained in measuring the same event more than once. The major sources of variation can be grouped into two major classes: common causes and special causes. Too much variation often leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services.

vendor A person or representative of a company that has a contract with the hospital and/or is seeking to provide support, services, or maintenance for a company's product(s) or service(s).

verification The process of checking the validity and completeness of a clinical or other credential from the source that issued the credential. *See also* primary source verification.

workplace violence An act or threat occurring at the workplace that can include any of the following: verbal, nonverbal, written, or physical aggression; threatening, intimidating, harassing, or humiliating words or actions; bullying; sabotage; sexual harassment; physical assaults; or other behaviors of concern involving all staff, patients, or visitors.

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