Joint Commission International

# Joint Commission International Accreditation Standards for Hospitals

**Including Standards for Academic Medical Center Hospitals**

**7th Edition** | Effective 1 January 2021

# Joint Commission International Mission

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The mission of Joint Commission International (JCI) is to improve the safety and quality of care in the international community through the provision of education, publications, consultation, and evaluation services.



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# Contents

# Summary of Changes to the Manual

Standards and measurable elements (MEs) published in this manual are effective as of 1 January 2021. Your organization is responsible for meeting all applicable changes by this date.

There are many changes to the *Joint Commission International Accreditation Standards for Hospitals Including Standards for Academic Medical Center Hospitals*, 7th Edition. A thorough review is strongly recommended.

Major changes to the 7th edition include the following:

- Expanded requirements in the "International Patient Safety Goals" (IPSG) chapter on safety of look-alike/sound-alike medication (IPSG.3.1) and concentrated electrolytes (IPSG.3.2) and added new requirements regarding the use of evidence-based interventions or bundles (IPSG.5.1)
- Combined the "Patient and Family Rights" (PFR) and "Patient and Family Education" (PFE) chapters to create a new chapter, "Patient-Centered Care" (PCC) and introduced a new requirement to measure, analyze, and improve the patient experience to enhance the quality of patient care (PCC.3)
- Added standards to the "Care of Patients" (COP) chapter on clinical alarm system management (COP.3.1), management of patients at risk of suicide or self-harm (COP.3.5), and management of lasers (COP.4 and COP.4.1)
- Updated the definitions and requirements for sentinel events, adverse events, no-harm events, and near misses (QPS.7 and QPS.7.1)
- Introduced new standards in the "Prevention and Control of Infections" (PCI) chapter on environmental cleanliness (PCI.7); cleanliness of laundry, linens, and scrubs (PCI.7.1); and on protection of patients and staff from bloodborne pathogens (PCI.8.1)
- Reorganized the "Facility Management and Safety" (FMS) chapter by the eight areas required to have a written facility management and safety program: safety, security, hazardous materials and waste, fire safety, medical equipment, utility systems, emergency management, and construction and renovation—and introduced new requirements for monitoring each area
- Created a new "Interim Measures" appendix in the FMS chapter to address safety of the building's occupants during construction, maintenance, or a breakdown or repair (addressed at FMS.8.3)
- Updated and added additional evidence-based references to support new and revised standards throughout the manual
- Moved standards cross-references throughout the manual from measurable elements and standards to the standards' intents and revised them as needed to align with standards renumbering and revisions in the 7th edition
- Completed a project to align glossaries across all JCI accreditation and certification programs

Details on specific changes in each chapter of the 7th edition follow. If a standard or ME from the 7th edition is *not* listed below, no substantive changes occurred since the 6th edition of this manual. Deletions from the 6th edition are not listed.

## Introduction

- Updated and reflowed the content of the Introduction to align with changes to the 7th edition
- Added information on the value of JCI accreditation and how to use the standards manual
- Moved "General Eligibility Requirements" into the Introduction

## Accreditation Participation Requirements (APR)

- APR.8, Rationale: Added an example of inappropriate representation of accreditation status
- Made minor editorial revisions throughout the chapter

## International Patient Safety Goals (IPSG)

- IPSG.1
  - Intent: Revised to address the labeling of elements associated with patient care (for example, dietary trays, mother's milk) and clarified expectations for using two patient identifiers
  - ME 1: Added requirement to include the labeling of elements related to patient care, using the same two identifiers
- Intent of IPSG.2 Through IPSG.2.2: Revised to clarify the definition of *critical results*, including examples
- IPSG.2.1
  - ME 1: Clarified the requirement to define critical results that may represent urgent or emergent life-threatening values for diagnostic tests
  - ME 2: Revised to focus on the development of a formal reporting process
- Intent of IPSG.3 Through IPSG.3.2: Revised to include the Institute for Safe Medication Practices definition of *high-alert medication* and examples; expanded to address new IPSG.3.1 on look-alike/sound-alike medications; provided further discussion of concentrated electrolytes, including examples
- IPSG.3
  - MEs 1 and 2: Split previous ME 1 to focus on writing a list of high-alert medications (ME 1) and combined with previous ME 3 to focus a uniform process for reducing risk of harm from them (ME 2)
  - **New ME 3:** Added requirement that high-alert medication list be reviewed annually
- IPSG.3.1
  - **New Standard:** Introduced requirements for a process for managing look-alike/sound-alike medications (previously addressed as part of IPSG.3 on high-alert medications)
  - MEs 1 and 2: Split and adapted previous IPSG.3, ME 2 to focus on a written look-alike/sound-alike medication list (ME 1) and combined with previous IPSG.3, ME 3 to focus on a uniform process for reducing risk of harm from them (ME 2)
  - **New ME 3:** Added requirement for hospital to annually review its look-alike/sound-alike list
- IPSG.3.2
  - Standard: Renumbered previous IPSG.3.1 to address hospital management of concentrated electrolytes
  - ME 1: Renumbered previous ME 3 and added requirement that only trained staff access concentrated electrolytes
  - ME 2: Clarified that concentrated electrolytes are stored outside the pharmacy only in circumstances as described in the intent of the standard
  - **New ME 3:** Added requirement to follow standardized protocols for electrolyte replacement therapy
- Intent of IPSG.5 and IPSG.5.1: Expanded to address new IPSG.5.1 on evidence-based guidelines addressing hospital-associated infections
- IPSG.5.1
  - **New Standard:** Introduced requirements for the use of evidence-based interventions to reduce risk of hospital-associated infections
  - **New ME 1:** Added requirement for hospital leaders to identify priority hospital-acquired infections on which to focus improvements
  - **New ME 2:** Added requirement that evidence-based interventions (such as bundles) be applied to the identified hospital-acquired infections
  - **New ME 3:** Added requirement that the use of evidence-based interventions is monitored for compliance and improved outcomes

- Intent of IPSG.6 and IPSG.6.1: Added information about high-risk areas for falls and fall risk screening
- Made minor editorial revisions throughout the chapter

## Access to Care and Continuity of Care (ACC)

- ACC.1
  - Standard and Intent: Combined with previous Standard ACC.1.1 and revised to include requirements on prioritization of patients with emergent, urgent, or immediate needs
  - ME 1: Combined with previous MEs 2 and 6; clarified that patients are accepted for treatment if it is determined that the needs of the patient match the hospital's mission and resources
  - ME 2: Combined previous ME 2 with MEs 1 and 6 and numbered as ME 1
  - ME 3: Renumbered previous ACC.1.1, ME 1
  - ME 4: Combined and renumbered requirements of previous ACC.1.1, MEs 4 and 5
  - ME 5: Renumbered previous ME 4
- ACC.1.1
  - Standard and MEs: Renumbered previous Standard ACC.1.2 and its MEs 1–5
  - Intent: Added examples of situations that would require the patient to be notified of delays
- ACC.2
  - Standard: Combined with previous Standard ACC.2.2.1 and focused on managing the entire patient flow process throughout the hospital
  - Intent: Revised to include content from previous Standard ACC.2.2.1 on patient flow
  - ME 1: Renumbered previous ACC.2.2.1, ME 1
  - ME 2: Renumbered previous ME 3
  - ME 3: Renumbered previous ME 4
  - MEs 4–6: Renumbered previous ACC.2.2.1, MEs 2–4
- ACC 2.3
  - Standard: Combined with previous Standard ACC 2.3.1 to address both admission and discharge and/or transfer criteria
  - ME 3: Renumbered previous ACC.2.3.1, ME 1
  - ME 4: Renumbered previous ME 5
  - ME 5: Renumbered previous ACC.2.3.1, ME 5
- ACC.3
  - Standard: Combined with previous Standard ACC.3.2 to include access to essential patient information
  - Intent: Revised to include components of patient's medical record summary
  - ME 4: Renumbered previous ACC.3.2, ME 1
  - ME 5: Combined and renumbered previous ACC.3.2, MEs 2–6 on the components of patient's medical record summary
  - ME 6: Renumbered previous ME 4
- ACC.3.1
  - ME 1: Combined previous MEs 1 and 2
  - MEs 2 and 3: Renumbered previous MEs 3 and 4
- Intent of ACC.4 and ACC.4.1: Combined the intents of these two standards and expanded discussion on patient and family education needs and addressing patient needs for continuing care and information at discharge
- ACC.4
  - Standard: Revised to focus on patient's readiness for discharge
  - ME 1: Renumbered previous ME 3 and revised to include patient's readiness for discharge
  - ME 3: Renumbered previous ME 1 and revised to include support services

  - **New ME 4:** Added requirement to provide information on site(s) for continuing care to patients who are not directly referred or transferred
  - **New ME 5:** Added requirement to provide information on when to return for care to patients who are not directly referred or transferred
  - **New ME 6:** Added requirement to provide written discharge planning and instructions to patients
- ACC.4.1
  - Standard: Revised to address patient and family education and ongoing care needs in discharge planning
  - **New ME 1:** Added requirement to focus patient and family education on patient's ongoing need for continuing care and services
  - **New ME 2:** Added requirement on providing patients and families with list of medications to be taken at home
  - ME 3: Renumbered previous ME 1
  - ME 4: Renumbered previous ME 3
  - ME 5: Renumbered previous ME 4
  - ME 6: Renumbered and combined previous MEs 2 and 5
- ACC.4.2:
  - Standard and Intent: Combined and renumbered previous Standards ACC.4.3 and ACC.4.3.2 on discharge summaries
  - ME 1: Renumbered previous ACC.4.3.2, ME 1
  - ME 2: Combined and renumbered previous ACC.4.3, MEs 1–6
  - MEs 3–5: Renumbered previous ACC.4.3.2, MEs 2–4
- ACC.4.2.1: Renumbered previous MOI.10 and its MEs 1–4
- ACC.4.3: Renumbered previous ACC.4.4 and its MEs 1–4
- Intent of Standard ACC.4.4 and ACC.4.4.1: Renumbered the intents of these two standards from previous ACC.4.5 and ACC.4.5.1 and added details about granting permission for a patient to leave the hospital during the course of treatment
- ACC.4.4:
  - Standard: Renumbered previous Standard ACC.4.5
  - MEs 1–4: Renumbered previous ACC.4.5, MEs 1–4
  - ME 5: Renumbered previous ACC.4.5, ME 6
  - ME 6: Renumbered previous ACC.4, ME 4
- ACC.4.4.1: Renumbered previous ACC.4.5.1 and its MEs 1–4
- ACC.5
  - Standard: Combined with previous Standard ACC.5.1 to include a requirement to develop a process to safely transfer patients to other health care organizations
  - Intent: Combined with intent of previous Standard ACC.5.1
  - ME 2: Expanded to address how and when responsibility for a patient is transferred
  - ME 3: Renumbered previous ACC.6, ME 3 and added new requirement to identify an individual responsible for the patient during transfer
  - MEs 4–6: Renumbered previous ACC.5.1, MEs 3–5
- ACC.5.1
  - Standard: Combined and renumbered previous Standards ACC.5.2 and ACC.5.3
  - ME 1: Combined and renumbered previous ACC.5.2, ME 1 and ACC.5.3, MEs 2–4
  - ME 2: Renumbered previous ACC.5.3, ME 1
  - ME 3: Renumbered previous ACC.5.3, ME 2
  - ME 4: Combined and renumbered previous ACC.5.3, MEs 3 and 4
- ACC.6
  - Intent: Expanded discussion of patient transportation needs and added examples

  - ME 1: Renumbered previous ACC.4, ME 5
  - ME 2: Combined previous MEs 1 and 2 and numbered ME 2, addressing transportation services and vehicles together
  - ME 3: Renumbered previous ME 4
  - ME 4: Renumbered previous ACC.4, ME 6
- Made minor editorial revisions throughout the chapter

## Patient-Centered Care (PCC)

- **New Chapter:** Combined and reorganized previous chapters "Patient and Family Rights" (PFR) and "Patient and Family Education" (PFE) to create this new "Patient-Centered Care" (PCC) chapter
- Overview: Revised the PFR overview to incorporate PFE concepts
- PCC.1
  - Standard: Renumbered previous Standard PFR.1
  - ME 1: Renumbered previous PFR.1, ME 1
  - MEs 2 and 3: Split previous PFR.1, ME 2 to focus on implementing (ME 2) and protecting (ME 3) patient and family rights
  - **New ME 4:** Added requirement on patients' right to identify who they wish to participate in their care decisions
  - ME 5: Renumbered previous PFR.1, ME 3
  - ME 6: Renumbered previous PFR.2, ME 6
- PCC.1.1
  - Standard: Combined and renumbered previous Standards PFR.1.1 and PFR.4
  - Intent: Combined the intents of the two standards and added additional information and examples on barriers to care and a written statement of patient and family rights
  - ME 1: Renumbered and adapted previous PFR.1.1, ME 1
  - ME 2: Combined, renumbered, and adapted previous PFR.1.1, MEs 2 and 3
  - ME 3: Adapted concepts from previous Standards PFR.2 and PFR.4
  - ME 4: Combined and renumbered previous PFR.4, MEs 1 and 2
  - ME 5: Renumbered previous PFR.4, ME 3
- PCC.1.2
  - Standard: Renumbered previous Standard PFR.1.2
  - ME 1: Renumbered previous PFR.1.2, ME 1
  - ME 2: Combined and renumbered previous PFR.1.2, MEs 2 and 3
  - ME 3: Renumbered previous PFR.1.2, ME 4
- PCC.1.3
  - Standard and Intent: Renumbered previous Standard PFR.1.3 and expanded to address patients' right to have access to their health information
  - MEs 1–3: Renumbered previous PFR.1.3, MEs 1–3
  - ME 4: Clarified that the hospital must have a process to grant permission to release health information to patients
  - **New ME 5:** Added requirement for a process to provide patients with access to their health information
  - **New ME 6:** Added requirement to provide timely access to patient's health information without a prohibitive cost
- PCC.1.4: Renumbered previous Standard PFR.1.4 and its MEs 1–3
- PCC.1.5: Renumbered and adapted previous Standard PFR.1.5 and its MEs 1–4
- PCC.2
  - Standard and Intent: Renumbered previous Standard PFR.2 and expanded to include families and address engagement and education in care decisions and care processes
  - MEs 1 and 2: Combined and renumbered previous PFR.2, MEs 1, 2, and 5

  - MEs 3 and 4: Split and adapted previous PFR.2, ME 3 to focus on informing patients about expected outcomes of care (ME 3) and unanticipated outcomes of care (ME 4)
  - ME 5: Renumbered previous PFR.2, ME 4
- PCC.2.1: Renumbered previous Standard PFR.2.1 and its MEs 1–6
- PCC.2.2: Renumbered previous Standard PFR.2.2 and its MEs 1–4
- PCC.3
  - **New Standard and Intent:** Introduced requirement to measure, analyze, and improve the patient experience to enhance the quality of patient care
  - **New ME 1:** Added requirement for leaders to develop and implement a process for assessing patient experience
  - **New ME 2:** Added requirement to aggregate and analyze patient experience data
  - **New ME 3:** Added requirement for leaders to prioritize areas for improving the patient experience
  - **New ME 4:** Added requirement to implement strategies to improve the patient experience
  - **New ME 5:** Added requirement to analyze the impact of improvements
- PCC.3.1: Renumbered previous Standard PFR.3 and its MEs 1–4
- PCC.4: Renumbered previous Standard PFR.5 and its MEs 1–4
- PCC.4.1: Renumbered previous Standard PFR.5.1 and its MEs 1–6
- PCC.4.2: Renumbered and adapted previous PFR.5.2 and its MEs 1–5
- PCC.4.3: Renumbered previous Standard PFR.5.3 and its MEs 1–4
- PCC.4.4: Renumbered and adapted previous PFR.5.4 and its MEs 1–3
- PCC.5
  - Standard and Intent: Combined and renumbered previous Standards PFE.1 and PFE.4
  - ME 1: Renumbered previous PFE.1, ME 1
  - ME 2: Combined and renumbered previous PFE.1, MEs 2 and 3
  - ME 3: Renumbered previous PFE.4, ME 1
  - ME 4: Combined and renumbered previous PFE.4, MEs 2 and 4
  - ME 5: Renumbered previous PFE.4, ME 3
- PCC 5.1
  - Standard and Intent: Combined and renumbered previous Standards PFE.2 and PFE.2.1
  - ME 1: Combined concepts from and renumbered previous PFE.2, MEs 1 and 2 and previous PFE.2.1, ME 1
  - ME 2: Combined, renumbered, and adapted previous PFE.2.1, ME 2 and previous PFE.2.1, MEs 3 and 4
  - **New ME 3:** Added requirement on accommodating patients' and families' identified needs when providing education
  - ME 4: Renumbered and adapted previous PFE.2, ME 3
- PCC.5.2: Renumbered previous Standard PFE.3 and its MEs 1–4
- PCC.6: Renumbered previous Standard PFR.6 and its MEs 1–4
- PCC.6.1: Renumbered previous Standard PFR.6.1 and its MEs 1–4
- Made minor editorial revisions throughout the chapter

## Assessment of Patients (AOP)

- AOP.1.1
  - Intent: Listed the types of assessments needed to be performed as part of the initial patient assessment and clarified that listing patients' current medications and known allergies should be part of the health history
  - ME 2: Revised to focus on listing of patient's current medications and known allergies as part of their assessment
  - ME 3: Combined and renumbered previous MEs 2–4
  - ME 4: Renumbered previous ME 5

- AOP.1.5
  - Standard: Clarified which outpatients the standard applies to (that is, those whose condition, diagnosis, or situation may indicate they are at risk for pain)
  - Intent: Provided additional information about screening patients for pain
  - ME 1: Revised requirement to focus on inpatients
  - **New ME 2:** Added requirement for screening for pain in outpatients whose condition, diagnosis, or situation may indicate a need for screening
  - ME 3: Renumbered previous ME 2 and restricted its focus to inpatients
  - ME 4: Renumbered previous ME 3
  - **New ME 5:** Added requirement to guide assessment and referral for outpatients who positively screened for pain
- AOP.1.7: Renumbered previous Standard AOP.1.8 and its MEs 1–3
- AOP.5.1
  - Standard and Intent: Combined with previous Standard AOP.5.2
  - ME 2: Combined and renumbered previous MEs 2–6
  - ME 3: Renumbered and adapted previous AOP.5.2, ME 1
  - MEs 4 and 5: Renumbered previous AOP.5.2, MEs 2 and 3
- AOP.5.2: Renumbered previous Standard AOP.5.1.1 and its MEs 1–5
- AOP.5.3
  - ME 2: Split previous ME 2 to focus on involving the laboratory safety program with the facility management program (ME 2) and the infection prevention and control program (ME 3)
  - MEs 4 and 5: Renumbered previous MEs 3 and 4
- AOP.5.5
  - ME 1: Combined previous MEs 1 and 2
  - MEs 2–5: Renumbered previous MEs 3–6
- AOP.5.6
  - ME 1: Combined previous MEs 1 and 2
  - MEs 2–4: Renumbered previous MEs 3–5
- AOP.5.10.1
  - ME 2: Combined previous MEs 2 and 3
  - ME 3: Renumbered previous ME 4
- AOP.6.1
  - Standard and Intent: Combined with previous Standard AOP.6.2
  - ME 2: Combined and renumbered MEs 2–6
  - ME 3: Renumbered AOP.6.2, ME 2
  - ME 4: Combined and renumbered AOP.6.2, MEs 3 and 4
  - ME 5: Renumbered AOP.6.2, ME 5
  - ME 6: Renumbered AOP.6.2, ME 6
- AOP.6.2
  - Standard: Renumbered previous Standard AOP.6.3 and expanded to include diagnostic imaging in a radiation safety program; revised to require compliance with applicable professional standards, laws, and regulations; and clarified that the program should include patients, staff, and visitors
  - Intent: Added information about magnetic resonance imaging–related safety concerns and clarified expectations for the radiation safety management program
  - ME 1: Expanded to align with the revised standard
  - ME 2: Renumbered previous AOP.6.3, ME 5
  - ME 3: Renumbered and adapted previous AOP.6.3, ME 4
  - ME 4: Combined and renumbered previous AOP.6.3, MEs 2 and 3
  - **New ME 5:** Added requirements for addressing hazards related to magnetic resonance imaging

- AOP.6.3: Renumbered previous Standard AOP.6.4 and its MEs 1–3
- AOP.6.4: Renumbered previous Standard AOP.6.5 and its MEs 1–6
- AOP.6.5: Renumbered previous Standard AOP.6.7 and its MEs 1–5
- AOP.6.6: Renumbered previous Standard AOP.6.8 and its MEs 1–4
- Made minor editorial revisions throughout the chapter

## Care of Patients (COP)

- Overview: Revised to address risk factors that can impact patient care and an example of patient support
- COP.2
  - Standard and Intent: Combined with previous Standard COP.2.2
  - ME 1: Combined previous COP.2, MEs 1 and 2
  - MEs 2–5: Renumbered previous COP.2.2, MEs 1–4
- COP.2.1: Renumbered previous Standard COP.2.3 and its MEs 1–3
- COP.2.2
  - Standard: Renumbered previous Standard COP.2.1
  - Intent: Added additional information about multidisciplinary patient care conferences
  - ME 1: Renumbered previous COP.2.1, ME 1
  - ME 2: Combined with previous COP.2.1, ME 4 to require documentation in the medical record
  - ME 3: Combined with previous COP.2.1, ME 4 to require documentation in the medical record and revised to include consideration on changes in patient's condition
  - **New ME 4:** Added requirement to document results or outcomes from any patient care team meetings or other collaborative discussions in the medical record
  - ME 5: Renumbered previous COP.2.1, ME 6
- COP.3
  - Intent: Changed item j) in the list of potential high-risk services from patients at risk for suicide (now addressed at new standard COP.3.5) to patient receiving palliative care
  - ME 1: Given the change to the intent, leaders will need to include those patients receiving palliative care as they identify high-risk patients and services
- COP.3.1
  - **New Standard and Intent:** Introduced requirement on clinical alarm system management
  - **New ME 1:** Added requirement for hospital leaders to develop and implement an alarm system management program
  - **New ME 2:** Added requirement to prioritize alarm signals according to patient safety risk
  - **New ME 3:** Added requirement for hospital leaders to develop strategies for managing alarms
  - **New ME 4:** Added requirement to educate staff on the purpose and operation of alarm systems
  - **New ME 5:** Added requirement to ensure that responsible staff are trained and competent to manage clinical alarms
- COP.3.2:
  - Standard: Renumbered previous Standard COP.3.1
  - MEs 2 and 3: Split previous COP.3.1, ME 2 to focus on early warning signs (ME 2) and when and how to seek further assistance (ME 3)
  - MEs 4 and 5: Renumbered previous COP.3.1, MEs 3 and 4
- COP.3.3
  - Standard: Renumbered previous Standard COP.3.2 and its MEs 1–3
  - Intent: Added expectation for timely review of internal data on resuscitations
  - **New ME 4:** Added requirement for the hospital to review internal data from previous emergency situations to identify improvement opportunities
- COP.3.4: Renumbered previous Standard COP.3.3 and its MEs 1–3

- COP.3.5
  - **New Standard and Intent:** Introduced requirement for hospitals to have a process to identify patients at risk of suicide or self-harm
  - **New ME 1:** Added requirement to establish criteria to screen for suicide and self-harm
  - **New ME 2:** Added requirement to use evidence-based tools to assess patients for suicidal ideation
  - **New ME 3:** Added requirement to conduct environmental risk assessments and act to minimize risk
  - **New ME 4:** Added requirement to implement protocols and procedures to mitigate risk of suicide and self-harm
  - **New ME 5:** Added requirement to analyze data and monitor implementation and effectiveness of protocols and procedures
  - **New ME 6:** Added requirement to ensure that staff are trained on screening criteria and tools as well as risk reduction protocols and procedures
- COP.4
  - **New Standard and Intent:** Introduced requirement to establish a program on safe use of lasers and other optical radiation devices
  - **New ME 1:** Added requirement to base the program on professional standards and applicable laws and regulations
  - **New ME 2:** Added requirement for a qualified individual to oversee and supervise the program
  - **New ME 3:** Added requirement for documented safety training and continuing education for staff
  - **New ME 4:** Added requirement for administrative and engineering controls to promote program safety
  - **New ME 5:** Added requirement for correct, appropriate use of personal protective equipment for staff and patients
  - **New ME 6:** Added requirement for qualified, trained individuals to conduct inspection, testing, and maintenance processes
- COP.4.1
  - **New Standard and Intent:** Introduced requirement to report and address adverse events resulting from lasers and other optical radiation devices
  - **New ME 1:** Added requirement to integrate the safety program into the hospital's facility management and safety structure
  - **New ME 2:** Added requirement to integrate the safety program into the hospital's infection prevention and control program
  - **New ME 3:** Added requirement to report adverse events and identify and implement action plans to prevent recurrence
- COP.5
  - Standard: Renumbered previous Standard COP.4
  - ME 2: Combined with previous COP.4, ME 3
  - MEs 3–5: Renumbered previous COP.4, MEs 4–6
- COP.5.1: Renumbered previous Standard COP.5 and its MEs 1–3
- COP.7
  - Intent: Expanded discussion on needs of the end-of-life care for dying patients (pulling in concepts from previous Standard AOP.1.7)
  - **New ME 2:** Added requirement to identify health care needs and support services needs of the patient and family as appropriate to their religious and cultural preferences
  - MEs 3–6: Renumbered previous MEs 2–5
- Made minor editorial revisions throughout the chapter

## Anesthesia and Surgical Care (ASC)

- ASC.3, Intent: Clarified the expectation that sedation policies and procedures are understood by all practitioners permitted to administer procedural sedation
- ASC.3.1
  - ME 1: Clarified that practitioners who provide sedation must show evidence of competence
- ASC.5
  - Standard and Intent: Combined with previous Standard ASC.5.1
  - MEs 2 and 3: Renumbered previous ASC.5.1, MEs 1 and 2
  - MEs 4 and 5: Renumbered previous ASC.5, MEs 2 and 3
- ASC.7.2, Intent: Added new Note cross-referencing Standard COP.2.1 for information about documentation on nonsurgical procedures and treatments
- Made minor editorial revisions throughout the chapter

## Medication Management and Use (MMU)

- MMU.1
  - Intent: Added medication error and adverse reporting to the list of processes that must be addressed in the organization's medication management system
  - ME 1: Given the change to the intent, expanded the list of items a written document on medication use must address to include medication error and adverse reporting; added concept of overseeing medication use from previous MMU.2.1, ME 1
  - ME 4: Given the change to the intent, expanded the list of items the hospital must annually review to include medication error and adverse reporting
  - ME 5: Combined with previous MMU.5.2, ME 1 and revised to include the concept of a uniform medication dispensing and distribution system from MMU.5.2
- MMU.2
  - Standard and Intent: Combined with previous Standard MMU.2.1 and revised
  - ME 1: Combined with previous MMU.2.1, ME 5; clarified that the list of medications include both brand name and generic name
  - ME 2: Combined with previous MMU.2.1, ME 2
  - ME 3: Clarified that the ME includes medications not stocked or not normally available to the hospital
- MMU.3
  - Intent: Revised to incorporate content from the intent of previous Standard MMU.3.1; provided further details on what types of medications and products require special handling and expectations for safe storage and handling
  - ME 3: Renumbered and adapted previous MMU.3.1, ME 2
  - MEs 4–6: Renumbered previous MEs 3–5
- MMU 3.1
  - Standard: Renumbered previous Standard MMU.3.2
  - Intent: Revised to provide guidance on safe practices for the use of adult and pediatric emergency carts
  - ME 1: Clarified that emergency medication must be immediately available in needed units
  - ME 2: Added requirement to include a replacement process for emergency medications
  - **New ME 3:** Added requirement regarding access to emergency medications
  - ME 4: Renumbered previous MMU.3.2, ME 3
  - **New ME 5:** Added requirement that the hospital uses a risk-based approach to monitor emergency medication administration
- MMU 3.2
  - Standard: Renumbered previous Standard MMU.3.3

  - Intent: Provided further information on what a medication recall is, why it might occur, and the need to have a process for receiving notifications
  - ME 1: Clarified that a medication recall process must address receiving and acting on notifications of medication recalls
  - **New ME 2:** Added requirement that the hospital has a process for identifying, retrieving, and returning or destroying recalled medications
  - **New ME 3:** Added requirement that the recall process addresses medication compounded in the hospital
  - MEs 4 and 5: Renumbered previous MMU.3.3, MEs 2 and 3
- MMU 4
  - **New Standard and Intent:** Introduced requirement for the hospital to have a process for completing medication reconciliation on the current list of medications taken by the patient at home against all newly prescribed or dispensed medications
  - **New ME 1:** Added requirement for the hospital to collect information required to conduct medication reconciliation
  - MEs 2 and 3: Renumbered previous MMU.4, MEs 4 and 5
- MMU 4.1: Renumbered previous Standard MMU.4.2 and its MEs 1–3
- MMU 4.2
  - Standard and Intent: Combined and renumbered previous Standards MMU.4 and MMU.4.1
  - ME 1: Combined and renumbered previous MMU.4, MEs 1 and 3
  - **New ME 2:** Added requirement that all medication orders and prescriptions contain the required listed elements
  - ME 3: Renumbered previous MMU.4.1, ME 1
  - ME 4: Combined and renumbered previous MMU.4, ME 2 and MMU.4.1, MEs 2 and 4
  - ME 5: Renumbered previous MMU.4.1, ME 3
  - ME 6: Combined and renumbered previous MMU.4.3, MEs 1 and 3
- MMU.5
  - Intent: Revised to provide information on and examples of sterile compounding, infection risks for single-use and multidose vials, safety measures, and maintaining a clean environment where medications are dispensed
  - ME 1: Renumbered previous ME 2
  - ME 2: Renumbered previous ME 1
  - ME 3: Revised requirement for training, competency, and resources for staff preparing or compounding sterile products and medications
  - **New ME 4:** Added requirement to use guidelines for the use of single-use and multidose vials
  - **New ME 5:** Added requirement that medications stored, prepared, and dispensed outside the pharmacy comply with the same cleanliness measures as the pharmacy
- MMU.5.1
  - Intent: Revised and included additional examples addressing appropriateness reviews for medication prescriptions and orders
  - ME 3: Clarified that individuals conducting reviews must be permitted to do so
  - ME 6: Included clinical decision support programs
- MMU.5.2
  - MEs 1–3: Renumbered previous MEs 2–4
- MMU.6
  - Standard and Intent: Combined with previous Standard MMU.4.3
  - ME 2: Renumbered previous ME 3
  - ME 3: Renumbered MMU.4.3, ME 2

- MMU.6.1
  - Intent: Added information about engaging and informing the patient about his or her medications
  - ME 5: Combined previous MEs 5 and 6
- Intent of MMU.6.2 and MMU.6.2.1: Expanded intent to cover the two standards that were created from previous Standard MMU.6.2; included further description of the labeling, storage, and control of the use of medications brought in by the patient or medication samples, bringing concepts from the intent of previous Standard MMU.3.1; and introduced the expectation to conduct appropriate risk assessments
- MMU.6.2
  - Standard: Split previous Standard MMU.6.2 to focus on medications brought into the hospital by the patient (MMU.6.2) and sample medications (MMU.6.2.1); clarified that self-administered medications can be brought into the hospital by the patient or can be prescribed for self-administration
  - ME 1: Renumbered and adapted previous MMU.3.1, ME 4
  - **New ME 2:** Added requirement for the hospital to perform a risk assessment for patient-supplied medications
  - ME 3: Renumbered and adapted previous ME 1
  - ME 4: Renumbered previous ME 2
- MMU.6.2.1
  - Standard: Split previous Standard MMU.6.2 to focus on medications brought into the hospital by the patient (MMU.6.2) and sample medications (MMU.6.2.1)
  - ME 1: Renumbered and adapted previous MMU.3.1, ME 3
  - **New ME 2:** Added requirement for the hospital to perform a risk assessment for medication samples
  - ME 3: Renumbered and adapted previous MMU.6.2, ME 3
- MMU.7
  - ME 1: Combined with previous ME 4
  - ME 3: Clarified that the process for recording adverse effects in the medical record and reporting them to the hospital must be standardized
  - **New ME 4:** Added requirement for using a standardized reporting process for adverse medication effects as part of the hospital quality program
- Made minor editorial revisions throughout the chapter

## Quality Improvement and Patient Safety (QPS)

- QPS.3
  - Standard and Intent: Revised to address implementation of evidence-based patient care
  - **New ME 1:** Added requirement on hospital leadership's role in building a culture and environment that supports implementation of evidence-based care
  - MEs 2–6: Renumbered previous MEs 1–5
- QPS.4, Intent: Revised to emphasize the use of performance measurement data
- QPS.6, ME 3: Revised language from established methodology to evidence-based methodology
- Intent of QPS.7 and QPS.7.1: Expanded intent to cover the two standards where there was previously one; revised and updated to align with Joint Commission International's Sentinel Event Policy, including categorizing a root cause analysis as a type of comprehensive systematic analysis; incorporated concepts from the intent of previous Standard QPS.9
- QPS.7
  - ME 1: Given the revised intent, increased the required elements hospital leaders must include in a definition of *sentinel event*
  - **New ME 5:** Added requirement for monitoring corrective actions

- QPS.7.1
  - **New Standard:** Introduced requirement for the hospital to identify and manage adverse events
  - ME 1: Renumbered and expanded previous QPS.9, ME 1 to include adverse events, no-harm events, and near miss events
  - **New ME 2:** Added requirement for a process to manage adverse, no-harm, and near miss events that includes a blame-free reporting mechanism (a concept from the intent of previous Standard QPS.9)
  - MEs 3–5: Split, renumbered, and expanded previous QPS.9, ME 4 to focus on analyzing adverse events (ME 3) and near miss and no-harm events (ME 4) to identify corrective actions and then implementing corrective actions on the results of those analyses (ME 5)
  - **New ME 6:** Added requirement to monitor corrective actions
- QPS.8
  - Intent: Added adverse events related to patient identification to the list of required data gathering and analysis
  - ME 3: Given the change to the intent, expanded the list of data the hospital must gather and analyze to include adverse events related to patient identification
- QPS.9: Renumbered previous Standard QPS.10 and its MEs 1–4
- QPS.10
  - Standard: Renumbered previous Standard QPS.11
  - Intent: Revised the list of essential components of a risk management program to include the scope, objectives, and criteria for assessing risk
  - ME 1: Renumbered previous QPS.11, ME 1
  - ME 2: Renumbered and revised previous QPS.11, ME 2 to focus on potential risks that could have the greatest impact on safety and patient care
  - ME 3: Renumbered previous QPS.11, ME 3
  - ME 4: Renumbered previous QPS.11, ME 4 and revised to clarify that results of risk reduction exercises drive the redesign and implementation of changes to high-risk processes
  - **New ME 5:** Added requirement for hospital leadership to implement appropriate communication strategies
- Made minor editorial revisions throughout the chapter

## Prevention and Control of Infections (PCI)

- PCI.1
  - Standard: Added clinical authority to required qualifications for the individual overseeing infection prevention and control activities
  - Intent: Revised to address qualifications for the program leader and that the program should collaborate with all areas
  - ME 1: Added accountability to ensure that the program complies with laws and regulations
  - **New ME 4:** Added requirement for the individual leading the program to coordinate with hospital leadership
  - ME 5: Renumbered and adapted previous PCI.3, ME 4
  - ME 6: Renumbered previous PCI.3, ME 5
- PCI.2
  - Intent: Provided additional information on the expectations for a designated mechanism to coordinate the overall infection surveillance, prevention, and control program
  - ME 3: Absorbed the concept of previous ME 4
- PCI.3
  - Standard: Renumbered previous Standard PCI.4

  - Intent: Reinforced expectation that leadership supply staffing and infrastructure to support the program
  - MEs 2 and 3: Split previous PCI.4, ME 2 to focus on approval and assignment of staffing for the program (ME 2) and the approval and allocation of resources for the program (ME 3)
  - ME 4: Renumbered previous PCI.4, ME 3
- PCI.4: Renumbered and adapted previous Standard PCI.5 and its MEs 1–4
- Intent of PCI.5 and PCI.5.1: Renumbered and adapted intent of PCI.6 and PCI.6.1; added information about and examples of risk assessment, evidence-based interventions, and ongoing monitoring
- PCI.5
  - Standard: Renumbered PCI.6 and its MEs 1–3, adding the concept of a data-driven approach
  - ME 4: Renumbered previous PCI.6.1, ME 1
- PCI.5.1
  - Standard: Renumbered and adapted Standard PCI.6.1
  - MEs 1 and 2: Split and expanded the concepts from previous PCI.6.1, ME 3 to focus on completing an annual, documented risk assessment (ME 1), implementing interventions based on that assessment (ME 2)
  - **New ME 3:** Added requirement to evaluate the effectiveness of those interventions mentioned
  - **New ME 4:** Added requirement for ongoing data monitoring
- PCI.6
  - Standard: Renumbered previous Standard PCI.7 (moved the concept of managing expired supplies to new PCI.7.1)
  - Intent: Revised to recommend that the hospital use the Earle H. Spaulding classification system to determine the appropriate level of sterilization/disinfection for each medical device; added information on the expectations of hospital leaders
  - MEs 1–5: Renumbered PCI.7, MEs 1–5
- PCI.6.1
  - Standard: Renumbered previous Standard PCI.7.1; moved the concept of managing expired supplies from previous Standard PCI.7
  - Intent: Added examples for the reuse of single-use devices and its associated risks and the management of expired supplies
  - ME 1: Renumbered previous PCI.7.1, ME 1 and clarified that reuse of single-use devices and materials must comply with laws and regulations
  - ME 2: Renumbered previous PCI.7.1, ME 2 and clarified that the process for managing when to retire those items must be standardized
  - MEs 3–6: Renumbered PCI.7.1, MEs 3–6
- PCI.7
  - **New Standard and Intent:** Moved the concept for identifying and implementing professional guidelines to address environment cleaning from previous standard PCI.3 into a stand-alone standard.
  - ME 1: Renumbered and adapted previous PCI.3, ME 2
  - **New ME 2:** Added requirement for the hospital to identify high-risk areas for infection and use appropriate cleaning processes
  - ME 3: Renumbered previous PCI.8, ME 5
  - **New ME 4:** Added requirement for the hospital to monitor and improve environmental cleaning processes
- PCI.7.1
  - **New Standard and Intent:** Moved the concept for using professional guidelines to assess and manage the cleaning and disinfection of laundry, linens, and scrubs provided by the hospital from PCI.3 into a stand-alone standard.
  - ME 1: Renumbered and adapted previous PCI.3, ME 3

  - **New ME 2:** Added requirement to use standard precautions when handling laundry, linens, and hospital-issued scrubs
  - **New ME 3:** Added requirement to handle those items in a manner that prevents cross contamination
  - **New ME 4:** Added requirement for staff to wear hospital-issued scrubs where required
- PCI.8
  - Standard and Intent: Combined and renumbered previous Standards PCI.7.2 and PCI.7.3
  - Intent: Revised to provide examples of and guidance on safe handling of sharps and management of human tissues and body parts
  - ME 1: Combined, adapted, and renumbered previous PC.7.2, MEs 1 and 2
  - MEs 2–4: Renumbered previous PCI.7.3, MEs 1–3
  - ME 5: Renumbered and adapted previous PCI.7.2, ME 3
  - **New ME 6:** Added requirement for staff to be trained in preventing cross contamination, maintaining any needed chain of custody, and safe handling procedures
- PCI.8.1
  - **New Standard and Intent:** Introduced requirement to protect patients and staff from bloodborne pathogen exposure
  - **New ME 1:** Added requirement to identify areas of risk for exposure to blood and body fluids and reduce the risk
  - **New ME 2:** Added requirement to have a process for reporting exposure to blood and body fluids
  - **New ME 3:** Added requirement to have a process for responding to blood and body fluid exposure
  - **New ME 4:** Added requirement to educate staff on the process
  - **New ME 5:** Added requirement to track and monitor exposure incidents
  - **New ME 6:** Added requirement to use exposure data to prevent future exposures
- PCI.9
  - Standard: Renumbered previous Standard PCI.7.4
  - Intent: Revised to provide examples of best practices in managing food services to prevent the spread of food-borne illness
  - ME 1: Renumbered and adapted previous PCI.7.4, ME 1 and reinforced applicability to food and nutrition products stored outside of the kitchen and food preparation areas
  - ME 2: Renumbered and adapted previous PCI.7.4, ME 3
  - ME 3: Renumbered previous PCI.7.4, ME 2
  - **New ME 4:** Added requirement for the hospital to use a process to maintain proper food temperature
  - ME 5: Renumbered and adapted previous MMU.3.1, ME 1
- PCI.10
  - Standard: Renumbered and revised previous Standard PCI.7.5, moving content on demolition, construction, and renovation to new Standard PCI.7.11
  - Intent: Revised to focus on mechanical and engineering controls used to proactively prevent infection
  - **New ME 1:** Added requirement for the hospital to operate and maintain negative and positive pressure ventilation systems in accordance with laws, regulations, and professional standards
  - **New ME 2:** Added requirement for the hospital to maintain temperature controls in accordance with laws, regulations, and professional standards
  - ME 3: Renumbered and adapted previous PCI.7.5, ME 1
- PCI.11
  - Standard and Intent: Moved requirement for the hospital to use a process to minimize infection risk during demolition, construction, and renovation from previous PCI.7.5
  - ME 1: Renumbered previous PCI.7.5, ME 2

  - MEs 2 and 3: Split previous PCI.7.5, ME 3 to focus on assessing the risk and impact from demolition/renovation on air quality and infection control (ME 2) and on managing that risk and impact (ME 3)
- Intent of PCI.12 and PCI.12.1: Added examples of transmission-based precautions and temporary negative-pressure isolation options
- PCI.12: Renumbered previous Standard PCI.8 and adapted its MEs 1–4
- PCI.12.1: Renumbered previous Standard PCI.8.1 and its MEs 1–3
- PCI.12.2
  - Standard: Renumbered previous Standard PCI.8.2 and its MEs 1–5
  - Intent: Added the response to emerging or reemerging infections within the community to the list of potential emergencies to address in the emergency preparedness program
  - ME 1: Given the change to the intent, added emerging community infections to the list of emergencies to address in the emergency preparedness program
  - ME 3: Revised requirement to involve regional, local, and national authorities in the annual emergency evaluation
- PCI.13
  - Standard: Renumbered previous Standard PCI.9 and its MEs 1–4
  - Intent: Included expectation to educate patients and visitors as needed on proper hand-disinfecting procedures and personal protective equipment
  - **New ME 5:** Added requirement to educate patients and visitors on hand-disinfection practices and how to correctly use personal protective equipment
- PCI.14
  - Standard: Renumbered previous Standard PCI.10 and its MEs 1–4
  - Intent: Added examples of monitoring data
  - **New ME 4:** Added requirement to include benchmarking infection rates in monitoring data
  - ME 5: Renumbered and adapted previous PCI.10, ME 4
- Made minor editorial revisions throughout the chapter

## Governance, Leadership, and Direction (GLD)

- GLD.1
  - ME 1: Combined previous MEs 1 and 2
  - MEs 2 and 3: Renumbered previous MEs 3 and 4
- GLD.1.1
  - ME 1: Combined previous MEs 1 and 2
  - MEs 2–4: Renumbered previous MEs 3–5
- GLD.3.1
  - ME 3: Clarified what data are reported to key stakeholders and listed minimum example of key stakeholders
- GLD.5, Intent: Added examples of leaders providing direction for measurement and improvement activities
- GLD.6
  - Standard: Reinforced the need for periodic inspections of compliance with contracted services
  - ME 3: Renumbered previous ME 4
  - ME 4: Renumbered previous ME 3 and clarified the requirement to inspect compliance with contracted services as needed
- GLD.6.2
  - Standard and Intent: Revised to address the credentialing, competency, and privileging of *all* contracted health care professionals
  - **New ME 6:** Added requirement to ensure a comparable credentials review of contracted licensed health care professionals

- GLD.7
  - **New ME 5:** Added requirement to provide leadership in the emergency and disaster management programs
  - ME 6: Renumbered previous ME 5
- GLD.8, ME 5: Renumbered previous ME 6
- GLD.11.1, MEs 1–3: Expanded to include the assessment of participation in quality activities as well as measurement activities in ongoing professional practice evaluations and performance evaluations of physicians, nurses, and other professional staff
- GLD.12.2
  - Intent: Added an example of a conflict of interest
  - ME 2: Renumbered previous GLD.8, ME 5
  - MEs 3 and 4: Renumbered previous MEs 2 and 3
- Made minor editorial revisions throughout the chapter

## Facility Management and Safety (FMS)

- Overview: Added expectation to include a comprehensive facility-wide risk assessment in the facility management and safety program when needed; revised the list of required written facility management and safety programs, separating safety from security and adding construction and renovation
- FMS.1
  - Intent: Revised to address safety of hospitals located inside larger, multiuse buildings
  - ME 1: Combined previous MEs 1 and 2
  - ME 2: Renumbered and adapted previous ME 3, adding requirement for documenting corrective actions taken to meet the conditions of facility reports or citations from external inspections
  - ME 3: Combined and renumbered previous FMS.4.2, MEs 1 and 2
  - ME 4: Renumbered and adapted previous FMS.4.2, ME 3, adding language to clarify that alternative strategies to reduce risks are implemented until resources can be allocated
  - **New ME 5:** Added requirement to address expectations for hospitals located inside multiuse buildings
- FMS.2
  - Standard: Renumbered previous Standard FMS.3
  - Intent: Revised to address leadership's responsibility on assigning a qualified individual to oversee the facility management and safety structure
  - ME 1: Combined previous FMS.3, MEs 1 and 2
  - ME 2: Renumbered previous FMS.3, ME 3
  - **New ME 3:** Added requirement for the individual who oversees the facility management and safety structure to be responsible for coordinating and managing facility risk assessment and risk reduction activities
  - ME 4: Renumbered previous FMS.2, ME 4
- FMS.3
  - **New Standard and Intent:** Introduced requirement on development of an annual comprehensive, facility-wide risk assessment
  - **New ME 1:** Added requirement to integrate the risk assessments to all eight facility management and safety programs when developing risk assessment
  - **New ME 2:** Added requirement to prioritize identified risks and implement improvements to reduce risk
  - **New ME 3:** Added requirement to evaluate the effectiveness of improvements that are applicable to facility management and safety programs

- FMS.4
  - Standard: Renumbered previous Standard FMS.10
  - Intent: Revised to discuss components of an annual report
  - ME 1: Combined previous FMS.10, MEs 1 and 2
  - **New ME 2:** Added requirement to integrate data from the facility management and safety programs into the quality and patient safety program
  - ME 3: Renumbered previous FMS.10, ME 3 and clarified expectations related to quarterly reporting monitoring data and progress on goals to hospital leadership
  - **New ME 4:** Added requirement to annually provide comprehensive, facility-wide risk assessment and improvements to hospital leadership
  - ME 5: Moved previous FMS.3, intent letter f) and added language to clarify requirement for hospital leadership to provide an annual report to the governing entity on the effectiveness of the facility management and safety programs
- FMS.5
  - Standard: Renumbered previous Standard FMS.4 and its MEs 1–3
  - Intent: Split and adapted the previously combined intent into one for safety (FMS.5) and one for security (FMS.6)
  - ME.1: Clarified that the program to provide a safe physical facility must be written and implemented
  - ME 3: Clarified requirements for the safety risk assessment
  - **New ME 4:** Added requirement for monitoring to ensure that safety risks are reduced or eliminated
- FMS.6
  - Standard: Renumbered previous Standard FMS.4.1
  - Intent: Split and adapted previously combined intent into one for safety (FMS.5) and one for security (FMS.6)
  - ME 1: Renumbered previous FMS.4.1, ME 1 and clarified that the program to provide a secure environment must be written and implemented
  - **New ME 2:** Added requirement for an annual security risk assessment
  - ME 3: Renumbered previous FMS.4.1, ME 3
  - ME 4: Renumbered previous FMS.4.1, ME 2 and added categories of who should be identified for the security program
  - **New ME 5:** Added requirement for monitoring to ensure that security risks are reduced or eliminated
- Intent of FMS.7 Through FMS.7.2: Combined, renumbered, and expanded intent from previous Standards FMS.5 and FMS.5.1 to identify requirements for the overall management of hazardous materials and waste.
- FMS.7
  - **New Standard and Intent:** Introduced requirement to develop a program for the overall management of hazardous materials and waste
  - **New ME 1:** Added requirement for the hospital to develop and implement a written program for managing hazardous materials and waste
  - **New ME 2:** Added requirement for the hospital to conduct an annual hazardous materials and waste risk assessment
  - **New ME 3:** Added requirement for the hospital to monitor and ensure that hazardous materials and waste risks are reduced or eliminated
- FMS.7.1
  - Standard: Renumbered and split previous Standard FMS.5 into one for hazardous materials (FMS.7.1) and one for hazardous waste (FMS.7.2)
  - ME 1: Renumbered and split previous FMS.5, ME 1, focusing on hazardous materials in FMS.7.1, and added language to require an annual update to the inventory

- MEs 2–4: Renumbered and split previous FMS.5, MEs 2–4, focusing on hazardous materials in FMS.7.1, and added language to ME 4 referencing safety data sheets (SDS)
- ME 5: Combined, renumbered, and adapted previous FMS.5.1, MEs 1 and 2
- ME 6: Renumbered and expanded previous FMS.5.1, ME 3

- FMS.7.2
  - Standard: Renumbered and split previous Standard FMS.5 into one for hazardous materials (FMS.7.1) and one for hazardous waste (FMS.7.2)
  - ME 1: Renumbered and split previous FMS.5, ME 1 to focus on identifying the types of hazardous waste
  - ME 2: Renumbered and split previous FMS.5, ME 2 to focus on establishing procedures for the handling and storage of hazardous waste
  - ME 3: Renumbered, split, and adapted previous FMS.5, ME 1 to focus on documenting quantities of hazardous waste, with the added disclaimer when laws and regulations require it
- FMS.8
  - Standard: Renumbered and adapted previous Standard FMS.7 to include ongoing assessment of risk and compliance with laws and regulations
  - Intent: Revised the list of items to include in fire safety risk assessment and expanded discussion to include information about and examples of risk assessment and response, interim measures, and reference to a new Appendix to the FMS chapter with additional interim measures
  - ME 1: Renumbered and adapted former FMS.7, ME 1
  - ME 2: Combined, renumbered, and adapted former FMS.7, MEs 2 and 3
  - **New ME 3:** Added requirement to implement interim measures when fire safety risks cannot be immediately addressed
  - **New ME 4:** Added requirement for monitoring to ensure that fire safety risks are reduced or eliminated
- FMS.8.1
  - **New Standard and Intent:** Moved the concepts of early detection, suppression, and containment from previous Standard FMS.7 into a stand-alone standard
  - MEs 1 and 2: Renumbered and adapted previous FMS.7, MEs 4 and 5
  - **New ME 3:** Added requirement for the fire safety program for features for containment of fire and smoke when required by local laws and regulations
- FMS.8.2
  - **New Standard and Intent:** Moved the concept of a safe exit from the facility from previous Standard FMS.7 into a stand-alone standard
  - ME 1: Renumbered and adapted previous FMS.7, ME 6
  - **New ME 2:** Added requirement for clearly visible exit signage
  - **New ME 3:** Added requirement for lighting of emergency exit corridors and stairs
- FMS.8.3
  - **New Standard and Intent:** Moved the concept of fire safety equipment inspection, testing, and maintenance from previous Standards FMS.7 and FMS.7.1 into a stand-alone standard and noted the application of new Appendix on interim measures.
  - ME 1: Renumbered and adapted previous FMS.7.1, ME 3, adding language to follow the stricter of either manufacturers' recommendations or as required by local codes, laws, and regulations
  - ME 2: Renumbered and adapted previous FMS.7.1, ME 4, adding results of inspection, testing, and maintenance and corrective action taken based on those results
  - **New ME 3:** Added requirement on correction of deficiencies identified in fire safety equipment and system inspections with interim measures until fully corrected
- FMS.8.4
  - Standard: Renumbered previous Standard FMS.7.1
  - Intent: Revised to discuss ways of evaluating fire safety program
  - ME 1: Renumbered FMS.7.1, ME 1 to focus on participation of all staff from all shifts in an annual exercise to evaluate the fire safety program

  - ME 2: Renumbered FMS.7.1, ME 2 to include staff's knowledge on the hospital's fire safety program
  - **New ME 3:** Added requirement to document the results of fire safety program exercises and reeducate staff who did not pass the exercise
- FMS.8.5
  - Standard: Renumbered previous Standard FMS.7.2 and its MEs 1–3
  - Intent: Added a description of what smoking includes
  - **New ME 4:** Added requirement prohibiting smoking in any area under construction or renovation
- Intent of FMS.9 and FMS.9.1: Renumbered and expanded intent from previous Standard FMS.8 to include new Standard FMS.9.1 to focus on management of medical equipment throughout the organization, including an annual risk assessment
- FMS.9
  - Standard: Renumbered and adapted a portion of previous Standard FMS.8
  - ME 1: Renumbered previous FMS.8, ME 1 and clarified that the program for management of medical equipment must be written
  - **New ME 2:** Added requirement to document an annual medical equipment risk assessment
  - **New ME 3:** Added requirement for monitoring to ensure that medical equipment risks are reduced or eliminated
- FMS.9.1
  - **New Standard:** Moved the concept of documented medical equipment inspection, testing, and preventive maintenance from previous Standard FMS.8 into a stand-alone standard
  - **New ME 1:** Added requirement for the medical equipment program to address both hospital-owned and nonhospital-owned medical equipment that is in the hospital
  - MEs 2–4: Renumbered previous FMS 8, MEs 2–4
- FMS.9.2
  - Standard: Renumbered previous Standard FMS.8.1 and its MEs 1–3
  - Intent: Added the expectation that the hospital conduct a root cause analysis in response to any sentinel events
  - ME 2: Clarified that reporting occurs through the hospital's incident and adverse event reporting process
- FMS.10
  - Standard: Renumbered previous Standard FMS.9; expanded definition of *critical utilities* to include medical gases
  - **New ME 1:** Added requirement to develop and implement a written utility system management program
  - **New ME 2:** Added requirement for annual utility system risk assessment
  - **New ME 3:** Added requirement for monitoring to ensure that utility system risks are reduced or eliminated (incorporating concepts from previous FMS.9.1, MEs 1–4)
- FMS.10.1
  - Standard and Intent: Renumbered and adapted previous Standard FMS.9
  - ME 1: Renumbered previous FMS.9, ME 1
  - ME 2: Combined, renumbered, and adapted previous FMS.9, MEs 2 and 3
  - ME 3: Adapted from previous FMS.9.1, ME 4
  - ME 4: Renumbered previous FMS.9, ME 4
- FMS.10.2
  - Standard and Intent: Combined, renumbered, and expanded previous Standards FMS.9.2 and FMS.9.2.1
  - ME 1: Renumbered and adapted previous FMS.9.2, ME 3
  - ME 2: Combined, renumbered, and expanded previous FMS.9.2, MEs 1 and 2 to include medical gas

  - ME 3: Renumbered and expanded FMS.9.2, ME 4 to include assessing for and reducing the risks of interruption, contamination, and failure of those essential utilities listed in ME 2
  - ME 4: Combined, renumbered and revised previous FMS.9.2.1, MEs 1 and 2 for the hospital to at least annually test the availability and quality of the alternative source(s) of water and document the results
  - ME 5: Renumbered previous FMS.9.2.1, ME 3 and added requirement to document the test results
  - ME 6: Renumbered previous FMS.9.2.1, ME 5
- Intent of FMS.10.3 and FMS.10.3.1: Revised intent of previous Standard FMS.9.3 and combined with additional information for new Standard FMS.10.3.1 on water quality in dental services and hemodialysis and acting to address problems with water quality
- FMS.10.3
  - Standard: Renumbered previous Standard FMS.9.3
  - MEs 1 and 2: Renumbered previous FMS.9.3, MEs 1 and 2
  - MEs 3 and 4: Renumbered previous FMS.10.3, MEs 4 and 5
  - **New ME 5:** Added requirement on testing and treatment of dental unit waterlines
- FMS.10.3.1
  - **New Standard and Intent:** Moved the concept to comply with professional standards for testing water used for hemodialysis for contaminants from FMS.9.3 into stand-alone standard.
  - **New ME 1:** Added requirement for hospital hemodialysis services to follow industry standards and professional guidelines to maintain water quality and implement control measures
  - ME 2: Renumbered and adapted previous FMS.9.3, ME 3
  - **New ME 3:** Added requirement to perform routine disinfection of the hemodialysis water distribution system
  - **New ME 4:** Added requirement to test all hemodialysis machines annually and document the results
  - **New ME 5:** Added requirement to establish and implement a process for reprocessing dialyzers
- FMS.11
  - Standard: Renumbered and adapted previous Standard FMS.6 to reinforce that the hospital must be prepared to respond to both internal and external emergencies
  - Intent: Revised to address what an evaluation of structural elements of hospital buildings would include and planning for a response when staff may not be able to come to the hospital in an emergency; revised the list of items for which the hospital must have a process in its emergency and disaster management program, including adding planning for alternative power and water sources (which is also part of revised Standard FMS.10.2)
  - ME 1: Renumbered and expanded previous FMS.6, ME 3 to include the revised list of critical elements in the intent
  - MEs 2 and 3: Renumbered previous FMS.6, MEs 1 and 2
  - ME: 4: Renumbered and revised previous FMS.6, ME 4 to include the revised list of critical elements in the intent in a written emergency and disaster management program
  - MEs 5 and 6: Renumbered previous FMS.6, MEs 5 and 6
- FMS.12
  - Standard: Renumbered previous Standard FMS.4.2.1 and its MEs 1–3 and expanded to include maintenance activities that affect patient care
  - Intent: Included examples of risks to individuals in the hospital; revised the list of critical elements to include in a preconstruction risk assessment, adding hazardous waste, fire safety, security, and emergency procedures
- FMS.13
  - Standard and Intent: Renumbered and combined previous Standards FMS.11–FMS.11.2

  - ME 1: Renumbered previous FMS.11, ME 1 and clarified that testing results must be documented
  - ME 2: Renumbered previous FMS.11, ME 2 and expanded requirement for who needs to be trained
  - MEs 3–6: Renumbered previous FMS.11.1, MEs 1–4, restricting revised ME 5 as applicable to the staff member's role and responsibilities
- **New Appendix**
  - Provided examples of interim measures, which 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, or a breakdown or repair
  - These measures are not required, but provide examples related to the requirements of Standards FMS.8 and FMS.8.3
- Made minor editorial revisions throughout the chapter

## Staff Qualifications and Education (SQE)

- Overview: Reinforced that credentialing licensed health care practitioners represents the first and most important opportunity for the hospital to protect patients
- SQE.3, Intent: Added expectation that the evaluation process for hiring qualified clinical staff members includes an assessment of the staff member's ability to operate medical equipment and clinical alarms and oversee medication management unique to the specific area
- SQE.7
  - ME 3: Split and clarified requirement on the orientation of staff who accompany independent practitioners and provide care and services
  - ME 4: Combined with previous ME 3 to include volunteers in the hospital orientation program
- Intent of SQE.8.1 and SQE.8.1.1: Expanded intent of previous Standard SQE.8.1 to cover new Standard SQE.8.1.1, providing additional staff examples
- SQE.8.1
  - Standard: Split Standard SQE.8.1 that requires that staff competence with resuscitative techniques meets the level of training identified to focus on staff members who provide patient care (SQE.8.1) and other staff identified by the hospital (SQE.8.1.1)
  - ME 1: Split previous ME 1 to distinguish basic life support training needs for all staff providing clinical care, including physicians, (SQE.8.1) and other staff who do not provide patient care (new SQE.8.1.1)
  - ME 2: Clarified that level of life support training (basic or advanced) must be appropriate to roles of staff providing clinical care
  - MEs 3 and 4: Retained requirements for staff who provide clinical care in SQE.8.1 and duplicated them for staff who do not provide patient care in SQE.8.1.1 as MEs 2 and 3
- SQE.8.1.1
  - Standard: Split Standard SQE.8.1 that requires that staff competence with resuscitative techniques meets the level of training identified to focus on staff members who provide patient care (SQE.8.1) and other staff identified by the hospital (new SQE.8.1.1)
  - ME 1: Split previous SQE.8.1, ME 1 to distinguish basic life support training needs for all staff providing clinical care (SQE.8.1) and other staff who do not provide patient care (SQE.8.1.1)
  - ME 2: Duplicated previously applicable SQE.8.1, ME 3 to require evidence that nonclinical staff have passed basic life support training
  - ME 3: Duplicated previously applicable SQE.8.1, ME 4 to require the identified staff be retrained on basic life support based on the required time frames established by the recognized training program
- SQE.8.2
  - Intent: Removed periodical preventive immunizations and examinations from the list of critical elements a staff health and safety program must address; added content on compassion fatigue

  - and staff burnout of health care practitioners; extracted content applicable to previous Standard SQE.8.2.1 and revised and expanded it as the intent of new Standard SQE.8.3
  - ME 2: Given the change to the intent, revised the list of critical elements the hospital must address in a staff health and safety program
  - **New ME 6:** Added requirement that the hospital creates a culture of wellness to support physical and mental well-being
- SQE.8.3
  - Standard: Renumbered previous Standard SQE.8.2.1
  - Intent: Moved and expanded intent of previous Standard SQE.8.2.1
  - MEs 1 and 2: Split previous SQE.8.2.1, ME 1 to focus on identifying infection risks (ME 1) and a staff vaccination and immunization program (ME 2)
  - MEs 3 and 4: Renumbered previous SQE.8.2.1, MEs 2 and 3
- SQE.11
  - Intent: Changed the term *ongoing monitoring and evaluation* to *ongoing professional practice evaluation* (here and throughout the manual) and revised the definition to align with current professional practice
  - ME 2: Combined with previous ME 3
  - MEs 3 and 4: Renumbered previous MEs 4 and 5
- SQE.13, Intent: Clarified that primary source verification is carried out for all nurses; described a time-limited exception for a JCI initial accreditation survey that refers only to the verification of credentials
- SQE.15, Intent: Clarified that primary source verification is carried out for all other health care practitioners; described a time-limited exception (reduced from 3 years to 12 months) for a JCI initial accreditation survey that refers only to the verification of credentials
- Made minor editorial revisions throughout the chapter

## Management of Information (MOI)

- Overview: Emphasized the importance of protecting patient information
- MOI.1
  - Standard and Intent: Specified groups with information needs from the information management process, including those who provide clinical services, the hospital's leaders, and those outside the hospital who require data and information from the organization
  - MEs 1–3: Clarified that the hospital must plan and implement processes to meet, not simply consider, information needs
  - ME 4: Expanded to include availability of trained staff, technical resources, and other resources
- Intent of MOI.2 and MOI.2.1: Expanded to address measures to secure and protect data and information, including paper and electronic medical records, security of electronic information systems, the process for granting and monitoring access, and best practices for security measures and strategies
- MOI.2
  - Standard: Revised to require processes to manage and control access to data and information
  - ME 1: Combined previous MEs 1–3
  - ME 2: Combined, renumbered, and adapted previous ME 4 and MOI.11, MEs 1 and 4
  - **New ME 3:** Added requirement for a process to grant authorized individuals access privileges to data and information in accordance with their level of access
  - ME 4: Renumbered and adapted previous MOI.11, ME 5 to allow access to data and information only in accordance with each individual's level of access
  - ME 5: Renumbered and adapted previous MOI.11, ME 2 to allow only authorized individuals to make entries in the patient medical record in accordance with their level of access
  - ME 6: Renumbered previous ME 5

- MOI.2.1
  - Standard: Combined, renumbered, and adapted previous Standards MOI.2 and MOI.6
  - **New ME 1:** Added requirement to conduct and document an annual risk assessment to identify and prioritize data security risks
  - ME 2: Combined and renumbered previous MOI.6, MEs 1 and 2
  - **New ME 3:** Added requirement to implement data security best practices to protect and secure data and information
  - **New ME 4:** Added requirement to identify, implement, and monitor goals and improvements to reduce or eliminate data security risks
- MOI.3
  - Intent: Clarified that "other information" includes text messages and e-mails that contain information for medical records
  - ME 1: Clarified that retention times must comply with laws and regulations
- MOI.4
  - Intent: Added information on patient and staff understanding of abbreviations and clarified that principles apply to medical records and any electronic communications, such as e-mail and texting, that are used for communicating about patient care
- MOI.5
  - Intent: Expanded to address timely dissemination of data to both internal and external personnel
  - ME 1: Expanded to identify groups with data and information needs
  - ME 2: Clarified that data and information are received in a manner that supports continuity of care
  - ME 3: Clarified that users may be within and outside the hospital
  - ME 4: Emphasized that staff have access to data and information needed to provide care safely and effectively
- MOI.6
  - Standard: Renumbered and expanded previous Standard MOI.7
  - Intent: Expanded description of benefits on education and training and provided information about and examples of ongoing training
  - ME 1: Combined and expanded previous MOI.7, MEs 1 and 2 to include clinical staff and address training on information systems and information security
  - **New ME 2:** Added requirement for the hospital to educate, train, and assess staff who use an electronic medical record system to ensure that they can effectively and efficiently use the system to carry out their responsibilities
- MOI.7
  - Standard: Renumbered previous Standard MOI.8
  - Intent: Added an additional key component to identify and track documents in circulation to be included in the guidance document addressing policies and procedures (from previous MOI.8, ME 3, to letter h)
  - ME 1: Given the change to the intent, expanded the key components a written guidance document must address
  - ME 3: Renumbered previous MOI.8, ME 4
- MOI.7.1: Renumbered previous Standard MOI.8.1 and its MEs 1–4
- Intent of MOI.8 and MOI.8.1: Renumbered from intent of previous Standards MOI.9 and MOI.9.1 and revised to address use of copy-and-paste, auto-fill, auto-correct, and other functions in documentation
- MOI.8
  - Standard: Renumbered previous Standard MOI.9
  - ME 1: Combined and expanded previous MOI.9, MEs 1 and 2, and now requires *two* unique identifiers for patient medical records
  - ME 2: Renumbered previous MOI.9, ME 3

  - ME 3: Combined, renumbered, and expanded previous MOI.11.1.1, MEs 1 and 2
  - MEs 4 and 5: Renumbered and expanded previous MOI.11.1.1, MEs 3 and 4
- MOI.8.1
  - Standard: Renumbered previous Standard MOI.9.1
  - ME 2: Renumbered previous MOI.9.1, ME 2 and clarified that medical records contain adequate information to promote continuity of care
  - ME 3: Combined previous MOI.9.1, MEs 3 and 4
- MOI.9
  - Standard: Renumbered previous Standard MOI.11.1 and its MEs 1–3
  - Intent: Extracted applicable information from intent of previous Standards MOI.11 and MOI.11.1 and added information about the use of documentation assistants or scribes
  - ME 4: Renumbered previous MOI.11, ME 3
  - **New ME 5:** Added requirement to address the use of scribes who assist with documentation in the patient medical record
- MOI.10: Renumbered previous Standard MOI.12 and removed reference to medical record completeness (as it's addressed in the MEs)
- MOI.11
  - **New Standard and Intent:** Introduced requirement for hospital leadership to identify a qualified individual to oversee health information technology systems
  - Intent: Built off intent of previous Standard MOI.13 and expanded to discuss the importance of health information technology systems and the individual overseeing health information technology, including identifying that individual's key responsibilities
  - ME 1: Renumbered and adapted previous GLD.7, ME 4
  - **New ME 2:** Added requirement for qualified individual to oversee the hospital's health information technology systems
  - ME 3: Combined, renumbered, and expanded previous MOI.13, MEs 1 and 2
  - ME 4: Renumbered and expanded previous MOI.13, ME 3, adding requirement for monitoring health information technology systems and implementing improvements based on evaluation results
- MOI.12
  - **New Standard and Intent:** Introduced requirement to maintain security and confidentiality of patient information when the hospital allows mobile devices for texting, e-mailing, and/or other communications (pulling in some concepts from previous Standard COP.2.2)
  - ME 1: Renumbered and adapted previous COP.2.2, ME 5
  - **New ME 2:** Added requirement to implement information security guidelines and processes when mobile devices are used to communicate patient data and information
  - **New ME 3:** Added requirement to document any data and information provided via text messages or e-mails on mobile devices in the medical record
  - **New ME 4:** Added requirement to obtain patient consent to participate in an electronic patient portal and/or receive text messages or e-mails
  - ME 5: Renumbered and adapted previous COP.2.2, ME 6 to expand potential communication platforms to require the hospital to address questions in a timely way
- MOI.13
  - Standard: Renumbered previous Standard MOI.14
  - Intent: Revised to provide information about and examples of communication prior to planned downtime or during unplanned downtime and strategies to recover
  - MEs 1 and 2: Renumbered previous MOI.14, MEs 1 and 2
  - ME 3: Renumbered and expanded previous MOI.14, ME 3 to reinforce that services provided by outside vendors must be included in the downtime response program

  - **New ME 4:** Added requirement to identify internal and external communication strategies for planned and unplanned downtime
  - ME 5: Renumbered and expanded previous MOI.14, ME 4 to address maintaining confidentiality and security of patient information
  - ME 6: Renumbered previous MOI.14, ME 5
- Made minor editorial revisions throughout the chapter

## Medical Professional Education (MPE)

- Made minor editorial revisions throughout the chapter

## Human Subjects Research Programs (HRP)

- Made minor editorial revisions throughout the chapter

## Summary of Key Accreditation Policies

- Created an outline at the start of the chapter that provides a way to easily navigate the chapter and find information quickly
- Revised "The Application Process" section to clarify the E-App process and submission time line
- Removed validation survey from the "Full Surveys" section as they are not commonly conducted
- Clarified information in the "Cancellation of a Survey" section on possible rescheduling fees
- Provided information in the "Postponement of a Survey" section on possible rescheduling fees
- Updated information in the "Payment Schedule of Survey Fees" section
- Aligned information in the "Accreditation Decisions" and "Appeal of Decisions to Deny or Withdraw Accreditation" sections with current JCI policy
- Made minor editorial revisions throughout the chapter

## Glossary

- Aligned glossaries across all JCI accreditation and certification programs resulting in the addition, substantive revision, and deletion of terms

# Introduction

This introduction presents Joint Commission International (JCI) and explains how the *Joint Commission International Accreditation Standards for Hospitals*, 7th Edition is organized. Like each of the six 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 is the world's largest health care accreditor. JCI's Gold Seal of Approval® is a widely recognized benchmark representing the most comprehensive evaluation process in the health care industry.

JCI standards are designed to do the following:

- Ensure a safe environment that reduces risk for care recipients and caregivers
- Offer quantifiable benchmarks for quality and patient safety
- Stimulate and demonstrate continuous, sustained improvement through a reliable process
- Improve outcomes and patient experience
- Enhance efficiency
- Reduce costs through standardized care

Given those goals, JCI accreditation benefits your organization in the following ways:

- *Guides the management of a health care organization:* JCI designed the standards to help leaders efficiently and effectively manage the organization and how patient care services are delivered to ensure care quality and patient safety.
- *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.

- *Helps organize and strengthen your improvement efforts:* Accreditation encompasses performance improvement concepts that help you continuously improve quality and standardize your processes of care, treatment, and services.
- *Gives you a competitive advantage:* Achieving accreditation is a visible demonstration to patients and the community that your hospital is committed to providing the highest-quality, safest care and services. It also sets you apart from other hospitals offering the same types of care, treatment, and services.

# Standards Development Process

The JCI standards development process represents a collaboration between JCI, accredited organizations, and international experts in patient quality and safety. This 7th edition considers developments in the science of quality improvement and patient safety as well as the experiences of the organizations that used the 6th edition hospital 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 Standards Advisory Panel, an international panel composed of experts with extensive experience in various health care fields
- Obtained direction from content-specific subject matter experts representing international organizations pertinent to the content area
- Sent an online field review of the revised standards to all accredited hospitals and promoted 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 to address patient safety and quality-of-care issues not covered in the previous edition
- Requests to clarify requirements and expectations for specific standards
- Evolving health care practices, evidence-based guidelines, and the changing health care environment

## Frequency of Standards Updates

JCI gathers information and experience related to the standards on an ongoing basis. If a standard no longer reflects contemporary health care practice, commonly available technology, quality management practices, and so forth, JCI will revise or delete it. It is current practice that the standards are revised and published approximately every three or four years. JCI informs accredited organizations of changes made to standards between publication of the standards. 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.

## Effective Date of Standards

The *Joint Commission International Accreditation Standards for Hospitals*, 7th Edition is effective 1 January 2021:

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 7th 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 7th edition. If you apply for survey and are surveyed before 1 January 2021, the on-site survey will assess compliance with the standards of the 6th edition.

# How This Manual Is Organized

This manual includes all the hospital and academic medical center hospital 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 four 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. For academic medical center hospitals only, standards related to medical professional education and human subjects research programs (Section IV)

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 this "Introduction," a chapter describing the key accreditation policies, a glossary, and an index. A "Summary of Changes to the Manual" is also included in the front of the manual.

The companion *Joint Commission International Survey Process Guide for Hospitals*, 7th Edition helps hospitals and academic medical centers learn about and prepare for the JCI on-site accreditation survey. During the on-site 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, and IV 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.
- *Icons:* Some standards are followed by a Ⓟ icon. Such standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. All written policies, procedures, and programs will be scored together at MOI.7 and MOI.7.1.
- *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. However, numbered or lettered lists in the intent statement do include required elements that must be in place to meet the standard and are addressed in the MEs of the standard (see below).

- *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 to better illustrate expectations for compliance. To make the examples more apparent to the user, the term **for example** or **example(s)** is printed in bold text. 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.)
- *Cross-references:* Placed in parentheses following a statement or paragraph within an intent, a cross-reference helps identify a related standard(s), whether it is located in the same chapter or a different chapter. These cross-references should help the user to quickly find related content concerning the topic of a particular standard.
- *References:* Located at the end of each standards chapter, the references list is used to provide organizations and surveyors with additional or clarifying information about the content addressed by a specific standards chapter. This feature provides support for standards by citing important evidence that provides assistance with compliance. References of various types—from clinical research to practical guidelines—may also be cited in the text of a standard's intent.

## 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 and III apply to all applicant hospitals, there are two 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).

## Academic Medical Center Standards

While 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 center hospitals 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.

However, unless they are deliberately included in the quality framework, education and research activities often are unnoticed partners in patient care quality and improvement. To address this concern, JCI standards in Section IV, 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 center hospitals.

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 IV 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 IV (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 hospital accreditation should contact JCI Accreditation's Central Office at JCIAccreditation@jcrinc.com.

# Using the Standards Manual

*Joint Commission International Accreditation Standards for Hospitals*, 7th Edition, when paired with its companion book *Joint Commission International Survey Process Guide for Hospitals*, 7th 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*, 7th 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.
- 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 provides services addressed by the current 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 hospital 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 7) at least four 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 an on-site survey, may discontinue an on-site 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.

## Sidebar. Understanding Terms

### 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 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.)
- 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.
- 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, dental hospital, or 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 hospital 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 on-site surveys, the Strategic Improvement Plan (SIP), and periodic updates of hospital-specific data and information.

Organizations are either compliant or not compliant with the APRs. When a hospital does not comply with certain APRs, the hospital may be asked to submit an SIP, or the noncompliance may result in being placed At Risk for Denial of Accreditation. However, refusal to permit performance of on-site survey activities, such as limiting or denying access to authorized JCI staff (APR.4), will lead to the loss or denial of accreditation. How the requirement is evaluated and the consequences of noncompliance are noted with each APR.

Please note that the APRs are not scored in the same manner as the standards chapters, and their evaluation does not directly impact the outcome of an *accreditation survey*.

## Requirements

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

**APR.1** The hospital meets all requirements for timely submissions of data and information to Joint Commission International (JCI).

**APR.2** The hospital provides JCI with accurate and complete information throughout all phases of the accreditation process.

**APR.3** 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.

**APR.4** The hospital permits on-site evaluations of standards and policy compliance or verification of quality and safety concerns, reports, or regulatory authority sanctions at the discretion of JCI.

**APR.5** 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.7** The hospital selects and uses measures as part of its quality improvement measurement system.

**APR.8** 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.9** 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.

To support this culture of safety, the hospital must communicate to staff that such reporting is permitted. In addition, the hospital must make it clear to staff that no formal disciplinary actions (**for example**, demotions, reassignments, or change in working conditions or hours) or informal punitive actions (**for example**, harassment, isolation, or abuse) will be threatened or carried out in retaliation for reporting concerns to JCI.

**APR.10** 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.

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
- Membership(s) in professional translation and interpretation associations
- Translation and interpretation proficiency testing results, when applicable
- 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.

**APR.11** 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.

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.

**APR.12** The hospital provides patient care in an environment that poses no risk of an immediate threat to patient safety, public health, or staff safety.

# Requirements, Rationales, Evaluation Methods, and Consequences of Noncompliance

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

## Requirement APR.1

The hospital meets all requirements for timely submissions of data and information to Joint Commission International (JCI).

### Rationale for APR.1

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 Safety Monitoring 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.

### Evaluation of APR.1

Evaluation occurs throughout the accreditation life cycle in relation to the required submissions.

### Consequences of Noncompliance with APR.1

If the hospital fails to meet the requirements for the timely submission of data and information to JCI, the hospital will be considered At Risk for Denial of Accreditation and 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. 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.2 and its consequences will apply.

## Requirement APR.2

The hospital provides JCI with accurate and complete information throughout all phases of the accreditation process.

### Rationale for APR.2

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 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.

### Evaluation of APR.2

Evaluation of this APR begins during the application process and continues as long as the hospital is accredited by or seeking accreditation by JCI.

### Consequences of Noncompliance with APR.2

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 will be considered At Risk for Denial of Accreditation and 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.

## Requirement APR.3

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.

### Rationale for APR.3

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 hospital ownership and/or name
- The revocation or restriction of operational licenses or permits, any limitation 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
- Alteration or changes in use of patient care buildings, construction of new or expansion of patient care buildings, or the occupation of buildings in new locations in the community, to expand the types and volume of patient care services 25% or more than was stated in the hospital's profile or was not reported as a patient care location in the E-App, or was not included in the scope of the previous accreditation survey
- Intentional expansion of the hospital'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 or deletion of one or more types of health care services, such as addition of a dialysis unit or discontinuation of trauma care
- The hospital has merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable JCI standards.

JCI accreditation 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, and so on. 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.

### Evaluation of APR.3

Evaluation of this APR begins during the electronic application process and continues as long as the hospital is accredited by or seeking accreditation by JCI. Changes reported may be evaluated off-site or by an extension survey.

### Consequences of Noncompliance with APR.3

If the hospital does not provide notification to JCI within 30 days of the effective date of any change(s), the hospital will be placed At Risk for Denial of Accreditation and an extension survey may be conducted.

## Requirement APR.4

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

### Rationale for APR.4

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.

### Evaluation of APR.4

Evaluation of this requirement is ongoing during any phase of accreditation.

### Consequences of Noncompliance with APR.4

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

## Requirement APR.5

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.5

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.

### Evaluation of APR.5

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.5

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.

## Requirement APR.6

Currently not in effect.

## Requirement APR.7

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

### Rationale for APR.7

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 (**for example**, GLD.11, GLD.11.1, and GLD.11.2). To comply with these standards, the organization's leadership selects 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 are free to 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

- the organization's quality leadership and team;
- a municipal, regional, or national health authority; and/or
- 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

JCI's measures are presented via its International Library of Measures and are detailed on *JCI Direct Connect*, JCI's client extranet portal. The Joint Commission International Library of Measures provides uniform, precise specifications for the collection of data standardized to permit comparison over time within a hospital and for comparisons among hospitals. Organizations are encouraged, but not required, to use the Library measures to comply with APR.7. Organizations may adapt or modify the Library measures to meet their specific needs; however, if organizations choose to publicize their use of the Library measures, they are required to follow all Library specifications, without deviation, as found on *JCI Direct Connect*. More information about the Library is available on the Continuous Compliance page of *JCI Direct Connect*, including guidance and tools related to collecting and aggregating measures and data.

### Evaluation of APR.7

The selection and use of quality measures are evaluated throughout all phases of accreditation, primarily during the on-site survey process.

### Consequences of Noncompliance with APR.7

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

## Requirement APR.8

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.8

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.

### Evaluation of APR.8

Conformance with this requirement is evaluated throughout all phases of accreditation of the hospital.

### Consequences of Noncompliance with APR.8

Failure of a hospital to withdraw or otherwise correct inaccurate information will place the organization At Risk for Denial of Accreditation and a for-cause survey may be conducted.

## Requirement APR.9

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.

To support this culture of safety, the hospital must communicate to staff that such reporting is permitted. In addition, the hospital must make it clear to staff that no formal disciplinary actions (**for example**, demotions, reassignments, or change in working conditions or hours) or informal punitive actions (**for example**, harassment, isolation, or abuse) will be threatened or carried out in retaliation for reporting concerns to JCI. (*Also see* GLD.13 and GLD.13.1)

### Rationale for APR.9

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 or punitive action because a staff member reports safety or quality-of-care concerns to JCI.

### Evaluation of APR.9

The evaluation of this requirement is throughout all phases of accreditation and includes, but is not limited to, information from both on-site and off-site activities or from investigation of complaints submitted to JCI.

### Consequences of Noncompliance with APR.9

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

## Requirement APR.10

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.

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
- Membership(s) in professional translation and interpretation associations
- Translation and interpretation proficiency testing results, when applicable
- 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.

### Rationale for APR.10

The integrity of the on-site evaluation process, as well as the integrity of the outcome, depend on the surveyor obtaining an unbiased, accurate understanding of his or her conversations with staff; and the hospital's staff communicating effectively in their language with the surveyor. 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.

### Evaluation of APR.10

The hospital will submit the resumes of the selected translators no later than eight (8) weeks prior to the start of any JCI on-site survey. 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

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.

## Requirement APR.11

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.

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.

### Rationale for APR.11

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. (*Also see* PCC.3.1)

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.

### Evaluation of APR.11

Surveyors will evaluate how the hospital meets this requirement during the on-site evaluation process.

### Consequences of Noncompliance with APR.11

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

## Requirement APR.12

The hospital provides patient care in an environment that poses no risk of an immediate threat to patient safety, public health, or staff safety.

### Rationale for APR.12

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.

### Evaluation of APR.12

Evaluation occurs primarily during the on-site survey process, and also through other hospital reports or complaints, and/or sanctions by a regulatory authority, during all phases of accreditation.

### Consequences of Noncompliance with APR.12

Immediate threats discovered on-site 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 At Risk for Denial of Accreditation and a follow-up survey is conducted.

# Section II: Patient-Centered Standards

# International Patient Safety Goals (IPSG)

## Overview

This chapter addresses the International Patient Safety Goals (IPSG), as required for implementation as of 1 January 2011 in all organizations accredited by Joint Commission International (JCI) under the International 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," "partially met," or "not met." The accreditation decision rules include compliance with the goals as a separate decision rule.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## Goals

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, Goals, Intents, and Measurable Elements.

### Goal 1: Identify Patients Correctly

**IPSG.1** The hospital develops and implements a process to improve accuracy of patient identifications. Ⓟ

### Goal 2: Improve Effective Communication

**IPSG.2** The hospital develops and implements a process to improve the effectiveness of verbal and/or telephone communication among caregivers. Ⓟ

**IPSG.2.1** The hospital develops and implements a process for reporting critical results of diagnostic tests. Ⓟ

**IPSG.2.2** The hospital develops and implements a process for handover communication. Ⓟ

### Goal 3: Improve the Safety of High-Alert Medications

**IPSG.3** The hospital develops and implements a process to improve the safety of high-alert medications. Ⓟ

**IPSG.3.1** The hospital develops and implements a process to improve the safety of look-alike/sound-alike medications. Ⓟ

**IPSG.3.2** The hospital develops and implements a process to manage the safe use of concentrated electrolytes. Ⓟ

### Goal 4: Ensure Safe Surgery

**IPSG.4** The hospital develops and implements a process for the preoperative verification and surgical/invasive procedure site marking. Ⓟ

**IPSG.4.1** The hospital develops and 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.5** The hospital adopts and implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections. Ⓟ

**IPSG.5.1** Hospital leaders identify care processes that need improvement and adopt and implement evidence-based interventions to improve patient outcomes and reduce the risk of hospital-associated infections. Ⓟ

### Goal 6: Reduce the Risk of Patient Harm Resulting from Falls

**IPSG.6** The hospital develops and implements a process to reduce the risk of patient harm resulting from falls for the inpatient population. Ⓟ

**IPSG.6.1** The hospital develops and implements a process to reduce the risk of patient harm resulting from falls for the outpatient population. Ⓟ

# Goals, Standards, Intents, and Measurable Elements

## *Goal 1: Identify Patients Correctly*

## Standard IPSG.1

The hospital develops and implements a process to improve accuracy of patient identifications. Ⓟ

### Intent of IPSG.1

Wrong-patient errors occur in virtually all aspects of diagnosis and treatment. Patients may be sedated, disoriented, not fully alert, or comatose; may change beds, rooms, or locations within the hospital; may have sensory disabilities; may not remember their identity; or may be subject to other situations that may lead to errors in correct identification. The intent of this goal is twofold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. (*Also see* IPSG.4.1; MMU.4.2; and MMU.5.2)

Safe care begins with proper identification. The identification process used throughout the hospital requires at least two ways in which to identify a patient, 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 cannot be used for identification. The two different patient identifiers used may be different in different circumstances. **For example**, during a verbal patient interaction, the patient identifiers used may consist of patient name and patient birth date. However, when labeling specimens, reporting diagnostic test results, or determining the unique identifier for the patient's medical record, the patient's name and an identification number may be used. The two identifiers used must be consistent within an area. **For example**, if the patient's name and date of birth are used in verbal interactions with the patient on the ward, these same two identifiers should be used in all verbal interactions with the patient. Similarly, if the 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. It

is a best practice that the patient be involved in the identification process to whatever extent possible. (*Also see* MOI.8.1)

There are special circumstances in which the hospital may need to develop a specific process for patient identification; **for example**, when a comatose or confused/disoriented patient arrives with no identification, in the case of a newborn when the parents have not immediately chosen a name, and other examples. The process takes into account 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. **For example**, patients are identified before providing treatments (such as administering medications, blood, or blood products; serving a restricted diet tray; or providing radiation therapy); (*Also see* COP.3.4 and MMU.6.1) performing procedures (such as insertion of an intravenous line or hemodialysis); and before any diagnostic procedures (such as taking blood and other specimens for clinical testing or performing a cardiac catheterization or diagnostic radiology procedure).

In addition to using two identifiers to identify the patient in circumstances involving patient interventions, at least two identifiers are also used in labeling elements associated with the patient's care and treatment plan. **For example**, blood samples and pathology samples must be labeled using at least two identifiers. Other **examples** include identifying the dietary trays, labeling mother's milk that is expressed and stored for hospitalized infants, and other treatments prepared specifically for the patient. (*Also see* AOP.5.7)

### Measurable Elements of IPSG.1

- ❑ 1. At least two patient identifiers, that **do not** include the use of the patient's room number or location in the hospital, are used to identify the patient and to label elements associated with the patient's care and treatment plan.
- ❑ 2. Patients are identified before performing diagnostic procedures, providing treatments, and performing other procedures.
- ❑ 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.2

The hospital develops and implements a process to improve the effectiveness of verbal and/or telephone communication among caregivers. Ⓟ

## Standard IPSG.2.1

The hospital develops and implements a process for reporting critical results of diagnostic tests. Ⓟ

## Standard IPSG.2.2

The hospital develops and implements a process for handover communication. Ⓟ

### Intent of IPSG.2 Through IPSG.2.2

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. (*Also see* COP.2 and MMU.4.2)

The reporting of critical results of diagnostic tests is also a patient safety issue. 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 in nature, and in which immediate medical action is likely necessary to preserve life or prevent a catastrophic occurrence. This is different from an *abnormal result*, which is defined as a result that is outside of the expected range for the test but is not an urgent or emergent life threat. Critical results may occur in outpatients and inpatients and in critical care areas and on general wards as well.

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 testing, portable imaging, and 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 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. 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 in light of the patient's clinical situation. (*Also see* AOP.5.4)

*Handover* communications can also be referred to as *handoff* communications. Handovers of patient care within a hospital occur

- between health care practitioners (**for example**, physician to physician, physician to nurse, nurse to nurse, and so on);
- 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; and
- between staff and patients/families, such as at discharge. (*Also see* ACC.4.1)

Breakdowns in communication can occur during any handover of patient care and can result in adverse events. Interruptions and other distractions from unit activities can inhibit clear communication of important patient information. Standardized, critical content for communication between the patient, family, caregiver, and health care practitioners can significantly improve the outcomes related to handovers of patient care. (*Also see* ACC.3)

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 for the operating theatre to the intensive care unit; however, the handovers are standardized for the type of handover occurring.

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 he or she completed the handover and to whom he or she transferred responsibility for care, and then sign, date, and time the entry. (*Also see* MOI.9)

Safe practices for effective communication 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; 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. (*Also see* COP.2)
- Use of standardized, critical content 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

## Measurable Elements of IPSG.2

❑ 1. Complete verbal orders are documented and read back by the receiver and confirmed by the individual giving the order.

❑ 2. Complete telephone orders are documented and read back by the receiver and confirmed by the individual giving the order.

❑ 3. Complete test results are documented and read back by the receiver and confirmed by the individual giving the result.

## Measurable Elements of IPSG.2.1

❑ 1. The hospital defines critical results that may represent urgent or emergent life-threatening values for diagnostic tests.

❑ 2. The hospital develops a formal reporting process, used throughout the hospital, that identifies how critical results of diagnostic tests are reported/communicated to health care practitioners.

❑ 3. The hospital identifies what information is documented in the medical record.

## Measurable Elements of IPSG.2.2

❑ 1. Standardized critical content is communicated between health care practitioners during handovers of patient care.

❑ 2. Standardized forms, tools, or methods that support a consistent and complete handover process are utilized.

❑ 3. Data from adverse events resulting from handover communications are tracked and used to identify ways in which handovers can be improved, and improvements are implemented.

## Goal 3: Improve the Safety of High-Alert Medications

### Standard IPSG.3

The hospital develops and implements a process to improve the safety of high-alert medications. Ⓟ

### Standard IPSG.3.1

The hospital develops and implements a process to improve the safety of look-alike/sound-alike medications. Ⓟ

### Standard IPSG.3.2

The hospital develops and implements a process to manage the safe use of concentrated electrolytes. Ⓟ

#### Intent of IPSG.3 Through IPSG 3.2

When medications are part of the patient treatment plan, appropriate management is critical to ensuring patient safety. Any medication, even those that can be purchased without a prescription, if used improperly can cause injury. However, high-alert medications cause harm that is likely to be more serious when they are given in error, which can lead to increased patient suffering 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 insulin, opioids, chemotherapeutic agents, antithrombotic agents, anticoagulants, thrombolytics, medications with a narrow therapeutic range (**for example**, digoxin), neuromuscular blocking agents, and epidural or intrathecal medications.

An **example** of a recent 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. A significant adverse event resulting in severe neurological damage and often death, has 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 Joint Commission, the World Health Organization (WHO), the American Society of Clinical Oncology (ASCO), the Oncology Nursing Society (ONS), and the National Comprehensive Cancer Network.

**Examples** of lists of high-alert medications are available from organizations such as ISMP and WHO. For safe management, the hospital needs to develop its own list(s) of high-alert medications based on its unique utilization patterns of medications and its own internal data about near misses (or close calls), medication errors, and sentinel events, as well as safety issues published in professional literature. (*Also see* MMU.7.1; QPS.7; and QPS.7.1) The list includes medications identified as high risk for adverse outcomes. Information from the literature and/or Ministry of Health may also be useful in helping to identify which medications should be included. It is recommended that this list be updated at least annually; if there are additions or changes to hospital services, patient populations, or new medications added to the hospital formulary that are deemed high risk, then the list may need to be updated on an interim basis.

The list of high-alert medications must be up to date, known by clinical staff, and accompanied by robust, well-developed risk reduction strategies that decrease the risk of errors and minimize harm. Strategies need to be applicable in various settings and sustainable over time. Many of these strategies should also be considered for use with other medications. **Examples** of strategies may 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
- Applying redundancies

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. Medications at risk for LASA confusion, or similar product packaging, may lead to potentially harmful medication errors. There are many medication names that sound or look like other medication names; **for example**, dopamine and dobutamine. Confusing names is a common cause of medication errors throughout the world. Contributing to this confusion are

- incomplete knowledge of drug names;
- newly available products;
- similar packaging or labeling;
- similar clinical use; and
- illegible prescriptions or misunderstanding during issuing of verbal orders. (*Also see* MMU.4.2)

Hospitals need to institute risk management strategies to minimize adverse events with LASA medications and enhance patient safety. A frequently cited medication safety issue is the incorrect or unintentional administration of concentrated electrolytes (**for example**, potassium chloride, potassium phosphate, sodium chloride, magnesium sulfate). The literature has identified several instances of death as a result of the inadvertent administration of a concentrated electrolyte in its concentrated form. The most effective means to reduce or to eliminate these occurrences is to develop a process for managing concentrated electrolytes that includes removing them from the patient care units to the pharmacy. Vials of concentrated forms of electrolytes that require dilution before IV administration should not be available as unit stock on any patient care units (including in operating room/anesthesia stock) as much as is possible given the pharmacy capabilities and 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, magnesium sulfate contained in emergency carts or in areas in which patients with preeclampsia may be treated (labor and delivery, emergency department, or intensive care unit), and concentrated sodium in areas treating patients who may suffer from increased intracranial pressure (intensive care unit, emergency department, and operating room). Wherever concentrated electrolytes are stored, they are clearly labeled with appropriate warnings (**for example**, CONCENTRATED electrolyte—Dilute before administration) and segregated from other medications. Only qualified and trained individuals should have access to these vials. (*Also see* MMU.3)

Administration of electrolyte replacement therapy for hypokalemia, hyponatremia, and hypophosphatemia is best performed using standardized guidelines and/or protocols that do not involve dispensing or handling concentrated vials on the patient care units. (*Also see* MMU.5.2)

## Measurable Elements of IPSG.3

❑ 1. The hospital identifies in writing its list of high-alert medications.

❑ 2. The hospital develops and implements a process for reducing the risk and harm of high-alert medications that is uniform throughout the hospital.

❑ 3. The hospital annually reviews and, as necessary, revises its list of high-alert medications.

### Measurable Elements of IPSG.3.1

- ❑ 1. The hospital identifies in writing its list of look-alike/sound-alike medications.
- ❑ 2. The hospital develops and implements a process for managing look-alike/sound-alike medications that is uniform throughout the hospital.
- ❑ 3. The hospital annually reviews and, as necessary, revises its list of look-alike/sound-alike medications.

### Measurable Elements of IPSG.3.2

- ❑ 1. Only qualified and trained individuals have access to concentrated electrolytes, and they are clearly labeled with appropriate warnings and segregated from other medications.
- ❑ 2. The hospital only stores vials of concentrated electrolytes outside of the pharmacy in situations identified in the intent.
- ❑ 3. Standard protocols are followed for adult, pediatric, and/or neonatal electrolyte replacement therapy to treat hypokalemia, hyponatremia, and hypophosphatemia.

## *Goal 4: Ensure Safe Surgery*

## Standard IPSG.4

The hospital develops and implements a process for the preoperative verification and surgical/invasive procedure site marking. Ⓟ

## Standard IPSG.4.1

The hospital develops and 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.4 and IPSG.4.1

Significant patient injury and adverse and sentinel events resulting from wrong-site, wrong-procedure, and wrong-patient surgery are ongoing concerns for hospitals. Such events can result from ineffective or inadequate communication between members of the team conducting the surgical or invasive procedure, lack of a process for marking the procedure site, and lack of patient involvement in the site marking. In addition, inadequate patient assessment, inadequate medical record review, a culture that does not support open communication among team members, problems related to illegible handwriting, and the use of abbreviations are frequent contributing factors.

Surgical and invasive procedures include all procedures involving an incision or puncture, including, but not limited to, open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies.

Organizations need to identify all areas within the hospital where surgical and invasive procedures take place; **for example**, the cardiac catheterization lab, interventional radiology department, gastrointestinal lab, and the like. 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

- verify the correct patient, procedure, and site;
- ensure that all relevant documents, images, and studies are available, properly labeled, and displayed; and
- verify that any required blood products, special medical equipment, and/or implants are present. (*Also see* ASC.7.4)

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 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. 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).

The surgical/invasive procedure site marking is done by the person who will perform the procedure. This person will do the entire surgical/invasive procedure and remain with the patient throughout the entire procedure. In cases of surgical procedures, the responsible surgeon typically performs the surgery and therefore would mark the site. There are different titles used for the responsible surgeon, such as attending or consultant surgeon. For nonsurgical invasive procedures, it may be a physician who will do the procedure, and it may take place in an area of the hospital outside of the operating theatre.

There are circumstances when a trainee 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 is in the role of assisting the responsible surgeon or physician, only the responsible 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 patients who are not competent to make health care decisions, children, and patients requiring emergent surgery.

### 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:

a) Correct patient identity (*Also see* IPSG.1)
b) Correct procedure to be done
c) Correct surgical/invasive procedure site

The time-out allows any unanswered questions or confusion to be resolved. The time-out is conducted in the location at which the procedure will be done and involves the active participation of the entire team. The patient does not have to participate in the time-out. When the time-out is complete, no one from the team leaves the room. 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. (*Also see* MOI.9)

### 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:

d) Name of the surgical/invasive procedure that was recorded/written
e) Completion of instrument, sponge, and needle counts (as applicable)
f) Labeling of specimens (when specimens are present during the sign-out process, labels are read aloud, including patient name) (*Also see* IPSG.1 and AOP.5.7)
g) Any equipment problems to be addressed (as applicable)

### Measurable Elements of IPSG.4

❑ 1. The hospital implements a preoperative verification process through the use of a checklist or other mechanism to document, before the surgical/invasive procedure, that the informed consent is appropriate to the procedure; that the correct patient, correct procedure, and correct site are verified; and that all required documents, blood products, medical equipment, and implantable medical devices are on hand, correct, and functional.

❑ 2. The hospital uses an instantly recognizable and unambiguous mark for identifying the surgical/invasive site that is consistent throughout the hospital.

❑ 3. Surgical/invasive site marking is done by the person performing the procedure and involves the patient in the marking process.

### Measurable Elements of IPSG.4.1

❑ 1. The full team actively participates in a time-out process, which includes a) through c) in the intent, in the area in which the surgical/invasive procedure will be performed, immediately before starting the procedure. Completion of the time-out is documented and includes date and time.

❑ 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 d) through g) in the intent.

❑ 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.

## *Goal 5: Reduce the Risk of Health Care–Associated Infections*

## Standard IPSG.5

The hospital adopts and implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections. Ⓟ

# Standard IPSG.5.1

Hospital leaders identify care processes that need improvement and adopt and implement evidence-based interventions to improve patient outcomes and reduce the risk of hospital-associated infections. Ⓟ

## Intent of IPSG.5 and IPSG.5.1

Infection prevention and control are challenging in most health care settings, and rising rates of health care–associated infections are a major concern for patients and health care practitioners. Infections common to all health care settings include catheter-associated urinary tract infections, bloodstream infections, and pneumonia (often associated with mechanical ventilation).

Central to the elimination of these and other infections is proper hand hygiene. 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. (*Also see* GLD.11.2)

The hospital adopts and implements current evidence-based hand-hygiene guidelines. Hand-hygiene guidelines are posted in appropriate areas, and staff are educated in proper hand-washing and hand-disinfection procedures. Soap, disinfectants, and towels or other means of drying are located in those areas where hand-washing and hand-disinfecting procedures are required. (*Also see* PCI.13)

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 a concept of enhancing teamwork and communication in multidisciplinary teams in order to improve the clinical care provided to patients. This initiative led to the creation of "bundles" of care. *Bundles* are defined by the 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. (*Also see* COP.3)

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 have a greater impact on reducing the risk of infection 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.

## Measurable Elements of IPSG.5

- ❑ 1. The hospital has adopted current evidence-based hand-hygiene guidelines.
- ❑ 2. The hospital implements a hand-hygiene program throughout the hospital.
- ❑ 3. Hand-washing and hand-disinfection procedures are used in accordance with hand-hygiene guidelines throughout the hospital.

### Measurable Elements of IPSG.5.1

- ❑ 1. Hospital leaders identify priority areas for improvement of hospital-acquired infections.
- ❑ 2. Hospital leaders identify and implement evidence-based interventions (such as bundles) for all applicable patients.
- ❑ 3. Evidence-based interventions (such as bundles) used to reduce the risk of health care–associated infections are evaluated by health care practitioners for compliance and improvement in clinical outcomes.

## *Goal 6: Reduce the Risk of Patient Harm Resulting from Falls*

## Standard IPSG.6

The hospital develops and implements a process to reduce the risk of patient harm resulting from falls for the inpatient population. Ⓟ

## Standard IPSG.6.1

The hospital develops and implements a process to reduce the risk of patient harm resulting from falls for the outpatient population. Ⓟ

### Intent of IPSG.6 and IPSG.6.1

Many injuries in hospitals to both inpatients and outpatients are a result of falls. The risk for falls is related to the patient, the situation, and/or the location. Risks associated with patients might include patient history of falls, medications use, alcohol consumption, gait or balance disturbances, visual impairments, altered mental status, and the like. Patients who have been initially assessed to be at low risk for falls may suddenly become at high risk. Reasons include, but are not limited to, surgery and/or anesthesia, sudden changes in patient condition, and adjustment in medications. Many patients require reassessment during their hospitalization. (*Also see* AOP.1.4)

Fall risk criteria identify the types of patients who are considered at high risk for falls. These criteria and any interventions applied are documented in the patient's medical record, as they provide the evidence to support the patient's fall risk category. The hospital has the responsibility to identify the types of patients within its patient population who may be at high risk for falls. The documented criteria facilitate the continuity of care among the health care practitioners caring for a patient. (*Also see* ACC.3) **For example**, a practitioner caring for a patient after he or she leaves the operating theatre may not know if the patient, who is at high risk for falls, was properly assessed and if interventions were applied unless proper documentation was completed.

In the context of the populations it serves, the services it provides, and its facilities, the hospital evaluates patient falls and takes action to reduce the risk of falling and reduce the risk of injury should a fall occur. The hospital establishes a fall risk reduction program based on appropriate policies and/or procedures. A fall 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 those identified patients, situations, and locations assessed to be at risk.

Specific situations can pose a risk for falls. **An example** of a potential situational risk is when a patient arrives at the outpatient department from a long term care facility by ambulance for a radiologic examination. The patient 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, organizations 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 assessment tools and/or methods appropriate for the hospital's patient population(s). **For example**, pediatric patients require a pediatric fall risk assessment tool, as a tool developed for adults will not accurately assess their risk for falls.

In the outpatient department(s), patients are screened for fall risk; however, only those patients whose condition, diagnosis, situation, and/or location identifies them as at risk for falls are screened. If fall risk is indicated from the screening, measures and/or interventions are implemented to reduce fall risk for those patients.

Screening generally involves performing a simple evaluation of the patient to determine if he or she exhibits a fall risk. 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. Organizations 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?"; "Have you fallen in the past year?"

The hospital determines which outpatients are screened for fall risk. Location and situational risk, as well as patient condition and characteristics, may help identify those who should be screened for falls. **Examples** could include 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, patients with visual impairments, pediatric patients under the age of two, and so on.

## Measurable Elements of IPSG.6

- ❑ 1. The hospital implements a process for assessing all inpatients for fall risk and uses assessment tools/methods appropriate for the patients being served.
- ❑ 2. The hospital implements a process for the reassessment of inpatients 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.
- ❑ 3. Measures and/or interventions to reduce fall risk are implemented for those identified inpatients, situations, and locations within the hospital assessed to be at risk. Patient interventions are documented.

## Measurable Elements of IPSG.6.1

- ❑ 1. The hospital implements a process for screening outpatients whose condition, diagnosis, situation, or location may put them at risk for falls and uses screening tools/methods appropriate for the patients being served.
- ❑ 2. When fall risk is identified from the screening process, measures and/or interventions are implemented to reduce fall risk for those outpatients identified to be at risk, and the screening and interventions are documented.
- ❑ 3. Measures and/or interventions to reduce fall risk are implemented in situations and locations in the outpatient department(s) assessed to be a risk for falls.

# References

## Patient Identification


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# 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 discharge, transfer, 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

- 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 or specialized services;
- coordination and continuity of care;
- referral, transfer, or discharge of the patient to his or her home or to another care setting; and
- safe patient transportation.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.

### Screening for Admission to the Hospital

**ACC.1** Patients who may be admitted to the hospital or who seek outpatient services are screened to identify if their health care needs match the hospital's mission and resources, and those with emergent, urgent, or immediate needs are given priority for assessment and treatment. Ⓟ

**ACC.1.1** The hospital considers the clinical needs of patients and informs patients when there are unusual delays for diagnostic and/or treatment services. Ⓟ

### Admission to the Hospital

**ACC.2** The hospital has a process for managing the flow of patients throughout the hospital that includes admitting inpatients and registering outpatients. Ⓟ

**ACC.2.1** Patient needs for preventive, palliative, curative, and rehabilitative services are prioritized based on the patient's condition at the time of admission as an inpatient to the hospital.

**ACC.2.2** At admission as an inpatient, the patient and family receive education and orientation to the inpatient ward, information on the proposed care and any expected costs for care, and the expected outcomes of care.

**ACC.2.3** The hospital establishes criteria for admission to and discharge from departments/wards providing intensive or specialized services. Ⓟ

## Continuity of Care

**ACC.3** The hospital designs and carries out processes to provide continuity of patient care services in the hospital, coordination among health care practitioners, and access to information related to the patient's care. Ⓟ

**ACC.3.1** During all phases of inpatient care, there is a qualified individual identified as responsible for the patient's care. Ⓟ



## Discharge, Referral, and Follow-Up

**ACC.4** The hospital develops and implements a discharge planning and referral process that is based on the patient's readiness for discharge. Ⓟ

**ACC.4.1** The hospital's discharge planning process addresses patient and family education and instruction related to the patient's ongoing need for continuing care and services.

**ACC.4.2** The complete discharge summary is prepared for all inpatients, and a copy of the discharge summary is contained in the patient's medical record.

**ACC.4.2.1** The medical records of patients receiving emergency care include the time of arrival and departure, the conclusions at termination of treatment, the patient's condition at discharge, and follow-up care instructions.

**ACC.4.3** The records of outpatients requiring complex care or with complex diagnoses contain profiles of the medical care and are made available to health care practitioners providing care to those patients. Ⓟ

**ACC.4.4** The hospital has a process for the management and follow-up of patients who notify hospital staff that they intend to leave against medical advice. Ⓟ

**ACC.4.4.1** The hospital has a process for the management of patients who leave the hospital against medical advice without notifying hospital staff. Ⓟ

## Transfer of Patients

**ACC.5** The hospital develops a process to transfer patients to other health care organizations based on status, the need to meet their continuing care needs, and the ability of the receiving organization to meet patients' needs. Ⓟ

**ACC.5.1** The receiving organization is given a written summary of the patient's clinical condition and the interventions provided by the referring hospital, and the process is documented in the patient's medical record.

## Transportation

**ACC.6** The hospital's transportation services comply with relevant laws and regulations and meet requirements for quality and safe transport. Ⓟ

# Standards, Intents, and Measurable Elements

## *Screening for Admission to the Hospital*

## Standard ACC.1

Patients who may be admitted to the hospital or who seek outpatient services are screened to identify if their health care needs match the hospital's mission and resources, and those with emergent, urgent, or immediate needs are given priority for assessment and treatment. Ⓟ

### Intent of ACC.1

Matching patient needs with the hospital's mission and resources depends on obtaining information on the patient's needs and condition through screening, usually at the point of first contact. The screening may be through triage criteria in the emergency department or outpatient urgent/immediate care clinic, visual evaluation, a physical examination, or the results of previously conducted physical, psychological, clinical laboratory, or diagnostic imaging evaluations. The screening can occur at a referring source, during emergency transport, or when the patient arrives at the hospital. It is important that decisions to treat, to transfer, or to refer are made only after the results of screening evaluations are available. Only those patients for whom the hospital has the clinical capability to provide the needed services, consistent with its mission, are considered for inpatient admission or registered for outpatient services. (*Also see* AOP.1)

Patients with emergent, urgent, or immediate needs are identified by staff who are trained, in a recognized triage process, to determine which patients need immediate care and how their care is given priority. Included in the triage process is the early recognition of the signs and symptoms of communicable diseases. When identified as emergent, urgent, or requiring immediate needs, these patients are assessed and receive care as quickly as necessary. Patients identified with potential communicable diseases are segregated and/or isolated as needed. (*Also see* PCI.12) Patients may be assessed by a physician or other qualified individual before other patients, receive diagnostic services as rapidly as possible, and begin treatment to meet their needs.

Certain screening exams or diagnostic tests may be required for every patient being admitted, or the hospital may identify specific screenings and tests for particular patient populations. **For example**, all patients with active diarrhea must have a screen for *Clostridioides difficile* (*C. diff*), and certain types of patients require screening for methicillin-resistant *Staphylococcus aureus*, such as all patients coming from long term care facilities. Specific screening tests or evaluations are identified when the hospital requires them prior to admission or registration.

When the hospital does not have the clinical capability to provide the needed services, the patient is transferred, referred, or assisted in identifying sources of services to meet his or her needs. When the hospital is not able to meet the needs of the patient with an emergency condition and the patient requires transfer to a higher level of care, the transferring hospital must provide and document stabilizing treatment within its capacity prior to transport. (*Also see* ACC.5 and ACC.6)

### Measurable Elements of ACC.1

- ❑ 1. Based on the results of screening, patients are accepted for outpatient treatment or inpatient care if it is determined that the needs of the patient match the hospital's mission and resources.
- ❑ 2. If the patient's needs do not match the hospital's mission and resources, the hospital will transfer, refer, or assist the patient in identifying and/or obtaining appropriate sources of care.
- ❑ 3. Staff utilize a recognized triage process that includes early recognition of communicable diseases, to prioritize and treat patients with immediate needs.
- ❑ 4. Emergent patients are assessed and stabilized within the capacity of the hospital prior to transfer, and treatment is documented in a record maintained by the transferring hospital.
- ❑ 5. 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.
- ❑ 6. Specific screening tests or evaluations are identified when the hospital requires them prior to admission or registration.



## Standard ACC.1.1

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.1.1

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; **for example**, waiting for an organ transplant, a delay in obtaining a diagnostic test due to limited appointments, or 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; it does not apply to minor or usual waiting periods for outpatient care or inpatient care, such as when a physician is behind schedule or when the emergency department is crowded, and the waiting room is full. (*Also see* ACC.2) For some services, such as oncology or transplant, delays may be consistent with national norms for those services and thus different from the delays for diagnostic and/or other treatment services.

### Measurable Elements of ACC.1.1

- ❑ 1. Inpatients and outpatients 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 delay and reasons for the delay are documented in the medical record.

## *Admission to the Hospital*

## Standard ACC.2

The hospital has a process for managing the flow of patients throughout the hospital that includes admitting inpatients and registering outpatients. Ⓟ

## Intent of ACC.2

Patient flow is considered to be the movement of patients throughout the hospital from the point of admission to the point of discharge; or in the case of outpatients, from the point of registration to the point of disposition. Managing the flow of patients throughout the hospital improves the coordination of care, patient safety, and health outcomes and is essential to preventing emergency department (ED) crowding and boarding of patients waiting for admission in the ED or other temporary locations in the hospital. Effective management of systemwide processes that support patient flow (such as registration of outpatients, elective and emergent admissions, assessment and treatment, patient transfer, shift changes, and discharge) can minimize delays in the delivery of care. The components of the patient flow address the following:

a) Available supply of inpatient beds
b) Facility plans for allocation of space, utilities, equipment, medical equipment, and supplies to support patient care for patients admitted to temporary locations in the hospital
c) Staffing plans to support care of patients admitted to temporary inpatient locations in the hospital or boarded in the ED or temporary holding areas
d) Patient flow through all areas where patients receive care, treatment, and services (such as inpatient units, laboratory, operating rooms, telemetry, radiology, and the postanesthesia care unit)
e) Efficiency of nonclinical services that support patient care and treatment (such as housekeeping and transportation)
f) Providing the same level of care to boarded patients waiting for an inpatient bed as the care provided to admitted patients in the inpatient unit (*Also see* COP.1)
g) Access to support services for boarded patients (such as social work, religious or spiritual support, and the like)

Monitoring and improving these processes are useful strategies to reduce patient flow problems. Staff from different departments and disciplines throughout the hospital—inpatient units, ED, medical staff, nursing, administration, environmental services, risk management—can make a significant contribution to understanding and resolving problems in patient flow. Measures and goals help identify impacts across units, reveal cycles and trends over time, and support accountability at all levels of the organization. (*Also see* GLD.3.1)

Boarding in the ED must be used as only a temporary solution to hospital crowding. Hospital plans identify a time frame by which boarded patients will be transferred from the ED and other temporary holding areas of the hospital to designated inpatient beds. The expectations here are intended to guide hospitals in providing safe areas, adequate and appropriate staffing for the care needed, and the assessment, reassessment, and care (within the hospital's capabilities) of patients who are subject to boarding while waiting for inpatient beds. (*Also see* ACC.1.1)

## Measurable Elements of ACC.2

- ❑ 1. The hospital develops and implements a process that supports the flow of patients through the hospital that addresses at least a) through g) in the intent.
- ❑ 2. There is a process for admitting emergency patients to inpatient units.
- ❑ 3. There is a process for holding patients for observation when needed.
- ❑ 4. The hospital plans and provides for the care of patients needing admission who are boarded in the ED and other temporary holding areas in the hospital.
- ❑ 5. The hospital identifies and implements a time limit on boarding patients waiting for inpatient beds.
- ❑ 6. The individuals who manage patient flow processes review the effectiveness to identify and implement process improvements.

## Standard ACC.2.1

Patient needs for preventive, palliative, curative, and rehabilitative services are prioritized based on the patient's condition at the time of admission as an inpatient to the hospital.

### Intent of ACC.2.1

When patients are considered for admission as an inpatient to the hospital, the screening assessment helps health care practitioners identify and prioritize the preventive, curative, rehabilitative, and palliative services needed by the patient and select the most appropriate service or unit to meet the patient's most urgent or priority needs.

### Measurable Elements of ACC.2.1

- ❑ 1. The screening assessment helps health care practitioners identify the patient's needs.
- ❑ 2. The service or unit selected to meet these needs is based on the screening assessment findings.
- ❑ 3. Patients' needs related to preventive, curative, rehabilitative, and palliative services are prioritized.

## Standard ACC.2.2

At admission as an inpatient, the patient and family receive education and orientation to the inpatient ward, information on the proposed care and any expected costs for care, and the expected outcomes of care.

### Intent of ACC.2.2

During the admission process, patients and their families receive sufficient information to make knowledgeable decisions. Information is provided about the proposed care, the expected outcomes, and any expected cost to the patient or family for the care when not paid for by a public or private source. When financial constraints related to the cost of care are present, the hospital seeks ways to overcome those constraints. Such information can be in written form or provided verbally, noting such in the patient's medical record.

Patient safety is an important aspect of patient care. Orientation to the inpatient environment and equipment related to the care and services provided is an essential component of patient safety. (*Also see* PCC.2 and COP.3.2)

### Measurable Elements of ACC.2.2

- ❑ 1. On admission as an inpatient, the patient and family receive education and orientation to the inpatient ward.
- ❑ 2. The patient and family receive information on the proposed care.
- ❑ 3. The patient and family receive information on the expected outcomes of care.
- ❑ 4. The patient and family receive information on any expected costs related to the proposed care.

## Standard ACC.2.3

The hospital establishes criteria for admission to and discharge from departments/wards providing intensive or specialized services. Ⓟ

### Intent of ACC.2.3

Departments/wards that provide intensive or specialized care (**for example**, postsurgical intensive care, the care of burn patients, or the care of organ/tissue transplant patients) are costly and usually are limited in space and

staffing, thus hospitals may restrict admission to these specialized departments/wards (**for example**, admission to the intensive care department/ward may be restricted to only those patients with reversible medical conditions and not allowed for patients whose condition has been identified as terminal). In such cases, the hospital must establish criteria for determining those patients who require the level of care provided in these specialized departments/wards. (*Also see* GLD.10)

To ensure consistency, the criteria should utilize prioritization and diagnostic and/or objective parameters, including physiologic-based criteria when possible. For hospitals with psychiatric services, admission to a locked psychiatric department/ward may include severity of illness criteria that may or may not include physiologic criteria. Individuals from the emergency, intensive, or specialized services participate in developing the criteria. The criteria are used to determine direct entry to the department/ward; **for example**, directly from the emergency department. The criteria are also used to determine admission into the department/ward from within the hospital or from outside the hospital (such as when a patient is transferred from another hospital).

Patients admitted to a specialized department/ward require reassessment and reevaluation to identify when the patient's condition has changed, such that specialized care may no longer be required. **For example**, when the patient's physiological status has stabilized and intensive monitoring and treatment are no longer necessary, or when the patient's status has deteriorated to the point that specialized care and services will no longer be provided, the patient may be discharged from the specialized department/ward or moved to an area that provides a less intensive level of care (such as a medical/surgical, hospice, or palliative care department/ward).



### Measurable Elements of ACC.2.3

- ❑ 1. The hospital has established entry and/or transfer criteria for admission to intensive and specialized departments/wards to meet special patient needs.
- ❑ 2. The criteria utilize prioritization, diagnostic, and/or objective parameters, including physiologic-based criteria when possible.
- ❑ 3. The hospital has established discharge and/or transfer criteria from intensive and specialized departments/wards to a different level of care.
- ❑ 4. The medical records of patients who are admitted to departments/wards providing intensive/specialized services contain evidence that they meet the criteria for services.
- ❑ 5. The medical records of patients who are transferred or discharged from departments/wards providing intensive or specialized services contain evidence that they no longer meet the criteria for those services.

## *Continuity of Care*

# Standard ACC.3

The hospital designs and carries out processes to provide continuity of patient care services in the hospital, coordination among health care practitioners, and access to information related to the patient's care. Ⓟ

### Intent of ACC.3

Patients may be transferred within the hospital from one service or inpatient unit to a different service or inpatient unit during their course of care and treatment. As patients move through the hospital from admission to discharge or transfer, several departments and services and many different health care practitioners may be involved in providing care. Throughout all phases of care, patient needs are matched with the required resources within and, when necessary, outside the hospital. Continuity is enhanced when all health care practitioners have the information needed from the patient's current and past medical experiences to help in

decision making, and, when multiple decision makers are providing care, these decision makers agree on the care and services to be provided.

For patient care to appear seamless, the hospital needs to design and to implement processes for continuity and coordination of care among physicians, nurses, and other health care practitioners in

a) emergency services and inpatient admission;
b) diagnostic services and treatment services;
c) surgical and nonsurgical treatment services;
d) outpatient care programs; and
e) other organizations and other care settings.

The patient's medical record(s) is a primary source of information on the care process and the patient's progress and thus is an essential communication tool. For this information to be useful and to support the continuity of the patient's care, it needs to be available during inpatient care, for outpatient visits, and at other times as needed and kept up to date. Medical, nursing, and other patient care notes are available to all of the patient's health care practitioners who need them for the care of the patient. (*Also see* MOI.5)



When the care team changes as a result of a transfer, continuity of patient care requires that essential information related to the patient be transferred with him or her so that medications and other treatments can continue uninterrupted, and the patient's status can be monitored. To ensure that each care team receives the information needed to provide care, the patient's medical record(s) is transferred or information from the patient's medical record is summarized at transfer and provided to the care team receiving the patient. Such a summary includes

f) the reason for admission;
g) significant findings;
h) diagnosis;
i) procedures performed;
j) medications;
k) other treatments; and
l) the patient's condition at transfer.

The leaders of the departments and services work together to design and to implement the processes of care coordination and continuity. These processes may be supported with the use of tools such as guidelines, clinical pathways, care plans, referral forms, checklists, and the like. (*Also see* COP.3) The hospital identifies individuals responsible for coordinating services. These individuals may coordinate all patient care (**for example**, between departments) or may be responsible for coordinating the care of individual patients (**for example**, case manager). This care coordination is best accomplished by using established criteria or policies that determine the appropriateness of transfers within the hospital. (*Also see* IPSG.2.2; COP.2; COP.9.3; and ASC.7.2)

## Measurable Elements of ACC.3

- ❑ 1. The leaders of departments and services design and implement processes that support continuity and coordination of care, including at least a) through e) identified in the intent.
- ❑ 2. The patient's medical record(s) is available to those practitioners who are authorized to have access and need it for the care of the patient.
- ❑ 3. The patient's medical record(s) is up to date to ensure communication of the latest information.
- ❑ 4. The patient's medical record(s) or a summary of patient care information is transferred with the patient to another service or unit in the hospital
- ❑ 5. If a summary of information is transferred with the patient, the summary contains at least f) through l) of the intent.
- ❑ 6. Continuity and coordination of care processes are supported by the use of tools, such as care plans, guidelines, or other such tools.

## Standard ACC.3.1

During all phases of inpatient care, there is a qualified individual identified as responsible for the patient's care. Ⓟ

### Intent of ACC.3.1

To maintain continuity of care throughout the patient's stay in the hospital, the individual with overall responsibility for coordination and continuity of the patient's care or particular phase of the patient's care is clearly identified. This individual may be a physician or other qualified individual. (*Also see* COP.2) The responsible individual is identified in the patient's medical record. A single individual providing the oversight of care during the entire hospital stay will improve continuity, coordination, patient satisfaction, quality, and potentially the outcomes and thus is desirable for certain complex patients and others the hospital may identify. This individual would need to collaborate and to communicate with the other health care practitioners. In addition, hospital policy identifies the process for the transfer of responsibility from the responsible individual to another individual during vacations, holidays, and other periods. The policy identifies those consultants, on-call physicians, locum tenentes, or others who take responsibility and how they are to assume that responsibility and to document their participation or coverage. When a patient moves from one phase of care to another (**for example**, from surgical to rehabilitation), the individual responsible for the patient's care may change, or the same individual may continue overseeing the care of the patient.

### Measurable Elements of ACC.3.1

- ❑ 1. A qualified individual(s) responsible for the coordination of the patient's care is identified in the patient's medical record and is available through all phases of inpatient care.
- ❑ 2. There is a process for transferring the responsibility for coordination of care from individual to individual.
- ❑ 3. The process identifies how these individuals assume the transferred responsibility and document their participation or coverage.

## *Discharge, Referral, and Follow-Up*

## Standard ACC.4

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

## Standard ACC.4.1

The hospital's discharge planning process addresses patient and family education and instruction related to the patient's ongoing need for continuing care and services.

### Intent of ACC.4 and ACC.4.1

Discharge planning is a process that is used to help determine what types of continued care and services a patient may need after leaving the hospital to ensure a safe and successful transition from one level of care to another level of care. Effective discharge planning can decrease the risk of hospital readmission, improve recovery, ensure safe medication practices, and help prepare patients and/or families in providing safe, posthospital care. The literature identifies that improvements in hospital discharge planning significantly improve the outcome for patients as they move to the next level of care.

Referring or discharging a patient to a health care practitioner outside the hospital, another care setting, home, or family is based on the patient's health status and readiness for discharge. The patient's physician

or individual responsible for his or her care must determine readiness for referral or discharge based on the policies and relevant criteria or indications of referral and discharge established by the hospital.

The discharge planning process includes identifying the patient's need for continuing care or services. Continuing needs may mean referral to a medical specialist, rehabilitation therapist, or even preventive health needs coordinated in the home by the family. 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 by appropriate health care practitioners or outside organizations. Patients may need support services and medical services at discharge. **For example**, patients may need social, nutritional, financial, psychological, or other support at discharge. The availability and actual use of these support services may, to a large degree, determine the need for continuing medical services. The discharge planning process includes the type of support service needed and the availability of such service.



For patients not directly referred or transferred to another health care practitioner, clear instructions on where and how to receive continuing care are essential to ensure optimal outcomes of care and 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.

When indicated, the hospital begins to plan for the continuing needs as early in the care process as possible. The patient, the patient's family, health care practitioners, and other staff involved in the patient's care, treatment, and services participate in planning the patient's discharge or transfer.

Patient and family education and instruction are important components of the discharge plan and support the patient's return to previous functional levels and maintenances 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. Standardized materials and processes are used to educate patients on topics related to their ongoing care and treatment after hospital discharge. Patient education and follow-up instructions are provided to the patient in a form and language the patient understands. (*Also see* PCC.2)

Based on the patient's identified continuing care needs, discharge education and instruction 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 as needed
- Safe and effective use of medical equipment, as appropriate
- Rehabilitation techniques, as appropriate.

### Measurable Elements of ACC.4

- ❑ 1. The hospital develops and implements a discharge planning and referral process that starts at the beginning of care and is based on the patient's readiness for discharge.
- ❑ 2. The patient's readiness for discharge is determined by the use of relevant criteria or indications that ensure patient safety.
- ❑ 3. The discharge planning process includes the need for both support services and continuing medical needs.
- ❑ 4. Patients not directly referred or transferred are provided with the name and location of a site(s) for continuing care.
- ❑ 5. Patients not directly referred or transferred are provided instructions, in writing, on when to return to the hospital for continued care, if appropriate, and when and how to obtain urgent care.
- ❑ 6. Discharge planning and instructions are documented in the patient record and provided to the patient in writing.

### Measurable Elements of ACC.4.1

- ❑ 1. Patient and family education and instruction are related to the patient's ongoing need for continuing care and services.
- ❑ 2. Patients and families are provided with a complete list of medications to be taken at home.
- ❑ 3. Patients and families are educated about the safe and effective use of all medications, potential side effects, and the prevention of potential interactions with over-the-counter medications and/or food.
- ❑ 4. Patients and families are educated about proper diet and nutrition.
- ❑ 5. Patients and families are educated about pain management as appropriate.
- ❑ 6. Patients and families are educated about safe and effective use of medical equipment and rehabilitation techniques as appropriate.

## Standard ACC.4.2

The complete discharge summary is prepared for all inpatients, and a copy of the discharge summary is contained in the patient's medical record.

### Intent of ACC.4.2

The discharge summary provides an overview of the patient's stay within the hospital. A summary of the patient's care is prepared at discharge from the hospital. Any qualified individual can compile the discharge summary, such as the patient's physician, a house officer, or a clerk. 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 given to the patient when indicated by hospital policy or by common practice consistent with laws and culture. In cases in which details of a patient's follow-up care are unknown, such as with patients who are visiting from a different region or country, a copy of the discharge summary is given to the patient. (*Also see* MOI.4) The copy of the discharge summary is placed in the patient's medical record.

The summary includes the following:

a) Reason for admission, diagnoses, and comorbidities
b) Significant physical and other findings
c) Diagnostic and therapeutic procedures performed

d) Medications administered during hospitalization with the potential for residual effects after the medication has been discontinued
e) All medications to be taken at home
f) The patient's condition/status at the time of discharge (**examples** include "condition improved," "condition unchanged," and the like)
g) Follow-up instructions

### Measurable Elements of ACC.4.2

❑ 1. A discharge summary is prepared by a qualified individual.

❑ 2. The discharge summary contains at least a) through g) of the intent.

❑ 3. A copy of the discharge summary is provided to the practitioner responsible for the patient's continuing or follow-up care.

❑ 4. A copy of the discharge summary is provided to the patient in cases in which information regarding the practitioner responsible for the patient's continuing or follow-up care is unknown.

❑ 5. A copy of the completed discharge summary is placed in the patient's medical record in a time frame identified by the hospital.



## Standard ACC.4.2.1

The medical records of patients receiving emergency care include the time of arrival and departure, the conclusions at termination of treatment, the patient's condition at discharge, and follow-up care instructions.

### Intent of ACC.4.2.1

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 who are discharged from the emergency department, the medical record includes the conclusions at termination of treatment, the patient's condition at discharge, and follow-up care instructions. (*Also see* ACC.1)

### Measurable Elements of ACC.4.2.1

❑ 1. The medical records of all emergency patients include arrival and departure times.

❑ 2. The medical records of discharged emergency patients include conclusions at the termination of treatment.

❑ 3. The medical records of discharged emergency patients include the patient's condition at discharge.

❑ 4. The medical records of discharged emergency patients include any follow-up care instructions.

## Standard ACC.4.3

The records of outpatients requiring complex care or with complex diagnoses contain profiles of the medical care and are made available to health care practitioners providing care to those patients. Ⓟ

### Intent of ACC.4.3

When the hospital provides ongoing care and treatment for outpatients with complex diagnoses and/or who need complex care (**for example**, patients seen several times for multiple problems, multiple treatments, in

multiple clinics, and/or the like), there may be an accumulated number of diagnoses and medications and an evolving clinical history and physical examination findings. It is important for any health care practitioner in all settings providing care to that outpatient to have access to information about the care being provided. (*Also see* ACC.3) The information may be contained in a patient profile or similar brief overview. The purpose of a profile is to have critical information quickly and easily available to health care practitioners, particularly when there are multiple outpatient providers. The development of a profile is required whether the outpatient department uses hard-copy or electronic medical records.

The process for providing this information to health care practitioners includes

- identifying the types of patients receiving complex care and/or with complex diagnoses (such as patients seen in the cardiac clinic with multiple comorbidities, or patients with end-stage renal failure);
- identifying the information needed by the clinicians who treat those patients;
- determining what process will be used to ensure that the medical information needed by the clinicians is easy to retrieve and easy to review; and
- evaluating the process to verify that the information and implementation meet the needs of the clinicians and improve the quality and safety of outpatient clinical services.



### Measurable Elements of ACC.4.3

- ❑ 1. The hospital identifies the types of outpatients receiving complex care and/or with complex diagnoses who require an outpatient profile.
- ❑ 2. The clinician(s) who treats the patient identifies necessary information to be included in the outpatient profile.
- ❑ 3. The hospital uses a process that will ensure the outpatient profile is easy to retrieve and review.
- ❑ 4. The process is evaluated to see if it meets the needs of the clinicians and improves the quality and safety of outpatient clinical visits.

## Standard ACC.4.4

The hospital has a process for the management and follow-up of patients who notify hospital staff that they intend to leave against medical advice. Ⓟ

## Standard ACC.4.4.1

The hospital has a process for the management of patients who leave the hospital against medical advice without notifying hospital staff. Ⓟ

### Intent of ACC.4.4 and ACC.4.4.1

When a patient decides to leave the hospital after an examination has been completed and a treatment plan recommended, whether it is an inpatient or an outpatient, this is identified as "leaving against medical advice." Inpatients and outpatients (including patients from the emergency department) have the right to refuse medical treatment and/or 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 inpatient or outpatient requests to leave the hospital without medical approval, the medical risks must be explained by the physician providing the treatment plan or his or her designee prior to discharge. Also, normal discharge procedures should be followed, if the patient allows. (*Also see* ACC.4.1) If the patient has a family physician who has not been involved, but is known to the hospital, the family physician must be notified of the patient's decision. Efforts should be made to identify the reason the patient is choosing to leave against medical advice. Hospitals need to understand these reasons in order to be able to provide better communication to patients and/or families and identify potential process improvements.

There may be special circumstances in which a patient may be granted permission to leave the hospital during the course of treatment. As permitted by hospital policy and regional laws and regulations, the hospital may develop a process to permit patients to leave the hospital for a period of time (such as on a weekend "pass"). The decision to grant leaves/passes must be based on the patient's physical and mental status and on family capability to provide safe care (if accompanying the patient), and it must include input from the treatment team and—as appropriate—the patient/family.

When a patient leaves the hospital against medical advice without notifying anyone in the hospital, or an outpatient receiving complex or lifesaving treatment (such as hemodialysis, chemotherapy, or radiation therapy) does not return for treatment, the hospital must make an effort to contact the patient to inform him or her of potential risks. If the patient has a family physician who is known to the hospital, the hospital, in order to reduce the risk of harm, should notify that physician.

The hospital designs this process to be consistent with applicable laws and regulations. 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. (*Also see* PCI.1)



### Measurable Elements of ACC.4.4

- ❑ 1. There is a process for managing inpatients and outpatients who notify staff that they are leaving against medical advice.
- ❑ 2. The process includes informing the patient of the medical risks of inadequate treatment.
- ❑ 3. The patient is discharged according to the hospital discharge process.
- ❑ 4. If the family physician of a patient leaving against medical advice is known and has not been involved in the process, the physician is notified.
- ❑ 5. The process is consistent with applicable laws and regulations, including requirements for reporting cases of infectious disease and cases in which 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 on an approved pass for a defined period of time.

### Measurable Elements of ACC.4.4.1

- ❑ 1. There is a process for the management of inpatients and outpatients who leave the hospital against medical advice without notifying hospital staff.
- ❑ 2. There is a process for the management of outpatients receiving complex treatment who do not return for treatment.
- ❑ 3. If the family physician is known and has not been involved in the process, the physician is notified.
- ❑ 4. The process is consistent with applicable laws and regulations, including requirements for reporting cases of infectious disease and cases in which patients may be a threat to themselves or others.

## *Transfer of Patients*

## Standard ACC.5

The hospital develops a process to transfer patients to other health care organizations based on status, the need to meet their continuing care needs, and the ability of the receiving organization to meet patients' needs. Ⓟ

## Intent of ACC.5

Transferring a patient to an outside organization is based on the patient's status and need for continuing health care services. Transfer may be in response to a patient's need for specialized consultation and treatment, urgent services, or less intensive services (such as subacute care or longer-term rehabilitation) or by request of the patient and/or the patient's family due to personal reasons. Criteria help to identify when a transfer is necessary in order to ensure that the patient's needs are met. (*Also see* ACC.1)

When referring a patient to another organization, the referring hospital must determine if the receiving organization provides services to meet the patient's needs and has the capacity to receive the patient. This determination is usually made well in advance, and the willingness to receive patients and the transfer conditions are described in formal or informal affiliations or agreements. This advance determination ensures continuity of care and that the patient's care needs will be met. Transfers may occur to other sources of specialized treatment or services without formal or informal transfer agreements.

Transferring a patient directly to another health care organization may be a brief process with an alert and talking patient, or it may involve moving a comatose patient who needs continuous nursing or medical oversight. In either case, the patient requires monitoring and may need specialized medical equipment, but the qualifications of the individual doing the monitoring and the type of medical equipment needed are significantly different. Thus, the condition and status of the patient determine the qualifications of the staff member monitoring the patient and the type of medical equipment needed during transfer.

A consistent process for how patients are transferred from one organization to another is required to ensure that patients are transferred safely. Such a process addresses

- how and when responsibility is transferred between practitioners and settings;
- criteria for when transfer is necessary to meet the patient's needs;
- who is responsible for the patient during transfer;
- what medications, supplies, and medical equipment are required during transfer;
- a follow-up mechanism that provides the condition of the patient during transfer and upon arrival to the receiving organization; and
- what is done when transfer to another source of care is not possible.

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

## Measurable Elements of ACC.5

- ❑ 1. The hospital develops a transfer process that is based on criteria to address patients' needs for continuing care.
- ❑ 2. The transfer process addresses how and when responsibility for continuing care is moved to another practitioner or setting and determines that the receiving organization can meet the needs of the patient to be transferred.
- ❑ 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.5.1

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

### Intent of ACC.5.1

To ensure continuity of care, patient information is transferred with the patient. A copy of the discharge summary or other written clinical summary is provided to the receiving organization with the patient. (*Also see* MOI.4) The summary includes at least

a) the patient's clinical condition or status;
b) the procedures and other interventions provided; and
c) the patient's continuing needs.

The medical record of each patient transferred to another health care organization contains documentation of the transfer. The documentation includes the name of the organization and the name of the individual agreeing to receive the patient, the reason(s) for the transfer, and any special conditions for transfer (such as when space at the receiving organization is available, or the patient's status). Also, it is noted if the patient's condition or status changed during transfer (**for example**, the patient dies or requires resuscitation). 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) is included in the medical record. (*Also see* MOI.8)

### Measurable Elements of ACC.5.1

❑ 1. A patient clinical summary document is transferred with the patient and includes at least a) through c) of the intent.

❑ 2. The medical records of transferred patients identify the name of the receiving health care organization and the name of the individual agreeing to receive the patient.

❑ 3. The medical records of transferred patients contain documentation or other notes as required by the policy of the transferring hospital.

❑ 4. The medical records of transferred patients state the reason(s) for transfer and any special conditions related to transfer.

## *Transportation*

## Standard ACC.6

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

### Intent of ACC.6

The process for referring, transferring, and/or discharging patients includes understanding their transportation needs and ensuring their safe transport home or to the next care setting. In particular, assessing the transportation needs of patients requiring assistance is necessary. **For example**, patients from long term care facilities or rehabilitative centers needing outpatient services or evaluation in the emergency department may arrive by ambulance or other medical vehicle. Upon completion of the service, the patient may require assistance with transportation back to his or her home or another facility. In other situations, patients may drive themselves to the hospital for a procedure that impairs their ability to drive themselves home (such as eye surgery or a procedure that requires procedural sedation). Assessing patients' transportation needs and ensuring

safe transportation for those patients who require assistance is the hospital's responsibility. 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 type of transportation will vary depending on the needs of the patient and may be by ambulance or other vehicles owned or contracted by the hospital or by a source designated by the family. The hospital ensures that staff responsible for monitoring the patient or providing other patient care during transport have the qualifications required for the type of patient being transferred. (*Also see* SQE.3)

When the transport vehicles are owned by the hospital, they need to comply with all applicable laws and regulations related to their operation, condition, and maintenance. The hospital identifies the transportation situations that have a risk of infection and implements strategies to reduce infection risk. (*Also see* PCI.4) The required drugs, medications, and other supplies needed within the vehicle are based on the types of patients transported. (*Also see* MMU.3 and PCI.6) **For example**, simply taking geriatric patients home from outpatient visits is very different than transferring an infectious disease or burn patient to another hospital.

If the hospital contracts for transport services, the hospital must be assured that the contractor meets similar standards for patient and vehicle safety. When transportation services are provided by the Ministry of Health, an insurance organization, or other entity not under the control or supervision of the hospital, reporting quality and safety issues to the responsible organization provides valuable feedback that can help in making quality decisions related to patient transports.

In all cases, the hospital evaluates the quality and safety of the transportation services. This includes the receipt of, evaluation of, and response to complaints regarding the transportation provided or arranged.

## Measurable Elements of ACC.6

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

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# Patient-Centered Care (PCC)

## Overview

Each patient and his or her 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

- 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; and
- 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.1** The hospital is responsible for providing processes that support patients' and families' rights during care.

**PCC.1.1** The hospital seeks to reduce physical, language, cultural, and other barriers to access and delivery of services and provides information and education to patients and families in a language and manner they can understand.

**PCC.1.2** The hospital provides care that supports patient dignity, is respectful of the patient's personal values and beliefs, and responds to requests for spiritual and religious observance.

**PCC.1.3** The hospital establishes a process to ensure patient privacy and confidentiality of care and information and allows patients the right to have access to their health information within the context of existing law and culture. Ⓟ

**PCC.1.4** The hospital takes measures to protect patients' possessions from theft or loss.

**PCC.1.5** Patients are protected from physical assault, and populations at risk are identified and protected from additional vulnerabilities.

**PCC.2** Patients and families are engaged in all aspects of their medical care and treatment through education and participation in care and treatment decisions and care processes. Ⓟ

**PCC.2.1** 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.2.2** The hospital supports the patient's right to assessment and management of pain and respectful compassionate care at the end of life.

**PCC.3** The hospital measures, analyzes, and—when necessary—improves the patient experience in order to enhance the quality of patient care. Ⓟ

**PCC.3.1** The hospital informs patients and families about its process to receive and to act on complaints, conflicts, and differences of opinion about patient care and the patient's right to participate in these processes. Ⓟ



## Patient Consent Process

**PCC.4** General consent for treatment, if obtained when a patient is admitted as an inpatient or is registered for the first time as an outpatient, is clear in its scope and limits. Ⓟ

**PCC.4.1** Patient informed consent is obtained through a process defined by the hospital and carried out by trained staff in a manner and language the patient can understand. Ⓟ

**PCC.4.2** Informed consent is obtained before surgery, anesthesia, procedural sedation, use of blood and blood products, and other high-risk treatments and procedures. Ⓟ

**PCC.4.3** Patients and families receive adequate information about the patient's condition, proposed treatment(s) or procedure(s), and health care practitioners so that they can grant consent and make care decisions.

**PCC.4.4** The hospital establishes a process, within the context of existing law and culture, for when others can grant consent.

## Patient and Family Education

**PCC.5** The hospital provides an education program that is based on its mission, services provided, and patient population, and health care practitioners collaborate to provide education.

**PCC.5.1** Each patient's educational needs and ability and willingness to learn are assessed and recorded in his or her medical record.

**PCC.5.2** Education methods take into account the patient's and family's values and preferences and allow sufficient interaction among the patient, family, and staff for learning to occur.

### Organ and Tissue Donation Information

**PCC.6** The hospital informs patients and families about how to choose to donate organs and other tissues.

**PCC.6.1** The hospital provides oversight for the process of organ and tissue procurement. Ⓟ

# Standards, Intents, and Measurable Elements

## *Patient and Family Rights*

## Standard PCC.1

The hospital is responsible for providing processes that support patients' and families' rights during care.

### Intent of PCC.1

The hospital leadership is primarily responsible for how a hospital will treat its patients. Thus, leadership needs to know and to understand patient and family rights and the hospital's responsibilities as identified in laws and regulations. Leadership then provides direction to department/service leaders who ensure that staff throughout the hospital assume responsibility for protecting these rights. To effectively protect and to advance patient rights, leadership works and seeks to understand its responsibilities in relation to the community served by the hospital. (*Also see* GLD.3.1)

Often, patients wish to have family participate in their care decisions; however, they may define family differently from the traditional definition of family. Patients have the right to identify who they consider to be their family and be allowed to have them involved in their care. In order for families to participate, they must be allowed to be present. When capable, patients are given the opportunity to decide if and to what extent they wish family to be involved, what information regarding their care would be provided to family or others, and under what circumstances. **For example**, the patient may not wish to have a diagnosis shared with family, or the family may not want the patient to know his or her diagnosis.

Patient and family rights are a fundamental element of all contacts among a hospital, its staff, and patients and families. The hospital develops and implements processes to ensure that all staff members are aware of and respond to patient and family rights issues when they interact with and care for patients throughout the hospital. The hospital uses a collaborative and inclusive process to develop the policies and procedures and includes patients and families in the process. (*Also see* COP.8.5 and COP.9)

### Measurable Elements of PCC.1

- ❑ 1. Hospital leadership works collaboratively to protect and to advance patient and family rights.
- ❑ 2. Hospital leadership implements patient and family rights as identified in laws and regulations.
- ❑ 3. Hospital leadership protects patient and family rights in relation to the cultural practices of the community or individual patients served.
- ❑ 4. Hospital leadership protects the patient's right to identify who the patient wishes to participate in care decisions.
- ❑ 5. The hospital has a process to determine the patient's preference, and in some circumstances the patient's family's preference, in determining what information regarding the patient's care would be provided to family or others, and under what circumstances.
- ❑ 6. All health care practitioners are trained on the processes for and their role in supporting patient and family rights and participation in care.

## Standard PCC.1.1

The hospital seeks to reduce physical, language, cultural, and other barriers to access and delivery of services and provides information and education to patients and families in a language and manner they can understand.

### Intent of PCC.1.1

Admission as an inpatient to a hospital or registration as an outpatient (**for example**, in the emergency department or ambulatory clinic) can be frightening and confusing for patients. Hospitals frequently serve communities with a diverse population. Patients may be aged, have disabilities, speak multiple languages or dialects, be culturally diverse, or present other barriers that make the process of accessing and receiving care very difficult. (*Also see* COP.1 and GLD.12) **For example**, patients with impaired mobility or who are visually impaired may have difficulty entering or navigating the hospital building. Communication may be difficult for patients and families who speak a different language, and patients may not be able to understand all aspects of their care and treatment. Patients may find it complicated and confusing when attempting to access care and understand their rights and responsibilities in the care process.

The hospital has identified barriers, implemented processes to eliminate or to reduce barriers, and takes action to reduce the impact of barriers for patients seeking care. **For example**, safe accessibility to building and care/treatment departments is evaluated and provided; disability and cultural signage may include the use of multilingual signs and/or international symbols, and translators may be used for patients speaking different languages.

The hospital prepares a written statement of patient and family rights and responsibilities that is available to patients when they are admitted as inpatients or registered as outpatients. The statement may be posted in the facility or available as a brochure. The statement is appropriate to the patient's age, understanding, and language. When written communication is not effective or appropriate, the patient and family are informed of their rights and responsibilities in a language and manner they can understand.

### Measurable Elements of PCC.1.1

- ❑ 1. The department/service leaders and staff of the hospital identify their patient population's most common and challenging barriers to accessing and receiving care.
- ❑ 2. The department/service leaders develop and implement a process to overcome or limit barriers to access to care and their impact on service delivery for patients seeking care.
- ❑ 3. Information about aspects of the patient's medical care and treatment are provided in a manner and language the patient understands.
- ❑ 4. Information about patient rights and responsibilities is provided to each patient in writing or other method, in a language the patient understands.
- ❑ 5. The statement of patient rights and responsibilities is posted or otherwise available from staff at all times.

## Standard PCC.1.2

The hospital provides care that supports patient dignity, is respectful of the patient's personal values and beliefs, and responds to requests for spiritual and religious observance.

### Intent of PCC.1.2

One of the most important human needs is the desire for respect and dignity. Often, patients experience feelings of loss due to increased dependency in situations such as the need for assistance with feeding, movement, and personal hygiene. The patient has the right to care that is respectful and considerate at all times, in all circumstances, and recognizes the patient's personal worth and self-dignity.

Each patient brings his or her own set of values and beliefs to the care process. Strongly held values and beliefs can shape the care process and how patients respond to care. Some values and beliefs are commonly held by all patients and are frequently 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. (*Also see* PCC.5.2) Staff seek to understand the care and services they provide within the context of the patient's values and beliefs. (*Also see* COP.7)

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 process may be carried out through on-site religious staff, local sources, or family-referred sources. The process to respond is more complex; **for example**, when the hospital or country does not officially "recognize" and/or have sources related to a religion or belief for which there may be a request.

### Measurable Elements of PCC.1.2

- ❑ 1. Staff provide care that is respectful and considerate of the patient's dignity and self-worth.
- ❑ 2. The patient's spiritual and cultural beliefs and the patient's values are respected.
- ❑ 3. The hospital responds to routine as well as complex requests related to religious or spiritual support.

## Standard PCC.1.3

The hospital establishes a process to ensure patient privacy and confidentiality of care and information and allows patients the right to have access to their health information within the context of existing law and culture. Ⓟ

## Intent of PCC.1.3

Patient privacy, particularly during clinical interviews, examinations, procedures/treatments, and transport, is important. Patients may desire privacy from other staff, from other patients, and even from family members or other designees identified by the patient. Also, patients may not wish to be photographed, to be recorded, or to participate in accreditation survey interviews. Although there are some common approaches to providing privacy for all patients, individual patients may have different or additional privacy expectations and needs according to the situation, and these expectations and needs may change over time. Thus, as staff members provide care and services to patients, they inquire about the patient's privacy needs and expectations related to the care or service. This communication between a staff member and his or her patient builds trust and open communication and may be documented in the patient's plan of care, particularly when the patient expresses different or additional privacy expectations.

Medical and other health information, when documented and collected, is important for understanding the patient and his or her needs and for providing care and services over time. This information may be in paper or electronic form or a combination of the two. The hospital respects such information as confidential and has implemented policies and procedures that protect such information from loss or misuse. The policies and procedures reflect information that is released as required by laws and regulations. (*Also see* MOI.2 and MOI.6)

Staff respect patient privacy and confidentiality by not posting confidential information on the patient's door or at the nursing station and by not holding patient-related discussions in public places. Staff are aware of laws and regulations governing the confidentiality of information and inform patients about how the hospital respects their privacy and the confidentiality of information. Patients are also informed about when and under what circumstances information may be released and how their permission will be obtained.

In addition to granting permission to share health information with others, 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. In addition, access to health information allows patients to review and monitor compliance with their treatment plans, fix any errors that may be in their health record, and monitor their progress in managing their disease(s), among other benefits.

Patient health information may be available in multiple forms. **For example**, in the hospitalized patient, health care information is contained in hospital medical records; however, some health information may also be available through a secure website, such as a patient portal. The hospital has a process for providing patients with access to their health information within the context of existing laws, regulations, and culture.



## Measurable Elements of PCC.1.3

- ❑ 1. Staff members meet patient expectations and needs for privacy, when expressed, during care and treatment.
- ❑ 2. A patient's expressed need for privacy is respected for all clinical interviews, examinations, procedures/treatments, and transport.
- ❑ 3. Confidentiality of patient information is maintained according to laws and regulations.
- ❑ 4. The hospital has a process for patients to grant permission for the release of information not covered by laws and regulations.
- ❑ 5. The hospital has a process for providing patients with access to their health information within the context of existing laws, regulations, and culture.
- ❑ 6. Access to health information is timely, and cost does not prevent access to this information for the purpose of maintaining continuity of care.

## Standard PCC.1.4

The hospital takes measures to protect patients' possessions from theft or loss.

### Intent of PCC.1.4

The hospital communicates its responsibility, if any, for the patient's possessions to patients and families. When the hospital takes responsibility for any or all of the patient's personal possessions brought into the hospital, there is a process to account for the possessions and to ensure that they will not be lost or stolen. This process considers the possessions of emergency patients, same-day surgery patients, inpatients, those patients unable to make alternative safekeeping arrangements, and those incapable of making decisions regarding their possessions. (*Also see* FMS.6)

### Measurable Elements of PCC.1.4

- ❑ 1. The hospital has determined its level of responsibility for patients' possessions.
- ❑ 2. Patients receive information about the hospital's responsibility for protecting personal belongings.
- ❑ 3. Patients' possessions are safeguarded when the hospital assumes responsibility or when the patient is unable to assume responsibility.

## Standard PCC.1.5

Patients are protected from physical assault, and populations at risk are identified and protected from additional vulnerabilities.

### Intent of PCC.1.5

The hospital is responsible for protecting patients from physical assault by visitors, other patients, and staff. This responsibility is particularly relevant to infants and children, the elderly, and others unable to protect themselves or to signal for help. The hospital seeks to prevent assault through such processes as investigating individuals in the facility without identification, monitoring remote or isolated areas of the facility, and quickly responding to those thought to be in danger of assault.

Each hospital identifies its at-risk patient groups (such as children, disabled individuals, the elderly) and establishes processes to protect the rights of individuals in these groups. Vulnerable patient groups and the hospital's responsibility may be identified in laws and regulations. Staff members understand their responsibilities in these processes. Children, disabled individuals, the elderly, and other identified populations at risk are protected. Comatose patients and individuals with mental or emotional disabilities are also included. Such protection extends beyond physical assault to other areas of safety, such as abuse, negligent care, withholding of services, or providing assistance in the event of a fire. (*Also see* FMS.5 and FMS.8)

### Measurable Elements of PCC.1.5

- ❑ 1. The hospital develops and implements a process to protect all patients from assault.
- ❑ 2. The hospital identifies vulnerable populations with additional risks of assault.
- ❑ 3. The hospital develops and implements a process to protect vulnerable populations from other safety issues.
- ❑ 4. The hospital monitors remote or isolated areas of the facility.

# Standard PCC.2

Patients and families are engaged in all aspects of their medical care and treatment through education and participation in care and treatment decisions and care processes. Ⓟ

## Intent of PCC.2

Patients and families become engaged in their health care process by making decisions about care, asking questions about care, requesting a second opinion, and even refusing diagnostic procedures and treatments. (*Also see* COP.7) For patients and families to participate in care decisions, they need basic information about the medical conditions found during assessment, including any confirmed diagnosis, and the proposed care and treatment. The hospital plans and offers education to patients (and, when applicable, their families) to ensure they are able to participate in care decisions and care for themselves after discharge. When patients are engaged in the decision-making process, they and their health care providers can collaboratively make better decisions regarding the patient's health, which can lead to improved patient outcomes. (*Also see* MOI.6)

During the care process patients have a right to be told of the expected outcomes of the planned care and treatment. In addition, when an unanticipated event or outcome has occurred during their care or treatment, it is important that they also be informed of that event. (*Also see* PCI.8.1) Unanticipated events may include hospital-acquired infections, pressure ulcers, or postoperative infections. Patients and families understand that they have a right to this information and who is responsible for telling them. For patients, it should be clear who will provide them with the information about their medical condition, care, treatment, outcomes, unanticipated events, and the like. (*Also see* PCC.4.1 and COP.8.5)

Patients and families understand the type of decisions that must be made about care and how to participate in those decisions. Although some patients may not wish to personally know a confirmed diagnosis or to participate in the decisions regarding their care, they are given the opportunity and can choose to participate through a family member, a friend, or a surrogate decision maker. (*Also see* ACC.2.2 and PCC.4.3)

When a patient requests a second opinion, it is expected that the hospital will not prohibit, prevent, or obstruct the patient's efforts but rather will facilitate the second opinion by providing the patient with information about his or her condition, such as test results, diagnosis, recommendations for treatment, and the like. The hospital must not withhold this information if a patient requests it for a second opinion. The hospital is not expected to provide and pay for a second opinion when requested by the patient. Policies address the patient's right to seek a second opinion without fear of compromise to his or her care within or outside the hospital.

The hospital supports and promotes patient and family involvement in all aspects of care. All staff members are trained on the policies and procedures and on their role in supporting patients' and families' rights to participate in the care process.



## Measurable Elements of PCC.2

- ❑ 1. The hospital supports and promotes patient and family engagement through participation in care processes and in decision making to the extent they wish.
- ❑ 2. Participation in the care process includes educating patients and family about their medical conditions, any confirmed diagnosis, and the planned care and treatment(s).
- ❑ 3. Patients are informed about the expected outcomes of care and treatment.
- ❑ 4. Patients are told of any unanticipated outcomes that may have occurred during the course of their care and treatment.
- ❑ 5. The hospital facilitates a patient's request to seek a second opinion without fear of compromise to his or her care within or outside the hospital.

## Standard PCC.2.1

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.2.1

Patients, or those making decisions on their behalf, may decide not to proceed with the planned care or treatment or to discontinue care or treatment after it has been initiated. Among the most difficult decisions for patients and their families (and for health care practitioners and the hospital as well) are those that involve withholding resuscitative services or forgoing or withdrawing life-sustaining treatment. No single process can anticipate all the situations in which such decisions must be made. For this reason, it is important for the hospital to develop a framework for making these difficult decisions. The framework

- helps the hospital identify its position on these issues;
- ensures that the hospital's position conforms to 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; and
- guides health care practitioners through the ethical and legal issues in carrying out such patient wishes.

To ensure that the decision-making process related to carrying out the patient's wishes is applied consistently, the hospital develops policies and procedures through a process that includes 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.2.1

- ❑ 1. The hospital identifies its position on withholding resuscitative services and forgoing or withdrawing life-sustaining treatments.
- ❑ 2. The hospital's position conforms to 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 such 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 guides health care practitioners on the ethical and legal considerations in carrying out patient wishes regarding treatment alternatives.

## Standard PCC.2.2

The hospital supports the patient's right to assessment and management of pain and respectful compassionate care at the end of life.

### Intent of PCC.2.2

Pain is a common part of the patient experience, and unrelieved pain has adverse physical and psychological effects. A patient's response to pain is frequently within the context of societal norms and cultural and religious traditions. Thus, patients are encouraged and supported in their reporting of pain.

Dying patients have unique needs that may also 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. To accomplish this, all staff members are made aware of patients' unique needs at the end of life. These needs include treatment of primary and secondary symptoms; pain management; response to the patient's and family's psychological, social, emotional, religious, and cultural concerns; and involvement in care decisions.

The hospital's care processes recognize and reflect the right of all patients to assessment and management of pain and assessment and management of a patient's unique needs at the end of life. (*Also see* COP.6 and COP.7)

### Measurable Elements of PCC.2.2

- ❑ 1. The hospital respects and supports the patient's right to assessment and management of pain.
- ❑ 2. The hospital respects and supports the patient's right to assessment and management of the dying patient's needs.
- ❑ 3. The hospital's staff understand the personal, cultural, and societal influences on the patient's experiences with pain.
- ❑ 4. The hospital's staff understand the personal, cultural, and societal influences on the patient's experiences with death and dying.

## Standard PCC.3

The hospital measures, analyzes, and—when necessary—improves the patient experience in order to enhance the quality of patient care. Ⓟ

### Intent of PCC.3

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. Evaluating the patient experience along with other elements of patient care, such as safety and effectiveness, provides more complete information about the quality of patient care.

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. (*Also see* QPS.4)

Measuring patient satisfaction is one way to capture patient experience information. However, hospital leaders need to be aware that patient satisfaction is a subjective measure, while patient experience is an objective measure. (*Also see* GLD.5) **For example**, asking patients if they were pleased with the room layout would be a patient satisfaction measure because preference on a room layout is subjective. Asking patients if they have access to their health care records is a measure of patient experience because patient data access is an objective measure. As an integral component of health care quality, patient experience includes several aspects of health care delivery that patients value highly when they seek and receive care, such as timely appointments, easy access to information, and good communication with health care providers.

Patient satisfaction measures that have an impact on patient care can be used to obtain initial patient experience data and meet the expectations of this standard. When patient satisfaction measures are used, hospital leaders should continuously enhance data collection to eventually identify patient experience information for meaningful improvement.

### Measurable Elements of PCC.3

- ❑ 1. Leadership develops and implements a process for assessing the patient experience and its impact on patient care.
- ❑ 2. Data from the patient experience are aggregated, analyzed, and transformed into information to identify strategies for improving the patient experience.
- ❑ 3. Leadership determines a priority area for improving the patient experience that will positively impact patient care.
- ❑ 4. Identified strategies for improving the patient experience are implemented.
- ❑ 5. Improvements to the patient experience are analyzed and revised in order to optimize their impact on quality of patient care.

## Standard PCC.3.1

The hospital informs patients and families about its process to receive and to act on complaints, conflicts, and differences of opinion about patient care and the patient's right to participate in these processes. Ⓟ

### Intent of PCC.3.1

Patients have a right to voice complaints about their care and to have those complaints reviewed and, when possible, resolved. Also, decisions regarding care sometimes present questions, conflicts, or other dilemmas for the hospital and the patient, family, or other decision makers. These dilemmas may arise from issues of access, treatment, or discharge. They can be particularly difficult to resolve when the issues involve, **for example**, withholding resuscitative services or forgoing or withdrawing life-sustaining treatment.

The hospital has established processes for seeking resolution of such dilemmas and complaints. (*Also see* APR.11) The hospital identifies in policies and procedures those who need to be involved in the processes and how the patient and family participate. (*Also see* SQE.11)

### Measurable Elements of PCC.3.1

- ❑ 1. Patients are informed about the process for voicing complaints, conflicts, and differences of opinion.
- ❑ 2. Complaints, conflicts, and differences of opinion are investigated by the hospital.
- ❑ 3. Complaints, conflicts, and differences of opinion that arise during the care process are resolved.
- ❑ 4. Patients and families participate in the resolution process.

# *Patient Consent Process*

## Standard PCC.4

General consent for treatment, if obtained when a patient is admitted as an inpatient or is registered for the first time as an outpatient, is clear in its scope and limits. Ⓟ

### Intent of PCC.4

Many hospitals obtain a general consent (rather than rely on implied consent) for treatment when the patient is admitted as an inpatient to the hospital or when the patient is registered for the first time as an outpatient. When a general consent is obtained, patients are given information on the scope of the general consent, such as which tests and treatments are included under the general consent. The hospital defines how a general consent is documented in the patient's medical record.

Whether or not a general consent is obtained, all patients are given information about those tests and treatments for which a separate informed consent will be obtained. In addition, all patients receive information about the likelihood of students (such as nursing students, physical therapy students, and others) and medical students and trainees participating in care processes.

### Measurable Elements of PCC.4

- ❑ 1. Patients and families are informed as to the scope of a general consent, when used by the hospital.
- ❑ 2. The hospital defines how a general consent, when used, is documented in the patient medical record.
- ❑ 3. Whether or not a general consent is obtained, all patients and families are informed about which tests and treatments require informed consent.
- ❑ 4. Whether or not general consent is obtained, all patients receive information about the likelihood of students and trainees participating in care processes.

## Standard PCC.4.1

Patient informed consent is obtained through a process defined by the hospital and carried out by trained staff in a manner and language the patient can understand. Ⓟ

### Intent of PCC.4.1

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 related to the planned care required for an informed decision. Informed consent may be obtained at several points in the care process. **For example**, informed consent can be obtained when the patient is admitted for inpatient care in the hospital and before certain procedures or treatments for which the risk is high. The consent process is clearly defined by the hospital in policies and procedures. Relevant laws and regulations are incorporated into the policies and procedures. (*Also see* GLD.17 and GLD.18)

Patients and families are informed as to which tests, procedures, and treatments require consent and how they can give consent (**for example**, given verbally, by signing a consent form, or through some other means). Education by hospital staff is provided to patients and families as part of the process of obtaining informed consent for treatment (**for example**, for surgery and anesthesia).

Patients and families understand who may, in addition to the patient, give consent. Designated staff members are trained to inform patients and to obtain and to document patient consent.

### Measurable Elements of PCC.4.1

- ❑ 1. The hospital develops and implements a clearly defined informed consent process and trains designated staff in that process.
- ❑ 2. The hospital educates patients about the informed consent process and when informed consent is required.
- ❑ 3. Patients learn about the process for granting informed consent in a manner and language that the patient understands.
- ❑ 4. Patients give informed consent consistent with the process.
- ❑ 5. There is a uniform recording of informed consent.
- ❑ 6. The identity of the individual providing the information to the patient and family is documented in the patient's medical record.

## Standard PCC.4.2

Informed consent is obtained before surgery, anesthesia, procedural sedation, use of blood and blood products, and other high-risk treatments and procedures. Ⓟ

### Intent of PCC.4.2

When the planned care includes surgical or invasive procedures, anesthesia, procedural sedation, use of blood and blood products, or other high-risk treatments or procedures, a separate consent is obtained. (*Also see* COP.3.4; ASC.3.3; ASC.5; and ASC.7.1) This consent process provides the information identified in PCC.4.3 and documents the identity of the individual providing the information. (*Also see* COP.8.5 and COP.9.1)

Not all treatments and procedures require a specific, separate consent. Each hospital identifies those high-risk procedures and treatments for which consent must be obtained. (*Also see* COP.3) The hospital lists these procedures and treatments and educates staff to ensure that the process to obtain consent is consistent. The list is developed collaboratively by those physicians and others who provide the treatments or perform the procedures. The list includes procedures and treatments provided on an outpatient basis and inpatient basis.

### Measurable Elements of PCC.4.2

- ❑ 1. Consent is obtained before diagnostic or therapeutic surgical or invasive procedures.
- ❑ 2. Consent is obtained before anesthesia and procedural sedation.
- ❑ 3. Consent is obtained before the use of blood and blood products.
- ❑ 4. The hospital lists those additional procedures and treatments that require separate consent.
- ❑ 5. Consent is obtained before the additional and/or other high-risk procedures and treatments.

## Standard PCC.4.3

Patients and families receive adequate information about the patient's condition, proposed treatment(s) or procedure(s), and health care practitioners so that they can grant consent and make care decisions.

### Intent of PCC.4.3

When informed consent is required for the treatment(s) or procedure(s), the following elements are included in the informed consent process and explained to the patient prior to obtaining consent:

a) The patient's condition

b) The proposed treatment(s) or procedure(s)
c) The name of the person providing the treatment
d) Potential benefits and drawbacks
e) Possible alternatives
f) The likelihood of success
g) Possible problems related to recovery
h) Possible results of nontreatment

When informed consent is not required, staff members clearly explain the proposed treatment(s) or procedure(s) to the patient and family. The information provided includes elements a) through h) as relevant to the patient's condition and planned treatment. (*Also see* ASC.5)

Staff members inform the patient of the name of the physician or other practitioner who has primary responsibility for the patient's care or who is authorized to perform the patient's treatment(s) or procedure(s). Frequently, patients have questions about their primary practitioners' experience, length of time with the hospital, and the like. The hospital needs to have a process for responding to patients when they request additional information about the practitioner responsible for their care.

### Measurable Elements of PCC.4.3

- ❑ 1. Patients are informed of elements a) through h) in the intent as part of the informed consent process when informed consent is required for the treatment(s) or procedure(s).
- ❑ 2. When informed consent is not required, patients are informed of elements a) through h) in the intent as relevant to their condition and planned treatment(s) or procedure(s).
- ❑ 3. Patients know the identity of the physician or other practitioner responsible for their care.
- ❑ 4. The hospital develops and implements a process to respond to a patient's request for additional information about the physician or other practitioner responsible for his or her care.



## Standard PCC.4.4

The hospital establishes a process, within the context of existing law and culture, for when others can grant consent.

### Intent of PCC.4.4

Informed consent for care sometimes requires that people other than (or in addition to) the patient be involved in decisions about the patient's care. This is particularly true when the patient does not have the mental or physical capacity to make care decisions, when culture or custom requires that others make care decisions, or when the patient is a child. When the patient cannot make decisions about his or her care, a surrogate decision maker is identified. When someone other than the patient gives consent, that individual is noted in the patient's medical record.

### Measurable Elements of PCC.4.4

- ❑ 1. The hospital develops and implements a process for when others can grant informed consent.
- ❑ 2. The process respects law, culture, and custom.
- ❑ 3. The patient's medical record lists the individual(s) granting consent.

## *Patient and Family Education*

# Standard PCC.5

The hospital provides an education program that is based on its mission, services provided, and patient population, and health care practitioners collaborate to provide education.

### Intent of PCC.5

Each hospital builds education into care processes based on its mission, services provided, and patient population. The hospital chooses how it organizes its educational resources in an efficient and effective manner. Thus, the hospital may choose to appoint an education coordinator or education committee, create an education service, or simply work with all staff to provide education in a coordinated manner.

When health care practitioners understand one another's contributions to patient education, they can collaborate more effectively. Collaboration, in turn, helps ensure that the information patients and families receive is comprehensive, consistent, and as effective as possible. Collaboration is based on the patient's needs and therefore may not always be necessary. Knowledge of the subject matter, sufficient time, and ability to communicate effectively are important considerations in providing valuable and successful education.

### Measurable Elements of PCC.5

- ❑ 1. The hospital plans education consistent with its mission, services, and patient population.
- ❑ 2. There is an established structure or mechanism and adequate resources for education throughout the hospital.
- ❑ 3. Patient and family education are provided collaboratively when indicated.
- ❑ 4. Those who provide the education have the subject knowledge and communication skills to do so.
- ❑ 5. Those who provide the education have the resources and time to do so.

# Standard PCC.5.1

Each patient's educational needs and ability and willingness to learn are assessed and recorded in his or her medical record.

### Intent of PCC.5.1

Education focuses on the specific knowledge and skills the patient and family will need to make care decisions, participate in his or her care, and continue care at home. This is in contrast to the general flow of information between staff and the patient that is informative but not of an educational nature.

To understand the educational needs of each patient and his or her family, there is an assessment process that identifies the types of surgeries, other invasive procedures, and treatments planned; the accompanying nursing needs; and the continuing care needs following discharge. This assessment permits the patient's caregivers to plan and to deliver the needed education. When the educational needs are identified, they are recorded in the patient's medical record. This helps all of the patient's caregivers participate in the education process.

Patient education is an important aspect of patient care, and a great deal of information is provided to patients during their hospitalization. There are many patient variables that determine if the patient and family are willing and capable to learn. Patients and families can experience barriers to learning that may include the patient's literacy level, culture, language, motivation, and physical limitations. Because everyone learns

differently, health care practitioners involved in patient education need to evaluate the patient's learning needs and readiness to learn.

Education by hospital staff is provided to patients and families to support decisions in the care process and documented in the patient medical record. **For example**, education provided as part of the process of obtaining informed consent for treatment (such as for surgery and anesthesia) is documented in the patient's medical record. In addition, when a patient or family directly participates in providing care (such as changing dressings, feeding the patient, administering medications and treatments), the patient and family are educated, and the education is documented. Each hospital decides the location and format for documenting educational assessment, planning, and delivery of information in the patient's medical record.

### Measurable Elements of PCC.5.1

- ❑ 1. Each patient's and, when appropriate, family's educational needs are assessed and recorded in the patient's medical record.
- ❑ 2. The patient's and family's barriers to learning are assessed and documented.
- ❑ 3. Education by hospital staff is provided to patients and families in a manner that accommodates their identified needs.
- ❑ 4. Education provided to patients and families is documented in the patient medical record.

## Standard PCC.5.2

Education methods take into account the patient's and family's values and preferences and allow sufficient interaction among the patient, family, and staff for learning to occur.

### Intent of PCC.5.2

Learning occurs when attention is paid to the methods used to educate patients and families. Understanding patients and families helps the hospital select educators and educational methods consistent with the patients' and families' values and preferences and to identify the families' roles and the instruction method. Patients and their families are encouraged to participate in the care process by speaking up and asking staff questions to ensure correct understanding and anticipated participation. Staff recognize the important role patients play in the provision of safe, high-quality care. The opportunity for interaction among staff, the patient, and his or her family permits feedback to ensure that the information is understood, useful, and usable. The hospital decides when and how verbal education is reinforced with written materials to enhance understanding and to provide a future educational reference.

### Measurable Elements of PCC.5.2

- ❑ 1. The education process takes into account the patient's and family's values and learning preferences.
- ❑ 2. There is a process to verify that patients and families receive and understand the education provided.
- ❑ 3. Those who provide education encourage patients and their families to ask questions and to speak up as active participants.
- ❑ 4. Verbal information is reinforced with written material that is related to the patient's needs and consistent with the patient's and family's learning preferences.

## Organ and Tissue Donation Information

**Note:** The following standards are intended to be used in situations in which organ or tissue transplantation will not occur but during those times 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 (found in COP.8 through COP.9.3) apply.

# Standard PCC.6

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

# Standard PCC.6.1

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

### Intent of PCC.6 and PCC.6.1

The shortage of available organs for transplant has encouraged many countries to develop procedures and systems to increase that supply. In some countries, laws determine that everyone is a donor unless specified otherwise (which is considered presumed consent). In other countries, explicit consent for organ donation is required. The hospital is responsible for defining the process of obtaining and recording consent for cell, tissue, and organ donation in relation to international ethical standards and the manner in which 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 manner in which organ procurement is organized for the community, region, or nation (such as a national or regional organ procurement agency or network).

The shortage of organs for transplant has resulted in questionable practices in the procurement and transplantation of organs. The practice of inducing vulnerable individuals or groups (such as illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees) to become living donors, organ trafficking (the buying and selling of organs over black market trade), the harvesting of organs without consent from executed prisoners or dead patients, and transplant tourism are inconsistent with ensuring organ donor and recipient safety.

Oversight for the process of organ and tissue procurement includes defining the donation process that is consistent with laws and regulations, respecting the community's religious and cultural values, ensuring ethical practices, and identifying requirements for consent. Hospital staff are trained on the donation process that supports patient and family choices. Staff are also trained in the 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. (*Also see* COP.9)

### Measurable Elements of PCC.6

- ❑ 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.

## Measurable Elements of PCC.6.1

- ❑ 1. The hospital defines the organ- and tissue-donation processes and ensures that the process is consistent with the region's laws and regulations and its religious and cultural values.
- ❑ 2. The hospital identifies consent requirements and develops a consent process consistent with those requirements.
- ❑ 3. Staff are trained in the issues and concerns related to organ donation 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.

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# 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.

**AOP.1** All patients cared for by the hospital have their health care needs identified through an assessment process that has been defined by the hospital. Ⓟ

**AOP.1.1** Each patient's initial assessment includes a physical examination and health history as well as an evaluation of psychological, spiritual/cultural (as appropriate), social, and economic factors.

**AOP.1.2** The patient's medical and nursing needs are identified from the initial assessments, which are completed and documented in the medical record within the first 24 hours after admission as an inpatient or earlier as indicated by the patient's condition. Ⓟ

**AOP.1.2.1** The initial medical and nursing assessments of emergency patients are based on their needs and conditions. Ⓟ

**AOP.1.3** The hospital has a process for accepting initial medical assessments conducted in a physician's private office or other outpatient setting prior to admission or outpatient procedure.

**AOP.1.3.1** A preoperative medical assessment is documented before anesthesia or surgical treatment and includes the patient's medical, physical, psychological, social, economic, and discharge needs.

**AOP.1.4** Patients are screened for nutritional status, functional needs, and other special needs and are referred for further assessment and treatment when necessary.

**AOP.1.5** All inpatients, and those outpatients whose condition, diagnosis, or situation may indicate they are at risk for pain, are screened for pain and assessed when pain is present.

**AOP.1.6** Individualized medical and nursing initial assessments are performed for special populations cared for by the hospital. Ⓟ

**AOP.1.7** The initial assessment includes determining the need for discharge planning. Ⓟ

**AOP.2** All patients are reassessed at intervals based on their condition and treatment to determine their response to treatment and to plan for continued treatment or discharge. Ⓟ

**AOP.3** Qualified individuals conduct the assessments and reassessments. Ⓟ

**AOP.4** Medical, nursing, and other individuals and services responsible for patient care collaborate to analyze and integrate patient assessments and prioritize the most urgent/important patient care needs.

## Laboratory Services

**AOP.5** Laboratory services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.

**AOP.5.1** A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff have the required education, training, qualifications, and experience to administer and perform the tests and interpret the results. Ⓟ

**AOP.5.2** A qualified individual is responsible for the oversight and supervision of the point-of-care testing program. Ⓟ

**AOP.5.3** A laboratory safety program is in place, followed, and documented, and compliance with the facility management and infection prevention and control programs is maintained. Ⓟ

**AOP.5.3.1** The laboratory uses a coordinated process to reduce the risks of infection as a result of exposure to infectious diseases and biohazardous materials and waste. Ⓟ

**AOP.5.4** Laboratory results are available in a timely way as defined by the hospital. Ⓟ

**AOP.5.5** All equipment used for laboratory testing is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities. Ⓟ

**AOP.5.6** Essential reagents and supplies are available, and all reagents are evaluated to ensure accuracy and precision of results. Ⓟ

**AOP.5.7** Procedures for collecting, identifying, handling, safely transporting, and disposing of specimens are established and implemented. Ⓟ

**AOP.5.8** Established norms and ranges are used to interpret and to report clinical laboratory results.

**AOP.5.9** Quality control procedures for laboratory services are in place, followed, and documented. Ⓟ

**AOP.5.9.1** There is a process for proficiency testing of laboratory services. Ⓟ

**AOP.5.10** Reference/contract laboratories used by the hospital are licensed and accredited or certified by a recognized authority.

**AOP.5.10.1** The hospital identifies measures for monitoring the quality of the services to be provided by the reference/contract laboratory.

## Blood Bank and/or Transfusion Services

**AOP.5.11** 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. Ⓟ

## Radiology and Diagnostic Imaging Services

**AOP.6** Radiology and diagnostic imaging services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.

**AOP.6.1** 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.6.2** A radiation and/or diagnostic imaging safety program for patients, staff, and visitors is in place, is followed, and is compliant with applicable professional standards, laws, and regulations. Ⓟ

**AOP.6.3** Radiology and diagnostic imaging study results are available in a timely way as defined by the hospital. Ⓟ

**AOP.6.4** 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.6.5** Quality control procedures are in place, followed, validated, and documented. Ⓟ

**AOP.6.6** The hospital regularly reviews quality control results for all outside contracted sources of diagnostic services.

# Standards, Intents, and Measurable Elements

## Standard AOP.1

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

### Intent of AOP.1

An effective patient-assessment process results in decisions about the patient's immediate and continuing 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 his or her health history
2) Analyzing the data and information, including the results of laboratory and imaging diagnostic tests, to identify the patient's health care needs
3) Developing a plan of care to meet the patient's identified needs

When a patient has been registered or admitted to a hospital for inpatient or outpatient care/treatment, whether in-person or through virtual means, a complete assessment needs to be performed related to the reason(s) the patient has come for care. The specific information the hospital requires at this stage, and the procedures for getting it, depend on the patient's needs and the setting in which care is being provided (**for example**, inpatient or outpatient care). Hospital policies and procedures define how this process functions and what information needs to be gathered and documented. (*Also see* ACC.1)

To consistently assess patient needs, the hospital defines, in policies, the minimum content of assessments to be performed by physicians, nurses, and other clinical disciplines. Assessments are performed by each discipline within its scope of practice, licensure, applicable laws and regulations, or certification. Only qualified individuals conduct the assessments. (*Also see* SQE.10) Any assessment forms used for assessments reflect this policy. The hospital defines assessment activities in both inpatient and outpatient settings in which care is provided. The hospital defines those elements common to all assessments and defines any differences, when permitted, in the scope of general medical and specialty services assessments. The assessment defined in policy may be completed by more than one qualified individual and at different points in time. All the content must be available when treatment is initiated. (*Also see* AOP.1.2 and AOP.1.2.1)

### Measurable Elements of AOP.1

- ❑ 1. The hospital defines the minimum content of assessments for inpatients for each clinical discipline that performs assessments and specifies the required elements of the history and physical examination.
- ❑ 2. The hospital defines the minimum content of assessments for outpatients for each clinical discipline that performs assessments and specifies the required elements of the history and physical examination.
- ❑ 3. Only qualified individuals permitted by licensure, applicable laws and regulations, or certification perform the assessments.
- ❑ 4. The hospital identifies the information to be documented for the assessments.

## Standard AOP.1.1

Each patient's initial assessment includes a physical examination and health history as well as an evaluation of psychological, spiritual/cultural (as appropriate), social, and economic factors.

### Intent of AOP.1.1

The initial assessment of a patient, outpatient or inpatient, is critical to identifying his or her needs and starting the care process. The initial assessment provides information to

- understand the care the patient is seeking;
- select the best care setting for the patient;
- form an initial diagnosis; and
- understand the patient's response to any previous care.

To provide this information, the initial assessment includes an evaluation of the patient's medical status through a physical examination and health history that includes a listing of the patient's current medications and known allergies. (*Also see* MMU.4) In addition, as appropriate to the patient's needs, the following assessments may also be performed:

a) An initial psychological assessment as indicated by the patient's condition
b) An initial social and economic assessment, as indicated by the patient's needs
c) An initial spiritual and cultural assessment, as indicated by the patient's needs

The psychological assessment determines the patient's emotional status (**for example**, if he or she is depressed, fearful, or belligerent and may harm him- or herself or others). Gathering social information on a patient is not intended to "classify" the patient. Rather, a patient's social, cultural, spiritual, family, and economic contexts are important factors that can influence his or her response to illness and treatment. Families can be very helpful in these areas of assessment and in understanding the patient's wishes and preferences in the assessment process. Economic factors are assessed as part of the social assessment or assessed separately when the patient and his or her family will be responsible for the cost of all or a portion of the care while an inpatient or following discharge. Many different qualified individuals may be involved in the assessment of a patient. The most important factors are that the assessments are complete and available to those caring for the patient. (*Also see* ACC.3)

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

### Measurable Elements of AOP.1.1

❑ 1. All inpatients and outpatients have an initial assessment that includes a health history and physical examination consistent with the requirements defined in hospital policy.

❑ 2. The assessment includes a listing of the patient's current medications and known allergies.

❑ 3. The assessment includes a) through c) in the intent, as indicated by his or her needs.

❑ 4. The initial assessment results in an initial diagnosis.

## Standard AOP.1.2

The patient's medical and nursing needs are identified from the initial assessments, which are completed and documented in the medical record within the first 24 hours after admission as an inpatient or earlier as indicated by the patient's condition. Ⓟ

## Standard AOP.1.2.1

The initial medical and nursing assessments of emergency patients are based on their needs and conditions. Ⓟ

### Intent of AOP.1.2 and AOP.1.2.1

The primary outcome from the patient's initial assessments is an understanding of the patient's medical and nursing needs so care and treatment can begin. To accomplish this, the hospital determines the minimum content of the initial medical and nursing and other assessments (*also see* AOP.1), the time frame for completion of assessments, and the documentation requirements for assessments (*also see* AOP.1.3). Although the medical and nursing assessments are primary to the initiation of care, there may be additional assessments by other health care practitioners, including special assessments (*also see* AOP.1.4 and AOP.1.5) and individualized assessments (*also see* AOP.1.6). These assessments must be integrated and the most urgent care needs identified. (*Also see* AOP.4)

The initial medical and nursing assessments are completed within 24 hours of admission to the hospital and available for use by all those caring for the patient. When the patient's condition indicates, the initial medical and nursing assessment is conducted and available earlier. Thus, emergency patients are assessed immediately, and policy may define that certain other patient groups are assessed sooner than 24 hours.

In an emergency, the initial medical and nursing assessments may be limited to the patient's apparent needs and condition. Also, when there is no time to record the complete history and physical examination of an emergency patient requiring surgery, a brief note and the preoperative diagnosis are recorded before surgery. (*Also see* ASC.7 and MOI.8.1)

### Measurable Elements of AOP.1.2

- ❑ 1. The initial medical assessment, including health history, physical exam, and other assessments required by the patient's condition, is performed and documented within the first 24 hours of admission as an inpatient or sooner as required by patient condition.
- ❑ 2. The initial medical assessment results in a list of specific medical diagnoses that includes primary and associated conditions requiring treatment and monitoring.
- ❑ 3. The initial nursing assessment is performed and documented within the first 24 hours of admission as an inpatient or sooner as required by patient condition.
- ❑ 4. The initial nursing assessment results in a list of specific patient nursing needs or conditions that require nursing care, interventions, or monitoring.

### Measurable Elements of AOP.1.2.1

- ❑ 1. The medical assessment of emergency patients is based on their needs and condition and documented in the patient medical record.
- ❑ 2. The nursing assessment of emergency patients is based on their needs and condition and documented in the patient medical record.
- ❑ 3. Before surgery is performed, there is at least a brief note and preoperative diagnosis documented for emergency patients requiring emergency surgery.

## Standard AOP.1.3

The hospital has a process for accepting initial medical assessments conducted in a physician's private office or other outpatient setting prior to admission or outpatient procedure.

### Intent of AOP.1.3

When the initial medical assessment is conducted in a physician's private office or other outpatient setting prior to care in the hospital as an inpatient or prior to an outpatient procedure such as same-day surgery, it must be within the previous 30 days. If, at the time of admission as an inpatient or at the time of the outpatient procedure, the medical assessment is greater than 30 days old, the medical history must be updated and the physical examination repeated. For medical assessments performed and documented 30 days or less prior to admission as an inpatient or prior to an outpatient procedure, any significant changes in the patient's condition since the assessment, or "no change" if appropriate, are documented at admission. This updating and/or reexamination can be accomplished by any qualified individual.

When an assessment is partially or entirely completed outside the hospital (**for example**, in a consultant surgeon's office), the findings are reviewed and/or verified at admission as an inpatient or prior to the outpatient procedure, as appropriate to the time between the outside assessment and admission, the critical nature of the findings, the complexity of the patient, and the planned care and treatment (**for example**, the review confirms the clarity of the diagnosis and any planned procedures or treatments, the presence of radiographs needed in surgery, and any change[s] in the patient's condition such as control of blood sugar; it also identifies any critical lab tests that may need repeating). (*Also see* AOP.4)

### Measurable Elements of AOP.1.3

- ❑ 1. Initial medical assessments conducted prior to admission to inpatient status or prior to an outpatient procedure in the hospital are less than or equal to 30 days old.
- ❑ 2. For assessments less than or equal to 30 days old, any significant 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 as an inpatient or prior to an outpatient procedure.
- ❑ 3. If the medical assessment is greater than 30 days old at the time of admission as an inpatient or prior to an outpatient procedure, the medical history is updated and the physical examination repeated.
- ❑ 4. The findings of all assessments performed outside the hospital are reviewed and/or verified at the time of admission to inpatient status or prior to an outpatient procedure.

## Standard AOP.1.3.1

A preoperative medical assessment is documented before anesthesia or surgical treatment and includes the patient's medical, physical, psychological, social, economic, and discharge needs.

### Intent of AOP.1.3.1

The *preoperative medical assessment* is a clinical risk assessment that assesses the health of a patient to determine if the patient is safe to undergo the anesthesia and surgery.

The initial preoperative medical assessment includes the patient's medical, physical, psychological, social, and economic needs prior to surgery. In addition, assessing the patient for any potential care needs following discharge is a valuable component of the preoperative medical assessment. (*Also see* ASC.7)

Results of the medical assessment and of any diagnostic tests, along with potential patient needs following discharge, are recorded in the patient's medical record before anesthesia or surgery.

### Measurable Elements of AOP.1.3.1

- ❑ 1. A preoperative medical assessment is performed before surgery for all patients for whom surgery is planned.
- ❑ 2. The preoperative medical assessment includes the patient's medical, physical, psychological, social, economic, and discharge needs.
- ❑ 3. The preoperative medical assessment of surgical patients is documented in the medical record before surgery.

## Standard AOP.1.4

Patients are screened for nutritional status, functional needs, and other special needs and are referred for further assessment and treatment when necessary.

### Intent of AOP.1.4

The information gathered at the initial medical and/or nursing assessment, through the application of screening criteria, may indicate that the patient needs further or more in-depth assessment of nutritional status or functional status, including a fall risk assessment. (*Also see* IPSG.6) The more in-depth assessment may be necessary to identify those patients in need of nutritional interventions and patients in need of rehabilitation services or other services related to their ability to function independently or at their greatest potential.

The most effective way to identify patients with nutritional or functional needs is through screening criteria. Screening generally involves performing a very simple, high-level evaluation of a patient to determine if the patient exhibits a risk that might indicate the need for a more in-depth assessment. **For example**, the initial nursing assessment form may contain basic criteria for a nutritional screen, such as five or six simple questions with a numerical score relating to recent decline in food intake, weight loss during the past three months, mobility, and the like. The patient's total score would then identify a patient at nutritional risk requiring a more in-depth nutritional assessment.

In each case, the screening criteria are developed by qualified individuals able to further assess and, if necessary, to provide any required patient treatment. **For example**, screening criteria for nutritional risk may be developed by nurses who will apply the criteria, dietitians who will supply the recommended dietary intervention, and nutritionists able to integrate nutritional needs with the other needs of the patient. (*Also see* COP.5 and COP.5.1) The screening criteria are implemented consistently throughout the hospital where needed.

The information gathered at the initial medical and/or nursing assessment may also identify a need for other assessments, such as dental, hearing, vision, and so on. (*Also see* AOP.1.2 and AOP.1.2.1) The hospital refers the patient for further assessments within the hospital when available, or through the community following discharge.

### Measurable Elements of AOP.1.4

- ❑ 1. Qualified individuals develop screening criteria to identify patients who require further nutritional assessment, and the criteria are implemented consistently throughout the hospital where needed.
- ❑ 2. Patients at risk for nutritional problems receive a nutritional assessment.
- ❑ 3. Qualified individuals develop screening criteria to identify patients who require further functional assessment, and the criteria are implemented consistently throughout the hospital where needed.
- ❑ 4. Patients in need of a functional assessment are referred for such an assessment.
- ❑ 5. When the need for additional specialized assessments is identified, patients are referred within the hospital or outside the hospital.
- ❑ 6. Specialized assessments conducted within the hospital are completed and documented in the patient's medical record.

## Standard AOP.1.5

All inpatients, and those outpatients whose condition, diagnosis, or situation may indicate they are at risk for pain, are screened for pain and assessed when pain is present.

### Intent of AOP.1.5

A screening procedure is used to identify patients with pain. A screening is a very high-level process that can be performed by clinicians, support staff (such as a registration clerk), or even the patient. A screening for pain may consist of one or more simple questions that can be asked during the registration process or on an intake form completed by the patient, or may be asked and documented by the physician referring the patient to the hospital or outpatient setting. **Examples** of questions that may be used in a screening exam 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?

Positive answers to questions such as these indicate the need for a more in-depth assessment of the patient's pain. When pain is identified in the outpatient setting, the patient may be more thoroughly assessed and treated in the hospital or provided with a referral for further assessment and treatment. The scope of treatment is based on the care setting and services provided. (*Also see* COP.6)

When the patient is an inpatient in the hospital, a more comprehensive assessment is performed as soon as pain is identified. This assessment is appropriate to the patient's age and measures pain intensity and quality, such as pain character, frequency, location, and duration. Additional information may include pain history, what makes pain better or worse, what are the patient's goals for pain relief, and the like. This assessment is recorded in a way that facilitates regular reassessment and follow-up according to criteria developed by the hospital and the patient's needs. (*Also see* AOP.1.2 and AOP.1.2.1)

### Measurable Elements of AOP.1.5

- ❑ 1. All inpatients are screened for pain and the screening is documented.
- ❑ 2. Outpatients whose condition, diagnosis, or situation may indicate they are at risk for pain are screened for pain.
- ❑ 3. When pain is identified in the inpatient, a comprehensive assessment of the patient's pain is performed.
- ❑ 4. The assessment is recorded in a way that facilitates regular reassessment and follow-up according to criteria developed by the hospital and the patient's needs.
- ❑ 5. When pain is identified in the outpatient, the patient may be more thoroughly assessed and treated in the outpatient setting or provided with a referral for further assessment and treatment.

## Standard AOP.1.6

Individualized medical and nursing initial assessments are performed for special populations cared for by the hospital. Ⓟ

### Intent of AOP.1.6

The initial assessment of certain types of patients or certain patient populations requires that the assessment process be modified. Such modification is based on the unique characteristics or needs of each patient population. Each hospital identifies those special patient groups and populations and modifies the assessment process to meet their special needs. In particular, when the hospital serves one or more of the special-needs patients or populations listed below, individualized medical and nursing assessments are performed:

- Infants
- Children
- Adolescents
- Frail elderly
- Terminally ill/dying patients
- Patients with intense or chronic pain
- Women in labor
- Women 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 receiving chemotherapy or radiation therapy
- Patients whose immune systems are compromised

The assessment of patients suspected of drug and/or alcohol dependency and the assessment of victims of abuse or neglect are shaped by the culture of the patient population. These assessments are not intended to be proactive case-finding processes. Rather, the assessment of these patients responds to their needs and condition in a culturally acceptable and confidential manner. The assessment process is modified to be consistent with local laws and regulations and professional standards related to such populations and situations and to involve the family when appropriate or necessary. (*Also see* AOP.1.2 and AOP.1.2.1)

### Measurable Elements of AOP.1.6

- ❑ 1. The hospital identifies, in writing, those special patient groups and populations it serves that require modifications to its assessment.
- ❑ 2. The assessment process for special-needs patient populations is modified to reflect their needs.
- ❑ 3. The modified assessment process is consistent with local laws and regulations and incorporates professional standards related to such populations.
- ❑ 4. Individualized medical and nursing assessments are performed and documented.

## Standard AOP.1.7

The initial assessment includes determining the need for discharge planning. Ⓟ

### Intent of AOP.1.7

Continuity of care requires special preparation and considerations for many patients, particularly as it relates to discharge planning. The process for developing a plan for discharge begins early in the assessment process. The initial assessment can help identify those patients for whom discharge planning is critical due to age, lack of mobility, continuing medical and nursing needs, or assistance with activities of daily living, among others. As arrangements for discharge may take some time, the assessment and planning processes are initiated as soon as possible after admission as an inpatient.

Discharge planning includes any special education the patient may require related to continuing care outside of the hospital. (*Also see* ACC.4.1; PCC.2; and PCC.5.1) **For example**, a newly diagnosed type 1 diabetic patient will need education related to diet and nutrition, as well as instruction on administration of insulin injections. A patient admitted for an acute myocardial infarction may need cardiac rehabilitation following discharge, as well as nutritional instruction. Successful discharges depend on effective planning.

### Measurable Elements of AOP.1.7

- ❑ 1. The hospital begins the discharge planning process early in the assessment process to identify those patients for whom discharge planning is critical.
- ❑ 2. Discharge planning includes identifying special needs and developing and implementing a plan to address those needs.
- ❑ 3. Patients, family as appropriate, and staff involved in the patient's care participate in the discharge planning process.

## Standard AOP.2

All patients are reassessed at intervals based on their condition and treatment to determine their response to treatment and to plan for continued treatment or discharge. Ⓟ

### Intent of AOP.2

Reassessment by all the patient's health care practitioners is key to understanding whether care decisions are appropriate and effective. Patients are reassessed throughout the care process at intervals based on their needs and plan of care or as defined in hospital policies and procedures. The results of these reassessments are noted in the patient's medical record for the information and use of all those caring for the patient.

Reassessment by a physician is integral to ongoing patient care. A physician assesses an acute care patient at least daily, including weekends, and when there has been a significant change in the patient's condition.

Reassessments are conducted and results are entered in the patient's medical record

- at regular intervals during care (**for example**, nursing staff periodically record vital signs, pain assessment, and lung and heart sounds, as needed based on the patient's condition);
- daily by a physician for acute care patients;
- in response to a significant change in the patient's condition; (*Also see* COP.3.2)
- if the patient's diagnosis has changed and the care needs require revised planning; and
- to determine if medications and other treatments have been successful and the patient can be transferred or discharged.

Some non-acute 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. The hospital identifies, in writing, those patients who do not require daily assessments.

### Measurable Elements of AOP.2

❑ 1. Patients are reassessed to determine their response to treatment and to plan for continued treatment and/or discharge.

❑ 2. Patients are reassessed at intervals based on their condition and when there has been a significant change in their condition, plan of care, or individual needs.

❑ 3. A physician reassesses patients at least daily, including weekends, during the acute phase of their care and treatment.

❑ 4. For non-acute patients, the hospital defines, in writing, the circumstances in which, and the types of patients or patient populations for which, a physician's assessment may be less than daily and identifies the minimum reassessment interval for these patients.

❑ 5. Reassessments are documented in the patient medical record.

## Standard AOP.3

Qualified individuals conduct the assessments and reassessments. Ⓟ

### Intent of AOP.3

The assessment and reassessment of patients are critical processes that require special education, training, knowledge, and skills. Thus, for each type of assessment, those individuals qualified to perform the assessment are identified and their responsibilities defined in writing. In particular, those individuals qualified to conduct emergency assessments or assessments of nursing needs are clearly identified. Assessments are performed by each discipline within its scope of practice, licensure, applicable laws and regulations, or certification. (*Also see* SQE.1.1 and SQE.10)

### Measurable Elements of AOP.3

❑ 1. Individuals qualified to conduct patient assessments and reassessments are identified and have their responsibilities defined in writing.

❑ 2. Only those individuals permitted by licensure, applicable laws and regulations, or certification perform patient assessments.

❑ 3. Emergency assessments are conducted by individuals qualified to do so.

❑ 4. Nursing assessments are conducted by individuals qualified to do so.

## Standard AOP.4

Medical, nursing, and other individuals and services responsible for patient care collaborate to analyze and integrate patient assessments and prioritize the most urgent/important patient care needs.

### Intent of AOP.4

A patient may undergo many kinds of assessments outside and inside the hospital by many different departments and services. As a result, there may be a variety of information, test results, and other data in the patient's record. (*Also see* AOP.1.3) A patient benefits most when the staff responsible for the patient work together to analyze the assessment findings and combine this information into a comprehensive picture of the patient's condition. From this collaboration, the patient's needs are identified, the order of their importance is established, and care decisions are made. Integration of findings at this point will facilitate the coordination of care provision. (*Also see* AOP.1.2 and AOP.1.2.1; and COP.2)

The process for working together is simple and informal when the patient's needs are not complex. Formal treatment team meetings, patient conferences, and clinical rounds may be needed for patients with complex or unclear needs. The patient, his or her family, and others who make decisions on the patient's behalf are included in the decision process when it is needed.

### Measurable Elements of AOP.4

- ❑ 1. Patient assessment data and information are analyzed and integrated.
- ❑ 2. Those responsible for the patient's care participate in the process.
- ❑ 3. Patient needs are prioritized based on assessment results.

## *Laboratory Services*

## Standard AOP.5

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

### Intent of AOP.5

The hospital has a system for providing laboratory services, including clinical pathology services, required by its patient population, clinical services offered, and health care practitioner needs. The laboratory services are organized and provided in a manner that meets applicable local and national standards, laws, and regulations.

Laboratory services, including those required for emergencies, may be provided within the hospital, by agreement with another organization, or both. Laboratory services are available after normal hours for emergencies. In addition, the hospital is able to identify and to contact 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.5

- ❑ 1. Laboratory services meet applicable local and national standards, laws, and regulations.
- ❑ 2. Laboratory services are available to meet the needs related to the hospital's mission and patient population, the community's health care needs, and emergency needs, including after normal hours.
- ❑ 3. Experts in specialized diagnostic areas are contacted when needed.
- ❑ 4. Outside sources are selected based on an acceptable record and compliance with laws and regulations.

## Standard AOP.5.1

A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service, and all laboratory staff have the required education, training, qualifications, and experience to administer and perform the tests and interpret the results. Ⓟ

### Intent of AOP.5.1

Clinical laboratory services are under the direction of an individual who is qualified by virtue of documented training, expertise, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the laboratory facility and the services provided in the laboratory as well as tests performed outside the laboratory, such as the testing performed at bedside (point-of-care testing). The oversight of services outside the laboratory includes ensuring consistent hospitalwide policies and practices, such as training and supply management, among others. It 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, he or she is a physician, preferably a pathologist. Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals. (*Also see* GLD.9) Responsibilities of the laboratory leader include

a) developing, implementing, and maintaining policies and procedures;
b) administrative oversight;
c) maintaining any necessary quality control program;
d) recommending outside sources of laboratory services; and
e) monitoring and reviewing all laboratory services.

The hospital identifies the education, training, qualifications, and experience of laboratory staff members performing and interpreting laboratory tests, those who are approved to perform point-of-care screening tests at the bedside, and those who direct or supervise staff who perform testing. Supervisory staff and technical staff are oriented to their work. Technical staff are given work assignments consistent with their training and experience. In addition, 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.

### Measurable Elements of AOP.5.1

- ❑ 1. The clinical laboratory, and other laboratory services throughout the hospital, are under the direction and oversight of one or more qualified individuals.
- ❑ 2. Responsibilities of the qualified laboratory leader include a) through e) of the intent.
- ❑ 3. All laboratory staff have the required education, training, and qualifications to administer, perform, and interpret tests.
- ❑ 4. A staffing program is implemented that allows staff to perform tests promptly and to provide staffing during all hours of operation and during emergencies.
- ❑ 5. Laboratory supervisory staff are identified and have the proper qualifications and experience.

## Standard AOP.5.2

A qualified individual is responsible for the oversight and supervision of the point-of-care testing program. Ⓟ

### Intent of AOP.5.2

*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.

When POCT is included in the hospital services, oversight and supervision for the services—regardless of where the services are performed—are provided by the individual responsible for managing the laboratory services or a designee. (*Also see* GLD.9) The hospital must have a clearly defined and well-structured approach to POCT to ensure that it is performed safely and correctly and that the results generated are accurate and reliable.

A POCT program includes thorough planning with leaders electing to implement POCT in their department/ward. Planning includes selection of tests to be performed, identification of staff who will be performing the test(s), and a protocol for reporting abnormal test results, including the process for reporting critical results. (*Also see* IPSG.2.1) Staff performing POCT require training for each test being performed, along with a competency evaluation to ensure that results are accurate. (*Also see* SQE.4)

Quality control performance, documentation, and evaluation are required to be performed within defined specifications recommended by the manufacturer; **for example**, on a daily basis or weekly basis, as well as between new batches of test kits. The quality control sample may be included with the test kit or may need to be purchased from the manufacturer or authorized representative. All staff performing POCT adhere to defined quality control procedures and understand what actions to take when the quality control sample is out of specification. (*Also see* AOP.5.9)

A POCT program should be monitored and evaluated in order to ensure that the program is meeting the needs of its customers (health care practitioners, testing staff, and patients). This may be accomplished by developing and monitoring quality improvement measures, through patient surveys and/or reviews of quality control and proficiency testing results, and utilization reports.

### Measurable Elements of AOP.5.2

- ❑ 1. The person responsible for managing the laboratory services, or a designee, provides oversight and supervision of the POCT program.
- ❑ 2. Staff performing point-of-care testing 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.
- ❑ 4. The POCT program includes quality control performance, documentation, and evaluation.
- ❑ 5. The POCT program is monitored and evaluated and included in quality improvement activities.

## Standard AOP.5.3

A laboratory safety program is in place, followed, and documented, and compliance with the facility management and infection prevention and control programs is maintained. Ⓟ

### Intent of AOP.5.3

The laboratory has an active safety program to the degree required by the risks and hazards encountered in the laboratory. The program addresses safety practices and prevention measures (**for example**, eyewash stations,

spill kits, and the like) for laboratory staff, other staff, and patients when present. The laboratory program is coordinated with the hospital's facility management and infection prevention and control programs.

The laboratory safety management program includes

- compliance with standards addressing facility management and infection prevention and control programs; (*Also see* PCI.2 and FMS.5)
- compliance with local and regional laws and regulations;
- availability of safety devices appropriate to the laboratory's practices and hazards encountered;
- the orientation of all laboratory staff to safety procedures and practices; (*Also see* SQE.7 and SQE.8) and
- in-service education for new procedures and newly acquired or recognized hazardous materials. (*Also see* FMS.7)

### Measurable Elements of AOP.5.3

❑ 1. A laboratory safety program addresses potential safety risks in the laboratory and other areas outside the laboratory where laboratory services are provided.

❑ 2. The laboratory safety program is part of the hospital's facility management program and reports to the hospital safety structure at least annually and when any safety events occur.

❑ 3. The laboratory safety program is part of the hospital's infection prevention and control program and reports to the infection prevention and control program at least annually and when any infection control events occur.

❑ 4. Identified safety risks are addressed by specific processes and/or devices to reduce the safety risks.

❑ 5. Laboratory staff are oriented to safety procedures and practices and receive ongoing education and training for new practices and procedures.

## Standard AOP.5.3.1

The laboratory uses a coordinated process to reduce the risks of infection as a result of exposure to infectious diseases and biohazardous materials and waste. Ⓟ

### Intent of AOP.5.3.1

There are policies, procedures, and practices implemented to reduce the hazards of exposure to biohazardous materials. Infections acquired in the laboratory are reported internally and, when appropriate, to public health agencies. The following biosafety hazards and practices are addressed in written procedures, and the requirements of the procedures are followed:

a) Exposures to aerosols and droplets are controlled (**for example**, when mixing, sonicating, centrifuging, and flaming inoculating loops).
b) Laboratory coats, gowns, or uniforms are worn to protect street clothes and prevent contamination.
c) Biosafety cabinets are used when required.
d) Rules govern how to handle laboratory exposure to infectious agents, accidental cuts, needlestick injuries, accidental ingestion, and contact of potentially infectious agents with mucus membranes. These rules include decontamination procedures, whom to contact for emergency treatment, and the location and use of safety equipment.
e) There are written procedures defining safe collection, transport, and handling of all specimens. The procedure includes prohibiting anyone in laboratory technical areas from eating, drinking, smoking, applying cosmetics, manipulating contact lenses, and mouth pipetting.
f) When relevant to their jobs, staff have received training about precautionary measures, modes of transmission, and prevention of bloodborne pathogens.

g) The laboratory also has a procedure to manage and reduce risk of exposure to infectious diseases, such as Ebola, MERS, tuberculosis, Zika, and other unknown potentially infectious pathogens. (*Also see* PCI.8.1)

When problems with practice are identified, or accidents occur, corrective actions are taken, documented, and reviewed.

### Measurable Elements of AOP.5.3.1

- ❑ 1. The laboratory has a defined process for reducing the risks of infection.
- ❑ 2. Infections acquired in the laboratory are reported, as defined in the policy, and in compliance with applicable laws and regulations.
- ❑ 3. The laboratory follows biosafety rules for relevant practices addressed in elements a) through g) in the intent.
- ❑ 4. When problems with practice are identified, or accidents occur, corrective actions are taken, documented, and reviewed.

## Standard AOP.5.4

Laboratory results are available in a timely way as defined by the hospital. Ⓟ

### Intent of AOP.5.4

The hospital defines the time period for reporting laboratory test results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergency tests and after-hours and weekend testing needs are included. Results from urgent tests, such as those from the emergency department, operating theatres, and intensive care units, are given special attention in the quality measurement process. 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. (*Also see* IPSG.2.1)

### Measurable Elements of AOP.5.4

- ❑ 1. The hospital establishes the expected report time for results.
- ❑ 2. The hospital measures the timeliness of reporting of urgent/emergency tests.
- ❑ 3. Laboratory results are reported within a time frame to meet patient needs.

## Standard AOP.5.5

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

### Intent of AOP.5.5

Laboratory staff work to ensure that all equipment, including medical devices used for point-of-care testing, function at acceptable levels and in a manner that is safe to the operator(s). The laboratory develops and implements a program to manage equipment and medical equipment that provides for

- 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; and
- documenting the management program.

Testing, maintenance, and calibration frequency are related to the laboratory's use of its equipment and its documented history of service. (*Also see* FMS.9 and FMS.9.1)

### Measurable Elements of AOP.5.5

- ❑ 1. The laboratory develops, implements, and documents a program to manage laboratory equipment, including a process for how equipment is selected and acquired.
- ❑ 2. There is a documented inventory of all laboratory equipment.
- ❑ 3. Laboratory equipment is inspected and tested when new and according to age, use, and manufacturers' recommendations thereafter, and the inspections are documented.
- ❑ 4. Laboratory equipment is calibrated and maintained according to manufacturers' recommendations, and the calibration and maintenance are documented.
- ❑ 5. The hospital has a system in place for monitoring and acting on laboratory equipment hazard notices, recalls, reportable incidents, problems, and failures.

## Standard AOP.5.6

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

### Intent of AOP.5.6

The hospital has identified those reagents and supplies necessary to provide laboratory services to its patients. There is a process to order or secure those essential reagents and supplies.

All reagents are stored and dispensed according to manufacturers' directives or packaging instructions. All reagents are evaluated according to written guidelines. Written guidelines ensure the complete and accurate labeling of reagents and solutions. (*Also see* AOP.5.9 and FMS.7)

### Measurable Elements of AOP.5.6

- ❑ 1. Essential reagents and supplies are identified and available, and there is a process to address when essential reagents are not available.
- ❑ 2. All reagents are stored and dispensed according to manufacturers' directives or packaging instructions.
- ❑ 3. The laboratory establishes and follows written guidelines for the evaluation of all reagents to ensure accuracy and precision of results.
- ❑ 4. All reagents and solutions are completely and accurately labeled.

## Standard AOP.5.7

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

### Intent of AOP.5.7

Procedures are established and implemented for

- ordering tests;
- collecting and identifying specimens; (*Also see* IPSG.1)
- transporting, storing, and preserving specimens; and
- receiving, logging, and tracking specimens.

These procedures are observed for specimens sent to reference/contract laboratory services for testing.

### Measurable Elements of AOP.5.7

- ❑ 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 reference/contract laboratory services are used.

## Standard AOP.5.8

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

### Intent of AOP.5.8

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 furnished when a reference/contract laboratory service performs the test. The reference ranges are appropriate to the hospital's geography and demographics and are reviewed and updated when methods change.

### Measurable Elements of AOP.5.8

- ❑ 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 furnished when tests are performed by reference/contract laboratory services.
- ❑ 4. Ranges are appropriate to the hospital's geography and demographics.
- ❑ 5. The laboratory reviews and updates ranges as needed.

## Standard AOP.5.9

Quality control procedures for laboratory services are in place, followed, and documented. Ⓟ

## Standard AOP.5.9.1

There is a process for proficiency testing of laboratory services. Ⓟ

### Intent of AOP.5.9 and AOP.5.9.1

Well-designed quality control systems are essential to providing excellent pathology and clinical laboratory services. (*Also see* AOP.5.2) Quality control procedures include

- validation of the test methods used for accuracy, precision, and reportable range;
- daily surveillance of results by qualified laboratory staff;
- testing of reagents;
- rapid corrective action when a deficiency is identified; and
- documentation of results and corrective actions.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognized by internal mechanisms. Thus, the laboratory participates in an approved proficiency-testing program when available. Alternatively, when approved programs are not available, the laboratory exchanges samples with a laboratory in another organization for purposes of peer comparison testing. The laboratory maintains a cumulative record of participation in a proficiency-testing process. Proficiency testing, or an alternative, is carried out for all specialty laboratory programs when available. (*Also see* AOP.5.10)

### Measurable Elements of AOP.5.9

- ❑ 1. The hospital establishes and implements a quality control program for the clinical laboratory.
- ❑ 2. The program includes the validation of test methods.
- ❑ 3. The program includes the daily surveillance and documentation of test results.
- ❑ 4. The program includes testing of reagents.
- ❑ 5. The program includes rapid correction and documentation of deficiencies.

### Measurable Elements of AOP.5.9.1

- ❑ 1. The laboratory participates in a proficiency-testing program, or an alternative, for all specialty laboratory services and tests.
- ❑ 2. For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with laws and regulations.
- ❑ 3. The laboratory maintains records of its participation in a proficiency-testing program.

## Standard AOP.5.10

Reference/contract laboratories used by the hospital are licensed and accredited or certified by a recognized authority.

## Standard AOP.5.10.1

The hospital identifies measures for monitoring the quality of the services to be provided by the reference/contract laboratory.

### Intent of AOP.5.10 and AOP.5.10.1

When the hospital uses the services of a reference/contract laboratory—whether for select tests or to provide all laboratory services—the following information is required:

a) A copy of a license from a recognized licensing authority
b) A copy of the certificate or letter of accreditation or certification from a recognized laboratory accreditation or certification program*
c) Documentation that the reference (contract) laboratory participates in an outside proficiency-testing program (*Also see* AOP.5.9)

In addition, the hospital identifies measures for monitoring the quality of the services provided by all reference/contract laboratories—**for example**, turnaround times for tests, critical results reporting, and problems with specimens such as missing identifiers or specimen rejections. Qualified individuals review and act on the results of the quality monitoring. (*Also see* GLD.6.1)

* A laboratory accreditation or certification program that is recognized is one that has been reviewed and endorsed by a laboratory professional society or governmental or private agency.

### Measurable Elements of AOP.5.10

- ❑ 1. The hospital maintains a copy of the license, from a recognized licensing authority, for all reference/contract laboratories used by the hospital.
- ❑ 2. The hospital maintains a copy of the certificate or letter of accreditation or certification, from a recognized laboratory accreditation or certification program, for all reference/contract laboratories used by the hospital.
- ❑ 3. The hospital maintains documentation that any reference/contract laboratory used by the hospital participates in an outside proficiency-testing program.

### Measurable Elements of AOP.5.10.1

- ❑ 1. The hospital determines the frequency and type of performance expectation data from reference/contract laboratories.
- ❑ 2. The qualified individual responsible for the laboratory or a qualified designee reviews the performance expectation data from reference/contract laboratories and takes action based on the results.
- ❑ 3. An annual report of the data from reference/contract laboratories is provided to those who make decisions to facilitate management of contracts and contract renewals.

## *Blood Bank and/or Transfusion Services*

## Standard AOP.5.11

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.5.11

Blood bank and/or transfusion services, when provided by the hospital, are under the direction of an individual who is qualified by virtue of documented training, expertise, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for all aspects of blood bank services provided in the hospital. The oversight of services includes establishment, implementation, and documentation of the processes for

a) blood donor selection;
b) blood screening for disease;
c) blood collection;
d) blood storage;
e) compatibility testing; and
f) blood distribution.

Quality control processes for all blood bank services are established, implemented, and documented to ensure the safety of blood bank and transfusion services. Blood donor and transfusion services are guided by laws and regulations and recognized standards of practice. (*Also see* COP.3.4)

### Measurable Elements of AOP.5.11

- ❑ 1. A qualified individual(s) is responsible for blood bank and/or transfusion services.
- ❑ 2. The blood bank has established, implemented, and documented processes for a) through f) of the intent.
- ❑ 3. Quality control measures are in place for all blood bank and transfusion services and are established, implemented, and documented.
- ❑ 4. The blood bank and transfusion services comply with applicable laws and regulations and recognized standards of practice.

## *Radiology and Diagnostic Imaging Services*

## Standard AOP.6

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

### Intent of AOP.6

The hospital has a system for providing radiology and diagnostic imaging services required by its patient population, clinical services offered, and health care practitioner needs. Radiology and diagnostic imaging services meet all applicable local and national standards, laws, and regulations.

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 can identify and contact experts in specialized diagnostic areas, such as radiation physics, radiation oncology, or nuclear medicine, when necessary. The hospital maintains a roster of such experts.

Outside sources are convenient for the patient to access, and reports are received in a timely way that supports continuity of 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.6

- ❑ 1. Radiology and diagnostic imaging services meet applicable local and national standards, laws, and regulations.
- ❑ 2. Radiology and diagnostic imaging services are available to meet the needs related to the hospital's mission and patient population, the community's health care needs, and emergency needs, including after normal hours.
- ❑ 3. The hospital maintains a roster of experts in specialized diagnostic areas and ensures that the roster 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.6.1

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.6.1

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, expertise, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the radiology and diagnostic imaging facility and the services provided. When this individual provides clinical consultation or medical opinion, he or she is a physician, preferably a radiologist. When radiation therapy or other special services are provided, they are under the direction of appropriately qualified individuals. (*Also see* GLD.9)

The radiology and diagnostic imaging leader's responsibilities include

a) developing, implementing, and maintaining policies and procedures;
b) administrative oversight;
c) maintaining any necessary quality control program;
d) recommending outside sources of radiology and diagnostic imaging services; and
e) monitoring and reviewing all radiology and diagnostic imaging services.

The hospital identifies which radiology and diagnostic imaging staff members perform diagnostic and imaging studies, those who are approved to perform point-of-care tests at the bedside, those who are qualified to interpret the results or to verify and report results, and those who direct or supervise the processes. Supervisory staff and technical staff have appropriate and adequate training, experience, and skills and are oriented to their work. 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 promptly and to provide necessary staffing during all hours of operation and for emergencies. (*Also see* SQE.4)

### Measurable Elements of AOP.6.1

❑ 1. Radiology and diagnostic imaging services are under the direction of one or more qualified individuals.

❑ 2. Responsibilities of the individual managing radiology and diagnostic imaging services include a) through e) of the intent.

❑ 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.

❑ 5. There is an adequate number of staff to meet patient needs.

❑ 6. Supervisory staff have proper qualifications and experience.

## Standard AOP.6.2

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

### Intent of AOP.6.2

Radiologic examinations and diagnostic imaging are life-saving tests that are used extensively in hospitals and are instrumental in the delivery of care. However, radiation exposure can pose potential risks of long-term

damage, depending on the dose of radiation delivered and the number of tests performed on any one person. The higher the dose, the greater the risk for long-term damage, and repeated doses have a cumulative effect that can also present greater risks. Health care practitioners should take care when ordering diagnostic imaging and weigh the medical necessity of the exposure to radiation against the risks. Unnecessary exposure to radiation should be avoided. Practitioners are encouraged to follow the principles of ALARA (maintain all radiation exposures As Low As Reasonably Achievable). The diagnostic procedures most commonly associated with avoidable radiation doses are computed tomography, 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.

Diagnostic imaging, such as magnetic resonance imaging (MRI) and ultrasonography, does not use ionizing radiation as radiology tests do, and therefore the risks from radiation are not present. However, there are other hazards from diagnostic imaging that need to be addressed for the safety of patients, staff, families, and visitors. Hazards from MRI include exposure to a strong magnetic field, presence of cryogenic gases, and exposure to acoustic noise. Hospitals must implement measures to address these hazards. **For example**, by clearly marking safety zones in the MRI area to indicate who can have access and what safety precautions are necessary in each zone. To address hazards related to cryogenic gases, which are required for cooling the magnets of the MRI equipment, proper ventilation and appropriate training for individuals who handle the cryogens are necessary. Measures should be taken to ensure patient and staff comfort and safety from acoustic noise during MRI examinations.

Additional precautions to prevent risk and injury in the MRI area include restricting access to the magnetic field area to only authorized staff and to patients accompanied by those staff, posting signs in and around the area to identify hazards, and ensuring only special non-ferromagnetic equipment enters the MRI environment, among other precautions.

The hospital has an active 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 reflects the risks and hazards encountered and addresses 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. (*Also see* PCI.2 and FMS.5)

The radiation safety management program includes

- 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; (*Also see* SQE.7 and SQE.8)
- 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; and
- compliance with standards addressing facility management and infection prevention and control programs.

### Measurable Elements of AOP.6.2

- ❑ 1. A comprehensive radiation and/or diagnostic imaging safety program for patients, staff, and visitors is in place, is followed, and is compliant with applicable professional standards, laws, and regulations.
- ❑ 2. Radiology and diagnostic imaging staff are oriented to safety precautions and procedures and receive ongoing education and training for any new procedures, equipment, and hazardous materials.
- ❑ 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 includes education about dosing 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 (**for example**, identification of safety zones, access restrictions, signage, availability of non-ferromagnetic equipment, and so on).
- ❑ 6. 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.6.3

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

### Intent of AOP.6.3

The hospital defines the time period for reporting diagnostic radiology and diagnostic imaging study results. Results are reported within a time frame based on patient needs, services offered, and the clinical staff's needs. Emergency tests and after-hours and weekend testing needs are included. Results from urgent radiology and diagnostic imaging studies, such as those from the emergency department, operating theatres, and intensive care units, are given special attention in the quality measurement process. Radiology and diagnostic imaging studies performed by outside contractors of services are reported according to hospital policy or contract requirement.

### Measurable Elements of AOP.6.3

- ❑ 1. The hospital establishes the expected report time for results.
- ❑ 2. The hospital measures the timeliness of reporting of urgent/emergency studies.
- ❑ 3. Radiology and diagnostic imaging study results are reported within a time frame to meet patient needs.

## Standard AOP.6.4

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.6.4

Radiology and diagnostic imaging staff work to ensure that all equipment functions at acceptable levels and in a manner that is safe to the operator(s). Radiology and diagnostic imaging develops and implements a program to manage equipment that provides for

- selecting and acquiring medical equipment;
- identifying and inventorying medical equipment;
- assessing equipment use through inspection, testing, calibration, and maintenance;
- monitoring and acting on equipment hazard notices, recalls, reportable incidents, problems, and failures; and
- documenting the management program.

Testing, maintenance, and calibration frequency are related to the use of the equipment and its documented history of service. (*Also see* FMS.9)

### Measurable Elements of AOP.6.4

- ❑ 1. Radiology and diagnostic imaging develops, implements, and documents a program to manage equipment.
- ❑ 2. The program identifies how radiology equipment is selected and acquired.
- ❑ 3. There is a documented inventory of all radiology equipment.
- ❑ 4. Radiology equipment is inspected and tested when new and according to age, use, and manufacturers' recommendations.
- ❑ 5. Radiology equipment is calibrated and maintained according to manufacturers' recommendations.
- ❑ 6. The hospital has a system in place for monitoring and acting on radiology equipment hazard notices, recalls, reportable incidents, problems, and failures.

## Standard AOP.6.5

Quality control procedures are in place, followed, validated, and documented. Ⓟ

### Intent of AOP.6.5

Sound quality control systems are essential to providing excellent radiology and diagnostic imaging services. (*Also see* GLD.11) Quality control procedures include

- validation of the test methods used for accuracy and precision;
- regular surveillance of imaging results by qualified radiology staff;
- rapid corrective action when a deficiency is identified;
- testing of reagents and solutions when used; and
- documentation of results and corrective actions.

### Measurable Elements of AOP.6.5

- ❑ 1. The hospital establishes and implements a quality control program for the radiology and diagnostic imaging services.
- ❑ 2. Quality control includes validating test methods.
- ❑ 3. Quality control includes regular surveillance and documentation of imaging results.
- ❑ 4. Quality control includes testing reagents and solutions, when used, and documenting test results.
- ❑ 5. Quality control includes rapid correction and documentation when a deficiency is identified.

## Standard AOP.6.6

The hospital regularly reviews quality control results for all outside contracted sources of diagnostic services.

## Intent of AOP.6.6

When the hospital contracts with outside sources of radiology and diagnostic imaging services, it regularly receives and reviews the quality control results for those contracted sources. (*Also see* GLD.6.1) Qualified individuals review the quality control results. (*Also see* GLD.6) When diagnostic imaging quality control of outside sources is difficult to obtain, the department/service leader develops an alternative approach for quality oversight.

## Measurable Elements of AOP.6.6

- ❑ 1. The frequency and type of quality control data from outside contracted sources are determined by the hospital.
- ❑ 2. The qualified individual responsible for the radiology quality control or qualified designee reviews the quality control results from the outside contracted source.
- ❑ 3. The responsible individual or qualified designee takes action based on the quality control results.
- ❑ 4. An annual report of the quality control data from the outside contracted source is provided to hospital leadership to facilitate management of contracts and contract renewal.

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# 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 use of clinical alarms and lasers.

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, his or her 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

- 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; and
- planned care is modified when necessary based on the patient's response.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.1** Uniform care of all patients is provided and follows applicable laws and regulations. Ⓟ

**COP.2** There is a process to integrate and to coordinate the care provided to each patient, and it includes a uniform process for prescribing patient orders.

**COP.2.1** Clinical and diagnostic procedures and treatments are carried out and documented as ordered, and the results or outcomes are recorded in the patient's medical record.

**COP.2.2** An individualized plan of care is developed and documented for each patient.

### Care of High-Risk Patients and Provision of High-Risk Services

**COP.3** The care of high-risk patients and the provision of high-risk services are guided by professional practice guidelines, laws, and regulations. Ⓟ

### Clinical Alarm System Management

**COP.3.1** Reduce the risk of harm associated with clinical alarms by developing and implementing risk reduction strategies for managing clinical alarm systems used for patient care. Ⓟ

### Recognition of Changes to Patient Condition

**COP.3.2** Clinical staff are trained to recognize and respond to changes in a patient's condition.

### Resuscitation Services

**COP.3.3** Resuscitation services are available throughout the hospital.

### Administration of Blood and Blood Products

**COP.3.4** Clinical guidelines and procedures are established and implemented for the handling, use, and administration of blood and blood products. Ⓟ

### Management of Patients at Risk of Suicide or Self-Harm

**COP.3.5** The hospital has a process to identify patients at risk for suicide and self-harm. Ⓟ

### Management of Lasers

**COP.4** The hospital establishes and implements a program for the safe use of lasers and other optical radiation devices used for performing procedures and treatments. Ⓟ

**COP.4.1** Adverse events resulting from the use of lasers and other optical radiation devices are reported, and action plans to prevent recurrence are implemented and monitored.

### Food and Nutrition Therapy

**COP.5** A variety of food choices, appropriate for the patient's nutritional status and consistent with his or her clinical care, is available.

**COP.5.1** Patients at nutrition risk receive nutrition therapy.

### Pain Management

**COP.6** Patients are supported in managing pain effectively. Ⓟ

### End-of-Life Care

**COP.7** The hospital provides end-of-life care for the dying patient that addresses the needs of the patient and family and optimizes the patient's comfort and dignity.

### Hospitals Providing Organ and/or Tissue Transplant Services

**COP.8** The hospital's leadership provides resources to support the organ/tissue transplant program.

**COP.8.1** A qualified transplant program leader(s) is responsible for the transplant program.

**COP.8.2** The transplant program includes a multidisciplinary team that consists of people with expertise in the relevant organ-specific transplant programs.

**COP.8.3** There is a designated coordination mechanism for all transplant activities that involves physicians, nurses, and other health care practitioners.

**COP.8.4** The transplant program uses organ-specific transplant clinical eligibility criteria and psychological and social suitability criteria for transplant candidates.

**COP.8.5** The transplant program obtains informed consent specific to organ transplantation from the transplant candidate. Ⓟ

**COP.8.6** 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.8.7** Individualized patient care plans guide the care of transplant patients.

### Transplant Programs Using Living Donor Organs

**COP.9** 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.9.1** Transplant programs performing living donor transplants obtain informed consent specific to organ donation from the prospective living donor. Ⓟ

**COP.9.2** Transplant programs that perform living donor transplants use clinical and psychological selection criteria to determine the suitability of potential living donors. Ⓟ

**COP.9.3** Individualized patient care plans guide the care of living donors.

# Standards, Intents, and Measurable Elements

## *Care Delivery for All Patients*

## Standard COP.1

Uniform care of all patients is provided and follows applicable laws and regulations. Ⓟ

### Intent of COP.1

Patients with the same health problems and care needs have a right to receive the same quality of care throughout the hospital. To carry out the principle of "one level of quality of care" requires that the department/service leaders plan and coordinate patient care. In particular, services provided to similar patient populations in multiple departments or settings are guided by policies and procedures that result in their uniform delivery. In addition, the 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 respect applicable laws and regulations that shape the care process and are best developed collaboratively. Uniform patient care is reflected in the following:

a) Access to and appropriateness of care and treatment do not depend on the patient's ability to pay or the source of payment.
b) Access to appropriate care and treatment by qualified practitioners does not depend on the day of the week or time of day.
c) Acuity of the patient's condition determines the resources allocated to meet the patient's needs. (*Also see* ACC.1)
d) The level of care provided to patients (**for example**, anesthesia care) is the same throughout the hospital.

e) Patients with the same nursing care needs receive comparable levels of nursing care throughout the hospital.

Uniform patient care results in the efficient use of resources and permits the evaluation of outcomes of similar care throughout the hospital. (*Also see* ACC.2; PCC.1.1; and GLD.12)

### Measurable Elements of COP.1

- ❑ 1. The hospital's department/service leaders collaborate to provide uniform care processes.
- ❑ 2. The provision of uniform care reflects local and regional laws and regulations.
- ❑ 3. Uniform care is provided and meets requirements a) through e) in the intent.

## Standard COP.2

There is a process to integrate and to coordinate the care provided to each patient, and it includes a uniform process for prescribing patient orders.

### Intent of COP.2

The patient care process is dynamic and involves many health care practitioners and can involve multiple care settings and departments and services. The integration and coordination of patient care activities are goals that result in efficient care processes, more effective use of human and other resources, and the likelihood of better patient outcomes. Thus, department/service leaders use tools and techniques to better integrate and to coordinate care for their patients (**for example**, team-delivered care, multidisciplinary patient rounds, combined care planning forms, integrated patient medical record, case managers). (*Also see* ACC.3 and AOP.4)

The patient's medical record facilitates and reflects the integration and coordination of care. In particular, each health care practitioner 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 that must be documented in the patient medical record. Such activities may include, **for example**, orders for laboratory testing, administration of medications, specific nursing care, nutrition therapy, rehabilitative therapy, and the like. (*Also see* MOI.9)

Patient care activities requiring orders are ordered by individuals qualified to do so. (*Also see* ACC.3.1) Such orders must be easily accessible if they are to be acted on in a timely manner. Locating orders on a common sheet or in a uniform location in the patient's medical record facilitates the carrying out of orders. Documented orders help staff understand the specifics of an order, when the order is to be carried out, and who is to carry out the order. (*Also see* MMU.4.2) Orders can be written on an order sheet that is transferred to the patient's medical record periodically or at discharge, or a computerized order entry system may be used in hospitals that are using electronic patient medical records.

Each hospital decides

- which orders must be written/documented and not by telephone, verbal, or text messaging (if verbal, telephone, or text orders are allowed); **for example**, telephone orders may be limited to emergency situations when a physician is not present, verbal orders may be limited to situations in which the ordering physician is performing a sterile procedure, and texting orders may be limited to diagnostic tests only;
- which diagnostic imaging and clinical laboratory test orders must provide a clinical indication/rationale;
- any exceptions in specialized settings, such as emergency departments and intensive care units;
- who is permitted to prescribe orders; (*Also see* MMU.4.1) and
- where orders are to be located in the patient medical record, including those that may be received via text. (*Also see* MOI.8 and MOI.12)

### Measurable Elements of COP.2

- ❑ 1. Care planning and care delivery are integrated and coordinated among settings, departments, and services.
- ❑ 2. The hospital develops and implements a uniform process for prescribing written/documented patient orders that includes identifying orders that may be received verbally, via telephone, and via text.
- ❑ 3. Diagnostic imaging and clinical laboratory test orders include a clinical indication/rationale when required for interpretation.
- ❑ 4. Orders are prescribed only by those qualified to do so.
- ❑ 5. Orders are found in a uniform location in medical records.

## Standard COP.2.1

Clinical and diagnostic procedures and treatments are carried out and documented as ordered, and the results or outcomes are recorded in the patient's medical record.

### Intent of COP.2.1

Clinical and diagnostic procedures and treatments performed, and the results or outcomes, are documented in the patient's medical record. (*Also see* PCC.2 and MOI.8.1) **Examples** of such procedures and treatments include endoscopies, cardiac catheterization, radiation treatment, computerized tomography (CT) exams, and other invasive and noninvasive diagnostic procedures and treatments. Information about who requested the procedure or treatment and the reason for the procedure or treatment are included in the documentation.

### Measurable Elements of COP.2.1

- ❑ 1. Procedures and treatments are carried out as ordered and are documented in the patient's medical record.
- ❑ 2. The person requesting, and the reason for requesting, the procedure or treatment are documented in the patient's medical record.
- ❑ 3. The results of procedures and treatments performed are documented in the patient's medical record.

## Standard COP.2.2

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

### Intent of COP.2.2

The plan of care outlines care and treatment to be provided to an individual patient. The plan of care identifies a set of actions that the health care team will implement to resolve or support the diagnosis identified by assessment. The overall goal of a plan of care is to achieve optimal clinical outcomes. (*Also see* COP.3)

The planning process is collaborative and uses the data from the initial assessment and from periodic reassessments performed by physicians, nurses, and other health care practitioners to identify and to prioritize the treatments, procedures, nursing care, and other care to meet the patient's needs. The patient and family are involved in the planning process with the health care team. The plan of care is developed within 24 hours of admission as an inpatient. Based on the reassessment of the patient performed by the patient's health care practitioners, the plan of care is updated as appropriate to reflect the evolving condition of the patient. The plan of care is evident in the patient's medical record through documentation by the patient's health care practitioners.

The plan of care for a patient must be related to his or her identified needs. Those 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 sudden 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 they may result in a new plan of care. Some departments may conduct multidisciplinary patient care conferences for patients who are receiving complex care from multiple services; **for example**, patients receiving rehabilitative services, patients with multiple diagnoses in intensive care units, or patients with complex discharge planning needs, and the like. Any results or conclusions from collaborative patient care team meetings or similar patient discussions are written in the patient's medical record. (*Also see* AOP.4)

One method of developing care plans is to identify and establish measurable goals. Measurable goals can be selected by the *responsible physician* in collaboration with the nurse and other health care practitioners. Measurable goals are observable, achievable targets related to patient care and expected clinical outcomes.

They 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. (*Also see* PCC.2)

### Measurable Elements of COP.2.2

- ❑ 1. The care for each patient is planned by the responsible physician, nurse, and other health care practitioners 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 by the multidisciplinary team based on any changes in the patient's condition identified from the reassessment of the patient by the health care practitioners, and is documented in the patient's medical record.
- ❑ 4. The results or conclusions of any patient care team meetings or other collaborative discussions are documented in the patient's medical record.
- ❑ 5. The plan of care is provided to each patient and evident in the patient's medical record through documentation by the health care practitioners providing the care.

## *Care of High-Risk Patients and Provision of High-Risk Services*

## Standard COP.3

The care of high-risk patients and the provision of high-risk services are guided by professional practice guidelines, laws, and regulations. Ⓟ

## Intent of COP.3

Hospitals care for patients with a variety of health care needs. Some patients are considered high risk because of their age, their condition, or the critical nature of their needs. Children and the elderly are commonly placed in this group, as they frequently cannot speak for themselves, do not understand the care process, and cannot participate in decisions regarding their care. Similarly, the frightened, confused, comatose, or emergency patient is unable to understand the care process when care needs to be provided efficiently and rapidly.

Hospitals also provide a variety of services, some of which are considered high risk because of the complex medical equipment needed to treat a life-threatening condition (dialysis patients), the nature of the treatment (patients on life support), the potential for harm to the patient (restraint), or toxic effects of certain high-risk medications (**for example**, chemotherapy).

Care for these high-risk patients is supported by the use of tools such as guidelines, procedures, care plans, clinical pathways, and the like. (*Also see* ACC.3 and COP.2.1) These tools are important for staff to understand and respond in a thorough, competent, and uniform manner. Hospital leadership is responsible for

- identifying the patients and services considered high risk in the hospital;
- using a collaborative process to develop written tools for guiding the uniform care; and
- training staff in implementing these tools.

Written tools for care must be tailored to the particular at-risk patient population or high-risk service to be appropriate and effective in reducing the related risk. It is particularly important that the procedure identify

- how planning will occur, including the identification of differences between adult and pediatric populations, or other special considerations;
- the documentation required for the care team to work and to communicate effectively;
- 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; and
- the availability and use of specialized medical equipment.

When serving any of the high-risk patients or providing any of the high-risk services identified below, the hospital establishes and implements guidelines and procedures for the services provided and for the patients served. (*Also see* COP.8.6; COP.9.2; COP.9.3; PCI.12; and PCI.12.1) The high-risk services are for

a) emergency patients;
b) comatose patients;
c) patients on life support;
d) care of patients with a communicable disease;
e) care of immunosuppressed patients;
f) care of patients receiving dialysis;
g) care of patients in restraints;
h) care of patients receiving chemotherapy;
i) care of vulnerable patient populations, including frail elderly, dependent children, and patients at risk for abuse and/or neglect; and
j) care of patients receiving palliative care

Additional patients and services are included when they are represented in the hospital's patient population and in the services it offers.

Hospital leadership also identifies additional risk as the result of any procedures or plan of care (**for example**, the need to prevent 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 dialysis patients; central line infections; and falls). Such risks, when present, need to be addressed and prevented by educating staff and developing appropriate policies, guidelines, and procedures. (*Also see* PCC.4.2.) The hospital uses measurement information to evaluate the services provided to high-risk patients and integrates that information into the hospital's overall quality improvement program.

### Measurable Elements of COP.3

- ❑ 1. Hospital leadership identifies the high-risk patients and services, including at least a) through j) of the intent when provided by the hospital.
- ❑ 2. Leadership establishes and implements policies, procedures, and/or principles of care for those high-risk services provided by the hospital.
- ❑ 3. Staff are trained to utilize the written tools for care of these high-risk patients and services.
- ❑ 4. Hospital leadership identifies additional risks that may affect high-risk patients and services and implements measures to reduce and/or prevent additional risks.
- ❑ 5. The development of hospital-acquired risks is tracked and included in the hospital's quality improvement program.

## *Clinical Alarm System Management*

# Standard COP.3.1

Reduce the risk of harm associated with clinical alarms by developing and implementing risk reduction strategies for managing clinical alarm systems used for patient care. Ⓟ

### Intent of COP.3.1

Clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. There are several underlying issues associated with alarm management that can increase the risk to patient safety. Issues 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 tailored to the patient's condition. Many patient care areas have numerous alarm signals, and the recurrent noise from improperly managed alarms tends to desensitize staff and cause them to miss or ignore alarm signals or even disable them. These issues vary greatly among hospitals and even within different wards in a single hospital. It is important for a hospital to understand its own situation and to develop a systematic, coordinated approach to clinical alarm system management. (*Also see* QPS.10)

Standardization contributes to safe alarm system management, but it is recognized that alarm management solutions may have to be designed for specific clinical units, groups of patients, or individual patients. **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. In designing customized solutions for proper alarm management, leaders begin by identifying the most important alarm signals to manage. Consideration of the following can be helpful in determining alarm signals that may pose a risk to patient safety:

- Input from the medical staff and clinical departments
- Data from medical devices on which alarms are causing false or nonactionable alarms that could impact specific patient populations
- 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 (*Also see* QPS.3)

When the alarms posing a risk to patient safety have been identified, along with the locations and situations under which these alarms are used, strategies are developed that address the following:

a) Clinically appropriate settings for alarm signals
b) Situations in which alarm signals can be disabled

c) Circumstances under which alarm parameters can be changed
d) Identification of those who have the authority to set alarm parameters
e) Designation of those who have the authority to change alarm parameters

### Measurable Elements of COP.3.1

- ❑ 1. Hospital leaders develop and implement an alarm system 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 strategies for managing alarms that consider a) through e) of the intent.
- ❑ 4. Health care practitioners and other appropriate staff are educated about the purpose and proper 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.

## *Recognition of Changes to Patient Condition*

## Standard COP.3.2

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

### Intent of COP.3.2

Staff who do not work in critical care areas may not have adequate knowledge and training to assess and monitor patients with critical conditions. However, a significant number of patients outside of critical care areas experience critical inpatient events. It is essential to recognize the age-specific signs indicating a sudden change of condition for an individual patient population; **for example**, the pediatric patient population versus the adult patient populations. 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. (*Also see* AOP.2) The literature identifies physiological criteria that can assist staff in early detection of deteriorating patients. A majority of patients who experience cardiopulmonary or respiratory arrest demonstrate clinical deterioration prior to arrest. When staff are able to identify these patients early and request additional assistance from specially trained individuals, clinical outcomes improve.

All clinical staff require education and training to provide the knowledge and skills to recognize and intervene when patient assessments identify 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. Hospitals that develop a systematic approach to early recognition and intervention of patients whose condition is deteriorating may reduce cardiopulmonary arrests and patient mortality. (*Also see* SQE.3)

### Measurable Elements of COP.3.2

- ❑ 1. The hospital develops and implements a systematic process for staff recognition of and response to a patient whose condition appears to be worsening.
- ❑ 2. The hospital develops and implements documented age-specific criteria describing early warning signs of a change or deterioration in a patient's condition.
- ❑ 3. The hospital develops and implements a process that identifies when and how to seek further assistance.
- ❑ 4. Based on the hospital's early warning criteria, staff seek additional assistance when they have concerns about a patient's condition.
- ❑ 5. The hospital informs the patient and family how to seek assistance when they have concerns about a patient's condition.

## *Resuscitation Services*

## Standard COP.3.3

Resuscitation services are available throughout the hospital.

### Intent of COP.3.3

*Resuscitation services* can be defined as clinical interventions for the emergent care of patients experiencing a critical, life-threatening event, such as cardiac or respiratory arrest. When a cardiac or respiratory arrest occurs, the immediate initiation of chest compressions or respiratory support may mean the difference between life and death or, at the very least, may help avoid potentially serious brain damage.

Successful resuscitation of patients in cardiopulmonary arrest is dependent on critical interventions, such as early defibrillation and accurate implementation of advanced life support. These services must be available to all patients, 24 hours a day, every day. Essential to providing these critical interventions is the quick availability of standardized medical equipment, medications for resuscitation, and staff properly trained in resuscitation. Basic life support must be implemented 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. Resuscitation services available within the hospital, including medical equipment and properly trained staff, 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). (*Also see* ASC.3; MMU.3.1; SQE.8.1; SQE.8.1.1; GLD.9; and FMS.9) To ensure that resuscitation is implemented in a timely manner, the hospital reviews internal data from previous emergency situations to determine response times and availability of appropriate equipment, and identifies areas for improvement.

**Note:** *All areas of the hospital* includes any areas where treatment and services are provided, including treatment or diagnostic areas in separate buildings on the hospital campus.

### Measurable Elements of COP.3.3

- ❑ 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 needs of the population served.
- ❑ 3. In all areas of the hospital, basic life support is implemented immediately upon recognition of cardiac or respiratory arrest, and advanced life support is implemented in fewer than 5 minutes.
- ❑ 4. The hospital reviews internal data from previous emergency situations and identifies areas for improvement.

## *Administration of Blood and Blood Products*

## Standard COP.3.4

Clinical guidelines and procedures are established and implemented for the handling, use, and administration of blood and blood products. Ⓟ

### Intent of COP.3.4

Blood must be administered in accordance with standards of practice and in a consistent manner in order to ensure the safety of the recipient. Therefore, clinical guidelines and procedures describe the process for

a) patient consent for administration; (*Also see* PCC.4.2 and GLD.11.2)
b) procurement of blood from the blood bank or blood storage area;
c) patient identification;
d) blood administration;
e) monitoring of the patient; and
f) identification of and response to signs of potential transfusion reactions

An individual with the education, knowledge, and expertise to oversee the blood and blood products administration ensures that processes, procedures, and clinical guidelines for transfusions are defined and implemented. (*Also see* AOP.5.11 and QPS.8)

### Measurable Elements of COP.3.4

- ❑ 1. An individual with education, knowledge, and expertise oversees the administration of blood and blood products.
- ❑ 2. Clinical guidelines and procedures are established and implemented for the handling, use, and administration of blood and blood products.
- ❑ 3. Clinical guidelines and procedures address the processes for a) through f) in the intent.

## *Management of Patients at Risk of Suicide or Self-Harm*

## Standard COP.3.5

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

## Intent of COP.3.5

Suicide is considered a sentinel event. (*Also see* QPS.7) The hospital presents a unique combination of risk factors—acute illness or presentation of symptoms, environmental risk factors, and varied levels of staff experience with suicide and self-harm. Therefore, 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.

Patients are screened if they meet criteria established by the hospital. The hospital identifies patient populations and/or criteria for which patients require screening for suicide and self-harm. **For example**, the hospital may choose to screen all patients at psychiatric and behavioral units, postpartum care units, acute care inpatient units, and emergency departments. Regardless of the treatment location, it is important for staff to be aware that patients being treated primarily for a medical condition often have comorbid behavioral health conditions, a change in clinical status that carries a poor prognosis, or psychosocial issues. These patients may be at risk for suicide, and it is important for staff to properly screen these individuals and identify other patient populations for suicidal ideation and self-harm as part of their overall clinical evaluation when indicated.

Staff are trained on how to identify patient populations who meet criteria for suicide and self-harm screening. Patients who meet criteria are screened for suicide and self-harm risk using tools that are appropriate to the patient population (**for example**, age-appropriate). (*Also see* SQE.3) Further assessment for suicide and self-harm risk is conducted on patients identified as "at risk" for suicide and self-harm or suicidal ideation through the use of screening tools. This assessment is completed through the use of evidence-based tools and focuses on suicidal ideation, intent, and plan; risk and protective factors; and past suicidal or self-harm behaviors.

The hospital implements protocols to minimize the risk of suicide and self-harm in patients who, upon assessment, are at risk for suicide and/or self-harm. These protocols may vary depending on the type of unit or ward, including the emergency department, and the patient population. **For example**, a general ward may implement a requirement for one-to-one monitoring for patients at risk of suicide, whereas psychiatric units may opt for hourly intentional rounding. These differences are influenced by variations in the physical environment of the care area, staffing ratios and training, and so on. Ultimately, the focus of these protocols is to keep patients safe, regardless of where they are being cared for in the hospital; department/service leaders conduct risk assessments and collaborate with clinical staff to identify and implement protocols that are most applicable and appropriate to each clinical care area.

Hospitals that care for patients at risk for suicide and self-harm, such as hospitals with a dedicated psychiatric unit and psychiatric hospitals, need to assess risks in the physical environment to identify areas and features that could be used to attempt suicide. (*Also see* FMS.3; FMS.5; and FMS.6) Patient rooms, patient bathrooms, corridors, and other areas should be included in the risk assessment. The most common hazards for suicide risk are anchor points used for hanging; however, there are many other types of hazards, and it is important to do a thorough assessment of the environment. **For example**, the risk assessment includes the accessibility of sharps, medications, cleaning chemicals, and so on. Nonpsychiatric units in hospitals should assess clinical areas to identify objects that could be used for self-harm so they can be removed when needed from the area around a patient who has been identified as high risk for suicide. **For example**, removal of anchor points, door hinges, and hooks that can be used for hanging.

### Measurable Elements of COP.3.5

- ❑ 1. The hospital establishes criteria for which patients are screened for suicide and self-harm, as clinically indicated.
- ❑ 2. The hospital uses evidence-based tools to assess patients for suicidal ideation based on established criteria. Patients who screen positive, are identified as "at risk" for suicide and/or self-harm based on the established criteria.
- ❑ 3. The hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used in a suicide or self-harm attempt; the hospital takes necessary action to minimize the risk(s).
- ❑ 4. The hospital implements protocols and procedures to mitigate the risk of patient suicide and/or self-harm.
- ❑ 5. The hospital monitors implementation and effectiveness of protocols and procedures for the prevention of patient suicide and/or self-harm by analyzing data regarding self-harm, the incidents, or deaths
- ❑ 6. Staff are trained on screening criteria, screening tools, and suicide and self-harm risk reduction protocols and procedures.

## *Management of Lasers*

## Standard COP.4

The hospital establishes and implements a program for the safe use of lasers and other optical radiation devices used for performing procedures and treatments. Ⓟ

## Standard COP.4.1

Adverse events resulting from the use of lasers and other optical radiation devices are reported, and action plans to prevent recurrence are implemented and monitored.

### Intent of COP.4 and COP.4.1

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. Laser surgeries are generally minimally invasive with less blood loss than conventional surgery, and patients typically experience shorter recovery times. The use of lasers is becoming more common in health care as laser technology evolves and the clinical applications broaden. Lasers are used in many surgical procedures and treatments. **For example**, lasers are used to perform LASIK and cataract surgery; they are used to remove skin lesions and treat varicose veins; and in dentistry, they are used to remove tooth decay and recontour soft tissue.

Lasers are used for noninvasive treatments as well, and other medical devices that use optical radiation are becoming more popular for patient treatments. **Examples** include intense pulsed light therapy to treat skin conditions such as acne, ultraviolet radiation to treat psoriasis, lasers to whiten teeth, high-intensity visible light for curing composites and adhesives during dental procedures, light therapy for treatment of pain and inflammation, and infrared radiation to treat strained muscles and tissues.

Nearly all lasers and 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 and 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.

Laser plumes are another potential hazard. These are the vapors, smoke, and particles produced during some surgical procedures. Laser plumes 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 and other optical radiation devices using industry standards and professional guidelines. The program complies with laws and regulations and includes the following:

- A qualified and trained individual who has oversight and supervision of the laser and optical radiation safety program
- Training in safety practices and procedures for all staff who are involved in the use of lasers and optical radiation devices; in addition, ongoing education and training is provided for new procedures, practices, devices, and equipment; the training and ongoing education are documented (*Also see* SQE.3 and SQE.8)
- Administrative and engineering controls to promote safety and prevent injury; some **examples** include
    - criteria and processes developed for authorizing staff who enter and/or work in the areas (hazard zones) where lasers and other optical radiation is used; in addition to health care practitioners who perform the laser procedures, staff who operate the lasers, and other staff who are part of the surgical/clinical care team, the hospital identifies staff who may also require access;
    - warning signs outside the procedure room(s) to alert staff, patients, families, and visitors when a treatment or procedure is being performed;
    - appropriate ventilation to help manage smoke plumes;
    - use of nonreflective instruments to prevent exposures to reflected light; and
    - use of drapes and other barriers to prevent staff, patients, families, and visitors from inadvertently being exposed to direct or reflected light
- Availability of personal protective equipment for staff and patients appropriate to the type of lasers and optical radiation devices used and type of procedures performed in the hospital (**for example**, goggles, corneal shields, masks, gloves, and gowns, as applicable) (*Also see* SQE.8.2)
- A maintenance program for lasers and optical radiation devices and a process for routine performance checks such as calibration and alignment (*Also see* FMS.9 and FMS.9.1)
- Coordination with the facility management and infection prevention and control programs; any facility safety events and infection control events are reported (*Also see* PCI.4 and FMS.5)
- Detecting and reporting adverse health effects and identifying and implementing improvements to prevent recurrence (*Also see* QPS.7.1)

### Measurable Elements of COP.4

- ❑ 1. The hospital's program for the safe use of lasers and optical radiation devices is based on industry standards and professional guidelines and complies with applicable laws and regulations.
- ❑ 2. A qualified individual with the appropriate training and experience has oversight and supervision of the laser and optical radiation safety program.
- ❑ 3. All staff involved in the use of lasers and 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 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 and optical radiation devices and type of procedures is available for staff and patients, and staff use it correctly and ensure that patients are protected during procedures.
- ❑ 6. The hospital has processes for inspection, testing, and maintenance of lasers and optical radiation devices, including routine calibration and alignment checks of lasers, and these activities are performed by qualified and trained individuals.

### Measurable Elements of COP.4.1

- ❑ 1. The laser safety and optical radiation program is part of the hospital's facility management and safety structure and provides reports to the facility management and safety structure at least annually and when any safety events occur.
- ❑ 2. The laser safety and optical radiation program is part of the hospital's infection prevention and control program and provides reports to the infection prevention and control program at least annually and when any infection control events occur.
- ❑ 3. When adverse events result from the use of lasers and/or optical radiation devices, the adverse events are reported, and action plans are identified and implemented to prevent recurrence.

## *Food and Nutrition Therapy*

## Standard COP.5

A variety of food choices, appropriate for the patient's nutritional status and consistent with his or her clinical care, is available.

### Intent of COP.5

Appropriate food and nutrition are important to patients' well-being and recovery. Food choices take into consideration the patient's age, cultural and dietary preferences, and planned care, which may include special dietary needs such as low cholesterol, diabetic diet, and clear liquids, depending on the patient's diagnosis. Based on the patient's assessed needs and plan of care, the patient's physician or other qualified caregiver orders food or other nutrients for the patient. (*Also see* AOP.1.4)

The patient participates in planning and selecting foods. When possible, patients are offered a variety of food choices consistent with their nutritional status. The patient's family may, when appropriate, participate in providing food, consistent with cultural, religious, and other traditions and practices and compatible with the patient's diagnosis. When the patient's family or others provide food to the patient, they are educated about foods that are contraindicated according 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 to prevent contamination.

### Measurable Elements of COP.5

- ❑ 1. A variety of food choices or nutrition, consistent with the patient's condition, care, and needs, is regularly available.
- ❑ 2. Prior to inpatients being fed, there is an order for food in the patient's medical record that is based on the patient's nutritional status and needs.
- ❑ 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 provided by family or others is stored under proper conditions to prevent contamination.

## Standard COP.5.1

Patients at nutrition risk receive nutrition therapy.

### Intent of COP.5.1

On initial assessment, patients are screened to identify those who may be at nutritional risk. (*Also see* AOP.1.4) These patients are referred to a nutritionist for further assessment. When it is determined that a patient is at nutritional risk, a plan for nutrition therapy is developed and carried out. The patient's progress is monitored and recorded in his or her 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.5.1

- ❑ 1. Patients assessed at nutrition risk receive nutrition therapy.
- ❑ 2. A collaborative process is used to plan, to deliver, and to monitor nutrition therapy.
- ❑ 3. The patient's response to nutrition therapy is monitored and documented in the medical record.

# *Pain Management*

## Standard COP.6

Patients are supported in managing pain effectively. Ⓟ

### Intent of COP.6

Pain can be a common part of the patient experience and may be associated with the condition or illness for which the patient is being treated. Pain may also be an expected part of certain treatments, procedures, or examinations. As part of care planning, 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. Whatever the origin of pain, unrelieved pain has adverse physical and psychological effects. Thus, patients in pain have the right to appropriate assessment and management of pain. (*Also see* PCC.2.2 and AOP.1.5)

Based on the scope of services provided, the hospital has processes to assess and to manage pain appropriately, including

- 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 conjunction with patient goals for pain management; (*Also see* COP.7)
- communicating with and educating patients and families about pain and symptom management in the context of their personal, cultural, and religious beliefs; and
- educating health care practitioners about pain assessment and management.

### Measurable Elements of COP.6

❑ 1. Based on the scope of services provided, the hospital has processes to identify patients in pain.

❑ 2. When pain is an expected result of planned treatments, procedures, or examinations, patients are informed about the likelihood of pain and options for pain management.

❑ 3. Patients in pain receive care according to pain management guidelines and according to patient goals for pain management.

❑ 4. Based on the scope of services provided, the hospital has processes to communicate with and to educate patients and families about pain.

❑ 5. Based on the scope of services provided, the hospital has processes to educate staff about pain.

## *End-of-Life Care*

Patients who are approaching the end of life require care focused on their unique needs. Dying patients may experience symptoms related to the disease process or curative treatments or may need help in dealing with psychosocial, spiritual, and cultural issues associated with death and dying. Their families and caregivers may require respite from caring for a terminally ill family member or help in coping with grief and loss.

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. These processes

- ensure that symptoms will be assessed and appropriately managed;
- ensure that terminally ill patients will be treated with dignity and respect;
- assess patients as frequently as necessary to identify symptoms;
- plan preventive and therapeutic approaches to manage symptoms; and
- educate patients and staff about managing symptoms.

# Standard COP.7

The hospital provides end-of-life care for the dying patient that addresses the needs of the patient and family and optimizes the patient's comfort and dignity.

### Intent of COP.7

Patients who are dying have unique needs for respectful, compassionate care as indicated by their assessment. 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.

Concern for the patient's comfort and dignity should guide all aspects of care during the final stages of life. End-of-life care provided by the hospital includes

- taking interventions to manage pain; (*Also see* COP.6)
- 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; and
- responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family.

To accomplish these goals, all staff are educated about the unique needs of patients and their families at the end of life. (*Also see* PCC.1.2 and SQE.3)

### Measurable Elements of COP.7

- ❑ 1. Staff are educated about the unique needs of patients and their families at the end of life.
- ❑ 2. The health care needs of the patient and the support service needs of the patient and the family are identified as appropriate to their religious and cultural preferences.
- ❑ 3. End-of-life care addresses the symptoms, conditions, and health care needs of the dying patient as indicated by his or her assessment.
- ❑ 4. End-of-life care addresses the dying patient's pain.
- ❑ 5. End-of-life care addresses the patient's and family's psychosocial, emotional, cultural, and spiritual needs, as appropriate, regarding dying and grieving.
- ❑ 6. The patient and family are involved in care decisions.

## *Hospitals Providing Organ and/or Tissue Transplant Services*

**Note:** The following standards address the hospital's responsibilities for organ and tissue transplantation, donation, and procurement.

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 subsequent to transplant include, to name a few, 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.

Leadership's 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 organizationwide responsibilities for organ and tissue donation and procurement. This includes any individual who has been 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.8

The hospital's leadership provides resources to support the organ/tissue transplant program.

### Intent of COP.8

The organ/tissue transplant program requires staff with specialized education and training and other resources in order to provide safe, high-quality care. (*Also see* SQE.3) Staff education and training must be specific to the responsibilities and requirements of organ/tissue transplant. 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 tissue/organs are not contaminated, and other resources as identified by the program service leader. In addition, resources related to information management systems are necessary to assist with the collection of data associated with risks, outcomes, and other information that support the quality of the transplant program. (*Also see* GLD.1.1; GLD.7; and GLD.9)

### Measurable Elements of COP.8

- ❑ 1. Trained staff are available to provide safe, high-quality care to the organ/tissue transplant program.
- ❑ 2. The hospital's leadership allocates resources for the organ/tissue transplant program.
- ❑ 3. Information management systems are used to support the quality of the organ/tissue transplant program.

## Standard COP.8.1

A qualified transplant program leader(s) is responsible for the transplant program.

### Intent of COP.8.1

The responsibility of a hospital offering organ and tissue transplant services is to provide safe, high-quality care to transplant donors and recipients. At the core of this responsibility is an infrastructure capable of supporting all transplant program activities. A key element of the infrastructure is an individual(s) responsible for oversight of the organ/tissue transplant program. (*Also see* GLD.9) Acting on a full-time or part-time basis, this individual(s) provides that oversight as part of his or her assigned responsibilities or job description. This individual(s) is qualified in transplant management through education, training, experience, licensure, and/or certification. The required qualifications depend on the activities carried out.

### Measurable Elements of COP.8.1

- ❑ 1. The transplant program has an infrastructure capable of supporting all aspects of the transplant program activities.
- ❑ 2. One or more individuals are qualified to oversee the scope and complexity of the organ/tissue transplant program.
- ❑ 3. The individual(s) fulfills the program's oversight responsibilities as defined by the transplant program.

## Standard COP.8.2

The transplant program includes a multidisciplinary team that consists of people with expertise in the relevant organ-specific transplant programs.

### Intent of COP.8.2

The success of a transplant program and positive outcomes for transplant recipients and living donors are dependent on a team of health care practitioners who have clinical knowledge and expertise in organ-specific transplantation. The nursing, psychological, pharmacological, and nutritional needs of an organ recipient

and a living organ donor are unique. As related to the type of transplant, a multidisciplinary team consists of individuals from

- medicine;
- nursing;
- nutrition;
- pharmacology;
- infection prevention and control;
- social services;
- psychological services; and
- rehabilitative services.

This team should have the qualifications, training, and experience to provide care and services to transplant recipients and living donors. (*Also see* SQE.3)

### Measurable Elements of COP.8.2

❑ 1. The transplant program documents the composition of the tissue/organ-specific transplant team.

❑ 2. The transplant program documents the team members' responsibilities.

❑ 3. 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.

❑ 4. 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.8.3

There is a designated coordination mechanism for all transplant activities that involves physicians, nurses, and other health care practitioners.

### Intent of COP.8.3

Transplant services carry unique and critical risks to organ/tissue recipients and, in the cases of living donors, to the donor as well. An important component in ensuring safe, high-quality care through all phases of the donor/recipient process is identifying an individual with overall responsibility for coordination and continuity of the live donor's and recipient's care. This individual may be a physician, registered nurse, or other qualified health care practitioner.

### Measurable Elements of COP.8.3

❑ 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 clinical transplant coordinator facilitates continuity of care for transplant patients (candidates and recipients) through the pre-transplant, transplant, and discharge phases of transplantation.

❑ 3. The clinical transplant coordinator facilitates continuity of care for living donors during the evaluation, donation, and discharge phases of donation.

❑ 4. The coordination of organ/tissue transplant activities is communicated to all staff involved in the transplant program activities.

## Standard COP.8.4

The transplant program uses organ-specific transplant clinical eligibility criteria and psychological and social suitability criteria for transplant candidates.

### Intent of COP.8.4

There are multiple areas for consideration when a decision needs to be made about allocating organs to recipients. Consideration may be given to the imminent need of the patient for a transplant, the benefit the patient may gain from the transplant, the availability of alternative treatments, the expected improvement in the patient's quality of life, and the amount of resources required for successful treatment.

Because human organs and tissues available for transplant are limited, criteria for recipient selection are developed. Criteria for transplant recipient selection helps identify the most appropriate patient and limits the potential for bias. Thus, criteria for access to organs and tissues are defined in a transparent manner, based on an objective evaluation of medical needs.

In addition, there are organ-specific criteria that must be taken into account in the decision for allocating an organ. **For example**, the viability of an organ outside of the body varies from organ to organ. Thus consideration must be given to the length of time it may take for an organ to reach the recipient.

### Measurable Elements of COP.8.4

- ❑ 1. The transplant program documents organ-specific clinical eligibility criteria for the transplant candidate.
- ❑ 2. The transplant program documents the psychological and social suitability criteria for the transplant candidate.
- ❑ 3. The results of a medical evaluation are included in the determination of suitability for transplantation.
- ❑ 4. The transplant program documents organ compatibility confirmation in the transplant candidate's medical record.

## Standard COP.8.5

The transplant program obtains informed consent specific to organ transplantation from the transplant candidate. Ⓟ

### Intent of COP.8.5

To consent, a patient must be informed of those factors related to the planned care required for an informed decision. (*Also see* PCC.2) Patients are informed about factors that could affect the success of the graft or the candidate's health as a recipient. Factors include, but are not limited to,

a) the donor's history, as appropriate to the laws and regulations of the country/region;
b) condition of the organ(s) used;
c) age of the organ(s); and
d) the potential risk of contracting infectious disease(s) if disease(s) cannot be detected in an infected donor.

In addition, there may be psychological, ethical, financial, and other factors that are unique to the transplant patient than for other patients, such as the need for immunosuppressive medications and the projected survival rate. (*Also see* AOP.1.1) 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 as well as local and regional laws and regulations. (*Also see* PCC.4.2)

### Measurable Elements of COP.8.5

- ❑ 1. The transplant program follows the hospital's policy when obtaining informed consent from transplant candidates.
- ❑ 2. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of potential psychosocial risks.
- ❑ 3. In addition to the information provided to any surgical patient as part of the informed consent process, 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, a) through d) of the intent.
- ❑ 4. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of the transplant center's observed and expected one-year survival rate; or when the transplant program has been in operation less than 18 months, the one-year survival rate as documented in the literature.
- ❑ 5. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate about potential rejection rates, immunosuppressive drugs, and possible associated costs.
- ❑ 6. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of alternative treatments.

## Standard COP.8.6

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.8.6

To reduce the risk of organ rejection, the transplant surgeon must ensure the compatibility of the donor organ(s) to the recipient. 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 takes place.

Transmission of infectious diseases and malignancies is a potential risk for recipients of donor 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.

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. (*Also see* GLD.11.2)

### Measurable Elements of COP.8.6

- ❑ 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 recovery takes place.
- ❑ 2. The transplant surgeon is responsible for confirming, in writing, the medical suitability of donor organs for transplantation into the recipient.
- ❑ 3. When an organ arrives at the transplant center, the transplanting surgeon and at least one other licensed 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 recovery and organ transplant occur.
- ❑ 5. When an organ arrives at the transplant center, the transplanting surgeon and at least one other licensed 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.8.7

Individualized patient care plans guide the care of transplant patients.

### Intent of COP.8.7

The care of the patient receiving an organ or tissue transplant is different based on the type of organ or tissue being transplanted. The patient's health history has an impact on his or her recovery. In addition, the patient's psychological status may have an impact on the success of the transplant. A psychological evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness. (*Also see* AOP.1.1) Individualized care plans are developed to guide the care of transplant patients. (*Also see* AOP.1.2 and COP.2.2)

### Measurable Elements of COP.8.7

- ❑ 1. The transplant program has documented 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 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 candidates receive a psychological evaluation by a psychiatrist, psychologist, or social worker 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 patient's medical record on an ongoing basis.

## Transplant Programs Using Living Donor Organs

# Standard COP.9

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.9

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. Living donors face difficult decisions and are at potential risk for lifelong complications and should not feel coerced or pressured into organ donation.

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 his or her decision-making abilities. (*Also see* PCC.1 and PCC.6)

### Measurable Elements of COP.9

- ❑ 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.9.1

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

### Intent of COP.9.1

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 he or she may decline to donate at any time. (*Also see* PCC.4.2)

### Measurable Elements of COP.9.1

- ❑ 1. Informed consent for living donation is obtained by trained staff and is in a language the prospective living donor can understand.
- ❑ 2. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective living donor of potential psychological risks of donation.
- ❑ 3. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective living donor of potential complications and risks associated with living organ donation.
- ❑ 4. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective living donor of potential future health problems.
- ❑ 5. The transplant program informs the prospective living donor of alternative treatments for the transplant candidate.
- ❑ 6. 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.9.2

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

### Intent of COP.9.2

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. (*Also see* AOP.1.1) The donor must also be evaluated for his or her ability to comprehend the donation process and the potential outcomes, including possible adverse outcomes.

### Measurable Elements of COP.9.2

- ❑ 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.
- ❑ 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 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.9.3

Individualized patient care plans guide the care of living donors.

## Intent of COP.9.3

In addition to the general health care needs of patients undergoing surgical procedures, 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. (*Also see* ACC.3 and COP.2.2)

## Measurable Elements of COP.9.3

- ❑ 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 multidisciplinary 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.

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# 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.

Anesthesia and procedural sedation are commonly viewed as a continuum from minimal sedation to full anesthesia along which patients gradually lose their reflexes to protect their airway, such as coughing and gagging. As individual patient response may move along that continuum, anesthesia and procedural sedation use should be organized in an integrated manner. Thus this chapter addresses anesthesia and procedural sedation 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 sedation for the purposes of anxiolysis or sedation required in the ICU for ventilator tolerance.

Because surgery carries a high level of risk, it must be carefully planned and carried out. Information about the surgical procedure and care after surgery is 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. (*Also see* PCC.4.2) 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.1** Sedation and anesthesia services are available to meet patient needs, and all such services meet professional standards and applicable local and national standards, laws, and regulations.

**ASC.2** A qualified individual(s) is responsible for managing the sedation and anesthesia services.

### Sedation Care

**ASC.3** The administration of procedural sedation is standardized throughout the hospital. Ⓟ

**ASC.3.1** Practitioners responsible for procedural sedation and individuals responsible for monitoring patients receiving procedural sedation are qualified. Ⓟ

**ASC.3.2** Procedural sedation is administered and monitored according to professional practice guidelines. Ⓟ

**ASC.3.3** The risks, benefits, and alternatives related to procedural sedation are discussed with the patient, his or her family, or those who make decisions for the patient.

### Anesthesia Care

**ASC.4** A qualified individual conducts a preanesthesia assessment and preinduction assessment.

**ASC.5** Each patient's anesthesia care and, when applicable, postoperative pain management are planned; and the plan as well as the risks, benefits, and alternatives are discussed with the patient and/or those who make decisions for the patient and documented in the patient's medical record.

**ASC.6** 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.6.1** Each patient's postanesthesia status is monitored and documented, and the patient is discharged from the recovery area by a qualified individual or by using established criteria. Ⓟ

### Surgical Care

**ASC.7** Each patient's surgical care is planned and documented based on the results of the assessment.

**ASC.7.1** The risks, benefits, and alternatives are discussed with the patient and his or her family or those who make decisions for the patient.

**ASC.7.2** Information about the surgical procedure is documented in the patient's medical record to facilitate continuing care.

**ASC.7.3** Patient care after surgery is planned and documented.

**ASC.7.4** Surgical care that includes the implanting of a medical device is planned with special consideration of how standard processes and procedures must be modified. Ⓟ



# Standards, Intents, and Measurable Elements

## *Organization and Management*

## Standard ASC.1

Sedation and anesthesia services are available to meet patient needs, and all such services meet professional standards and applicable local and national standards, laws, and regulations.

### Intent of ASC.1

Sedation and anesthesia are commonly viewed as a continuum from minimal sedation to full anesthesia. A patient's response may move along that continuum during which the patient's protective airway reflexes are at risk. Sedation and anesthesia use are complex processes that must be integrated into patient care planning. Sedation and anesthesia require a complete and comprehensive patient assessment, continued patient monitoring, and objective recovery criteria.

The hospital has a system for providing sedation and anesthesia services required by its patient population, clinical services offered, and health care practitioners' needs. Sedation and anesthesia services are provided according to professional practice standards for care and meet all applicable local and national laws and regulations. Sedation and anesthesia services are available after normal hours of operation for emergencies.

Sedation and anesthesia services (including services required for emergencies) may be provided by the hospital, by agreement with an outside source (**for example**, an individual anesthesiologist or anesthesia group practice), or both. Any use of outside anesthesia sources is based on the recommendation of the leader of sedation and anesthesia services. Outside sources meet applicable laws and regulations and have acceptable quality and patient safety records as defined in a contract for services. (*Also see* GLD.6 and GLD.6.1)

### Measurable Elements of ASC.1

- ❑ 1. Sedation and anesthesia services meet professional standards of practice and applicable local and national laws and regulations.
- ❑ 2. Sedation and anesthesia services are available to meet patient needs.
- ❑ 3. Sedation and anesthesia services are available for emergencies after normal hours of operation.
- ❑ 4. Outside sedation and anesthesia sources are selected based on the recommendations of the leader of sedation and anesthesia services, acceptable records of performance, and compliance with applicable laws and regulations.
- ❑ 5. There is a contract in place when outside sources for sedation and anesthesia services are used.

## Standard ASC.2

A qualified individual(s) is responsible for managing the sedation and anesthesia services.

### Intent of ASC.2

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 responsibility for the anesthesia services provided. (*Also see* GLD.6 and GLD.9) Responsibilities include

- developing, implementing, and maintaining policies and procedures;
- providing administrative oversight;
- maintaining any necessary quality control program;
- recommending outside sources of sedation and anesthesia services; and
- monitoring and reviewing all sedation and anesthesia services.

### Measurable Elements of ASC.2

- ❑ 1. Sedation and anesthesia services are uniform throughout the hospital.
- ❑ 2. Sedation and anesthesia services are under the direction of one or more qualified individuals.
- ❑ 3. Responsibilities for recommending outside sources of sedation and anesthesia services are defined and carried out.
- ❑ 4. Responsibilities for monitoring and reviewing all sedation and anesthesia services are defined and carried out.

## Sedation Care

# Standard ASC.3

The administration of procedural sedation is standardized throughout the hospital. Ⓟ

### Intent of ASC.3

*Procedural sedation* is defined as ". . . the technique of administering sedatives or dissociative agents with or without analgesics 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. Procedural sedation is often performed in many areas of the hospital outside of the operating theatre. Because procedural sedation, like anesthesia, poses significant potential risks to patients, the administration of procedural sedation must be uniform throughout the hospital. 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. Thus hospitals must develop specific guidelines for how and where procedural sedation may be used.

Standardization of procedural sedation is supported by policies and procedures that are understood by all practitioners permitted to administer procedural sedation and identifies

a) areas in the hospital where procedural sedation may occur;
b) special qualifications or skills of staff involved in the procedural sedation process; (*Also see* SQE.3)
c) the differences between pediatric, adult, and geriatric populations or other special considerations; (*Also see* AOP.1.6)
d) the immediate availability and use of specialized medical equipment, appropriate to the age and history of the patient; (*Also see* COP.3.3) and
e) the informed consent process for both the procedure and the use of sedation. (*Also see* PCC.4.2)

During procedural sedation, an individual 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. (*Also see* SQE.8.1 and SQE.8.1.1)

### Measurable Elements of ASC.3

❑ 1. The administration of procedural sedation is standardized throughout the hospital.

❑ 2. Standardization of procedural sedation includes identifying and addressing at least a) through e) in the intent.

❑ 3. Emergency medical equipment and supplies are immediately available and customized to the type of sedation being performed and the age and medical condition of the patient.

❑ 4. An individual with advanced life-support training appropriate for the age and history of the patient, is immediately available when procedural sedation is being performed.

# Standard ASC.3.1

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

### Intent of ASC.3.1

The qualifications of the physician, dentist, or other individual 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. 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. As such, the individual responsible for procedural sedation must be competent in

a) techniques and various modes of sedation;
b) pharmacology of sedation drugs and the use of reversal agents;
c) monitoring requirements; and
d) response to complications. (*Also see* SQE.10)

The health care practitioner performing the procedure should not be responsible for providing 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. (*Also see* SQE.3) The individual responsible for providing the monitoring must be competent in

e) monitoring requirements;
f) response to complications;
g) use of reversal agents; and
h) recovery criteria.

### Measurable Elements of ASC.3.1

❑ 1. Health care practitioners responsible for providing procedural sedation show evidence of competence in at least a) through d) of the intent.

❑ 2. The individual responsible for patient monitoring during procedural sedation is competent in at least elements e) through h) in the intent.

❑ 3. Procedural sedation competencies for all staff involved in sedation are documented in the personnel files.

## Standard ASC.3.2

Procedural sedation is administered and monitored according to professional practice guidelines. Ⓟ

### Intent of ASC.3.2

The degrees of sedation occur on a continuum from mild to deep sedation, and a patient may progress from one degree to another. Many factors influence the patient's response to sedation and can affect the degree to which a patient is sedated. Factors include the medications administered, the route and dosages, the age of the patient (pediatric, adult, or geriatric), and the patient's medical 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.

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. (*Also see* AOP.1.1) The responsible, qualified practitioner conducts a presedation assessment of the patient to

a) identify any airway problems that may influence the type of sedation used;
b) evaluate at-risk patients for appropriateness of procedural sedation;
c) plan the type of sedation and the level of sedation the patient will need based on the procedure being performed;
d) safely administer sedation; and
e) interpret findings from patient monitoring during procedural sedation and recovery.

The scope and content of this assessment are based on professional guidelines and are defined in hospital policy.

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 providing 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. Objective criteria help identify patients who are recovered and/or ready for discharge. (*Also see* QPS.8)



### Measurable Elements of ASC.3.2

- ❑ 1. A presedation assessment is performed and documented that includes at least a) through e) to evaluate risk and appropriateness of procedural sedation for the patient.
- ❑ 2. A qualified individual monitors the patient during the period of sedation and documents the monitoring.
- ❑ 3. Established criteria are used and documented for the recovery and discharge from procedural sedation.

## Standard ASC.3.3

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

### Intent of ASC.3.3

The procedural sedation planning process includes educating the patient, his or her family, or decision maker on the risks, benefits, and alternatives related to procedural sedation. This discussion occurs as part of the process to obtain consent for procedural sedation as required in PCC.4.2 and PCC.4.3. A qualified individual provides this education.

### Measurable Elements of ASC.3.3

- ❑ 1. The patient, family, and/or decision makers are educated on the risks, benefits, and alternatives of procedural sedation.
- ❑ 2. The patient, family, and/or decision makers are educated about postprocedure analgesia.
- ❑ 3. A qualified individual provides and documents the education.

# Anesthesia Care

## Standard ASC.4

A qualified individual conducts a preanesthesia assessment and preinduction assessment.

### Intent of ASC.4

Because anesthesia carries a high level of risk, administration is carefully planned. The patient's preanesthesia assessment is the basis for that plan, for identifying what findings from monitoring during anesthesia and recovery may be significant, and for the use of postoperative analgesia. The preanesthesia assessment provides information needed to

- identify any airway problems;
- select the anesthesia and to 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; and
- provide information for the use of analgesia following surgery.

An anesthesiologist or another qualified individual conducts the preanesthesia assessment. 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. (*Also see* AOP.1.1 and AOP.1.3) 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.4

❑ 1. A preanesthesia assessment is performed for each patient.

❑ 2. A separate preinduction assessment is performed to reevaluate patients immediately before the induction of anesthesia.

❑ 3. The two assessments are performed by an individual(s) qualified to do so and documented in the patient medical record.

## Standard ASC.5

Each patient's anesthesia care and, when applicable, postoperative pain management are planned; and the plan as well as the risks, benefits, and alternatives are discussed with the patient and/or those who make decisions for the patient and documented in the patient's medical record.

### Intent of ASC.5

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. The anesthesia planning process includes educating the patient, his or her family, or decision maker on the risks, benefits, and alternatives related to the planned anesthesia. (*Also see* PCC.4.3) This discussion occurs as part of the process to obtain consent for anesthesia as required in PCC.4.2. An anesthesiologist or a qualified individual provides this education. (*Also see* PCC.5.2)

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. (*Also see* COP.2.1; QPS.8; and MOI.8.1)

### Measurable Elements of ASC.5

- ❑ 1. The anesthesia care for each patient is planned and documented in the patient's medical record.
- ❑ 2. The patient, family, and/or decision makers are educated on the risks, benefits, and alternatives of anesthesia.
- ❑ 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.
- ❑ 4. The anesthesia agent, dose (when applicable), and anesthetic technique are documented in the patient's anesthesia record.
- ❑ 5. The anesthesiologist and/or nurse anesthetist and anesthesia assistants are identified in the patient's anesthesia record.



## Standard ASC.6

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.6

Physiological monitoring provides reliable information about the patient's status during anesthesia (general, spinal, regional, and local) and the recovery period. 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 information guides medical and nursing care and identifies the need for diagnostic and other services. 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. (*Also see* GLD.7) The results of monitoring are documented in the patient's medical record. (*Also see* COP.2.1 and MOI.8.1)

### Measurable Elements of ASC.6

- ❑ 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.
- ❑ 3. The results of monitoring are documented in the patient's medical record.

## Standard ASC.6.1

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

### Intent of ASC.6.1

Monitoring during the anesthesia period is the basis for monitoring during the postanesthesia recovery period. 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. 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.

Discharge from the postanesthesia recovery areas or discontinuation of recovery monitoring is by one of the following alternative ways:

a) 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.
b) The patient is discharged (or recovery monitoring is discontinued) by a nurse or similarly qualified individual in accordance with postanesthesia criteria developed by hospital leadership, and the patient's medical record contains evidence that criteria are met.
c) The patient is discharged to a unit that is capable of providing postanesthesia or postsedation care of selected patients, such as a cardiovascular intensive care unit or neurosurgical intensive care unit, among others.

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

### Measurable Elements of ASC.6.1

- ❑ 1. Patients are monitored during the postanesthesia recovery period.
- ❑ 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 the alternatives described in a) through c) in the intent.
- ❑ 4. Time recovery is started and time recovery phase is complete are recorded in the patient's medical record.



## *Surgical Care*

# Standard ASC.7

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

### Intent of ASC.7

Because surgery carries a high level of risk, its use is carefully planned. The patient's assessment(s) is the basis for selecting the appropriate surgical procedure and for identifying what findings during monitoring may be significant. (*Also see* AOP.1.1 and AOP.1.2) The assessment(s) provides information necessary to

- select the appropriate procedure and the optimal time;
- perform the procedures safely; and
- interpret the findings of patient monitoring.

Procedure selection depends on the patient's history, physical status, and diagnostic data as well as the risks and benefits of the procedure for the patient. Procedure selection considers the information from the admitting assessment, diagnostic test, and other available sources. The assessment process is carried out in a shortened time frame when an emergency patient needs surgery. (*Also see* AOP.1.2.1)

The surgical care planned for the patient is documented in the patient's medical record, including a preoperative diagnosis. The name of the surgical procedure alone does not constitute a diagnosis. (*Also see* AOP.1.3.1)

### Measurable Elements of ASC.7

❑ 1. The responsible physician documents the assessment information used to develop and to support the planned invasive procedure in the patient's medical record before the procedure is performed.

❑ 2. The surgical care for each patient is planned based on the assessment information.

❑ 3. A preoperative diagnosis and the planned procedure are documented in the patient's medical record prior to the procedure.

## Standard ASC.7.1

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



### Intent of ASC.7.1

Patients and their families or decision makers receive adequate information to participate in care decisions and to provide the informed consent required in PCC.4.2. The information includes

- the risks of the planned procedure;
- the benefits of the planned procedure;
- the potential complications; and
- the surgical and nonsurgical options (alternatives) available to treat the patient.

In addition, when blood or blood products may be needed, information on the risks and alternatives is discussed. (*Also see* PCC.4.1) The patient's surgeon or other qualified individual provides this information. (*Also see* PCC.5.2)

### Measurable Elements of ASC.7.1

❑ 1. The patient, family, and decision makers are educated on the risks, benefits, potential complications, and alternatives related to the planned surgical procedure.

❑ 2. The education includes the need for, risks and benefits of, and alternatives to blood and blood-product use.

❑ 3. The patient's surgeon or other qualified individual provides and documents the education.

## Standard ASC.7.2

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

### Intent of ASC.7.2

A patient's postsurgical care depends on the events and findings of the surgical procedure. The most important issue is that all actions and results essential to the patient's condition are entered in the patient's medical record. This information could be presented in the form of a template—either paper or electronic—or an operative report, such as a written operative progress note. 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. (*Also see* MOI.8.1) The documented information about the surgery includes at least

a) postoperative diagnosis;
b) name of operative surgeon and assistants;
c) procedures performed and description of each procedure findings;
d) perioperative complications;

e) surgical specimens sent for examination;
f) amount of blood loss and amount of transfused blood; and
g) date, time, and signature of responsible physician.

Some information may be contained in other notations in the medical record. (*Also see* ACC.3) **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. (*Also see* ASC.7.4)

The time immediately after surgery is defined as "upon completion of surgery, before the patient is transferred to the next level of care." This definition 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.2.1.

### Measurable Elements of ASC.7.2

- ❑ 1. Surgical reports, templates, or operative progress notes include at least a) through g) from the intent.
- ❑ 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.7.3

Patient care after surgery is planned and documented.

### Intent of ASC.7.3

Each patient's postsurgical medical and nursing care needs differ depending on the surgical procedure performed and the medical history of the patient. In addition, 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.

Postsurgical care planning can begin before surgery based on the patient's assessed needs and condition and the type of surgery being performed. The postsurgical plan of care also includes the patient's immediate postoperative needs. The planned care is 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.

The 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 postsurgical 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. (*Also see* COP.2.2)

### Measurable Elements of ASC.7.3

- ❑ 1. The postsurgical care provided by medical, nursing, and others meets 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 medical, nursing, and others as needed based on the patient's 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.



## Standard ASC.7.4

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

### Intent of ASC.7.4

Many surgical procedures involve the permanent implantation of a medical device. An *implantable medical device* can be defined as 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.

A permanent implantable medical device can be a prosthesis (such as a hip), a stent, a cardioverter defibrillator, a pacemaker, intraocular lenses, and an infusion pump, among other **examples**.

Surgical procedures involving the permanent implantation of medical devices require that routine surgical care be modified to account for special factors such as

a) the selection of devices based on current science and research;
b) ensuring that implants are present in the operating theatre; (*Also see* IPSG.4)
c) 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);
d) the reporting process for implantable device–related adverse events;
e) the reporting of implantable device malfunctions to regulatory agencies;
f) unique infection prevention and control considerations; and
g) any special discharge instructions for the patient.

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. (*Also see* SQE.10)

The ability to trace implantable medical devices is essential for tracing surgical site infections and identifying patients who may have received nonsterile implants. In addition, the tracing process allows the hospital to assess the reliability of the sterilization process. Therefore, the hospital has a process for tracing implantable medical devices. (*Also see* ASC.7.2 and GLD.7.1)

In the event of a recall of an implantable medical device, the hospital informs and follows up with those patients who received the device. (*Also see* FMS.9.2) 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.

## Measurable Elements of ASC.7.4

- ❑ 1. The hospital's surgical services identify the types of implantable medical devices that are included within its scope of services.
- ❑ 2. Policies and practices include a) through g) in the intent.
- ❑ 3. The hospital has a process for tracing implantable medical devices.
- ❑ 4. The hospital develops and 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.

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# 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. A medication system that supports optimal medication management must include processes that support safe and effective medication use. Safe, effective medication use involves a multidisciplinary, 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 antibiotic stewardship 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.1** Medication use in the hospital is organized to meet patient needs, complies with applicable laws and regulations, and is under the direction and supervision of a licensed pharmacist or other qualified professional. Ⓟ

**MMU.1.1** The hospital develops and implements a program for the prudent use of antibiotics based on the principle of antibiotic stewardship. Ⓟ

#### Selection and Procurement

**MMU.2** There is a method for overseeing the hospital's medication list, including how listed medications are used; a method for ensuring medications for prescribing or ordering are stocked; and a process for

medications not stocked or not normally available to the hospital or for times when the pharmacy is closed. Ⓟ

## Storage

**MMU.3** Medications are properly and safely stored. Ⓟ

**MMU.3.1** Emergency medications are available, uniformly stored, monitored, and secure when stored out of the pharmacy. Ⓟ

**MMU.3.2** The hospital has a medication recall system. Ⓟ

## Ordering and Transcribing

**MMU.4** The hospital identifies and documents a current list of medications taken by the patient at home and reviews the list against all new medications prescribed or dispensed. Ⓟ

**MMU.4.1** The hospital identifies those qualified individuals permitted to prescribe or to order medications.

**MMU.4.2** The hospital identifies safe prescribing, ordering, and transcribing practices and defines the elements of a complete order or prescription. Ⓟ

## Preparing and Dispensing

**MMU.5** Medications are prepared and dispensed in a safe and clean environment.

**MMU.5.1** Medication prescriptions or orders are reviewed for appropriateness. Ⓟ

**MMU.5.2** A system is used to safely dispense medications in the right dose to the right patient at the right time.

## Administration

**MMU.6** Qualified individuals permitted to administer medications are identified and document the medications that are administered in the patient's medical record.

**MMU.6.1** Medication administration includes a process to verify the medication is correct based on the medication prescription or order.

**MMU.6.2** Policies and procedures govern medications brought into the hospital by the patient or family and medication prescribed for patient self-administration. Ⓟ

**MMU.6.2.1** Policies and procedures govern medications brought into the hospital as samples. Ⓟ

## Monitoring

**MMU.7** Medication effects on patients are monitored. Ⓟ

**MMU.7.1** The hospital establishes and implements a process for reporting and acting on medication errors and near misses (or close calls). Ⓟ

# Standards, Intents, and Measurable Elements

## *Organization and Management*

## Standard MMU.1

Medication use in the hospital is organized to meet patient needs, complies with applicable laws and regulations, and is under the direction and supervision of a licensed pharmacist or other qualified professional. Ⓟ

### Intent of MMU.1

Medications, as an important resource in patient care, must be organized effectively and efficiently. A safe medication management system addresses an organization's medication processes, which in many organizations includes the following (as applicable):

a) Planning
b) Selection and procurement
c) Storage
d) Ordering
e) Preparing and dispensing
f) Administration
g) Monitoring
h) Medication error and adverse event reporting
i) Evaluation

Medication management is not only the responsibility of the pharmaceutical service but also of managers and health care practitioners. How this responsibility is shared depends on the hospital's structure and staffing. In those cases in which a pharmacy is not present, medications may be managed on each clinical unit according to hospital policy. In other cases, in which 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, and specialized units.

However medication is organized within the hospital, a qualified individual directly supervises the activities of the pharmacy or pharmaceutical service. (*Also see* GLD.9) 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.

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 by pulling together all information and experience related to medication management as identified in a) through i) above. The review allows hospitals to understand the need and priority of continued system improvements in quality and safety of medication use.

### Measurable Elements of MMU.1

- ❑ 1. A written document addressing items a) through i) of the intent, as appropriate, identifies how medication use is organized, managed, and overseen throughout the hospital.
- ❑ 2. All settings, services, and individuals who manage medication processes are included in the organizational structure.
- ❑ 3. 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.
- ❑ 4. The hospital documents at least one review of the medication management system, addressing items a) through i) of the intent as appropriate, annually.
- ❑ 5. A uniform medication dispensing and distribution system is available and complies with applicable laws and regulations.
- ❑ 6. Appropriate sources of drug information are readily available to those involved in medication use.

## Standard MMU.1.1

The hospital develops and implements a program for the prudent use of antibiotics based on the principle of antibiotic stewardship. Ⓟ

### Intent of MMU.1.1

The overuse and misuse of antibiotics has resulted in the growth of superbugs that are increasingly resistant to available antibiotics. According to the US Centers for Disease Control and Prevention (CDC), drug-resistant bacteria cause 23,000 deaths and 2 million illnesses each year. The Institute for Healthcare Improvement reported that 25,000 people die each year in Europe from antimicrobial resistance, and microbial resistance is growing in the Middle East, Africa, and Asia. Some estimate that more than 700,000 deaths occur worldwide per year due to antibiotic resistance.

In addition to resistance and the growth of superbugs, there are often side effects and/or complications to antibiotic treatment, including acquiring *Clostridioides difficile* (*C. diff*), kidney or liver damage, hearing loss, hemolytic anemia, and other such complications. The proper use of antibiotics is important in the prevention of unnecessary complications due to improper antibiotic use.

Health care practitioners are contributing to the development of antimicrobial resistance in several ways. **For example**, continuing antibiotics when they are no longer necessary, using a broad-spectrum antibiotic when it is not required or continuing the broad-spectrum antibiotic unnecessarily after the sensitivity results are received, using the wrong antibiotic or prescribing the wrong dose, or continuing the prophylactic antibiotic after it is no longer recommended.

In order to reduce the development and spread of resistant bacteria and deliver better patient outcomes, hospitals must implement measures to ensure optimal use of antibiotics. (*Also see* PCI.5; PCI.5.1; and GLD.11.2) Implementation of an antibiotic stewardship program will help hospitals reach the goal of providing patients requiring antibiotic treatment with the right antibiotics, at the right time, at the right dose, and for the right duration.

An antibiotic stewardship program may include the following elements: tracking patterns of antibiotic prescribing and resistance, informing staff on antibiotic use and resistance on a regular basis, and educating staff about optimal antibiotic use. It is imperative for the program to have the support of hospital leadership, which includes leadership's commitment to providing support that includes staffing, financial resources, evidence-based resources, and information technology to ensure an effective stewardship program. In addition to infection prevention and control professionals, the antibiotic stewardship program involves physicians, nurses, pharmacists, trainees, patients, families, and others. (*Also see* PCI.2)

Tracking the effectiveness of the program is an important element of the program's success. **Examples** of identifying effectiveness may include evidence of a decrease in the inappropriate use of antibiotics and a decrease in multidrug-resistant organisms, documentation that prescribers are following accepted practice guidelines, and appropriate optimal use of prophylactic antibiotics. Successful tracking of the effectiveness of the program requires a mechanism for oversight. Oversight may include an individual, a small work group, a coordinating committee, a task force, or some other mechanism.

### Measurable Elements of MMU.1.1

- ❑ 1. The hospital develops and implements a program for antibiotic stewardship that involves infection prevention and control professionals, physicians, nurses, pharmacists, trainees, patients, families, and others.
- ❑ 2. The program is based on scientific evidence, accepted practice guidelines, and local laws and regulations.
- ❑ 3. The program includes guidelines for the optimal use of antibiotic therapy for treatment of infections, including the proper use of prophylactic antibiotic therapy.
- ❑ 4. There is a mechanism to oversee the program for antibiotic stewardship.
- ❑ 5. The effectiveness of the antibiotic stewardship program is monitored.

## *Selection and Procurement*

## Standard MMU.2

There is a method for overseeing the hospital's medication list, including how listed medications are used; a method for ensuring medications for prescribing or ordering are stocked; and a process for medications not stocked or not normally available to the hospital or for times when the pharmacy is closed. Ⓟ

### Intent of MMU.2

Every hospital must decide which medications to make available for prescribing and ordering by the health care practitioners. This decision is based on the hospital's mission, patient needs, and types of services provided. The hospital develops a list (often referred to as a formulary) of all the medications it stocks or that are readily available from outside sources. 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. (*Also see* GLD.7.1) Medications are occasionally out of stock due to delayed delivery, national shortages, or other reasons not anticipated through normal inventory control. There is a process to notify prescribers of the shortage and suggested substitutes.

The hospital has a method, such as designating a committee, to maintain and to monitor the medication list and to monitor the use of medications in the hospital; **for example**, monitoring the use of antibiotics. Those involved in the oversight of the list include health care practitioners involved in the ordering, dispensing, administering, and monitoring processes for medications. Decisions to add or to remove medications from the list are guided by criteria that include the indication for use, effectiveness, risks, and 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. **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.2

- ❑ 1. There is a list of medications by both brand name and generic name, stocked in the hospital or readily available from outside sources, and the list is reviewed annually.
- ❑ 2. The process used to develop and monitor the list (unless determined by regulation or an authority outside the hospital) includes representation from health care practitioners involved in ordering, dispensing, administering, and patient-monitoring processes in the hospital.
- ❑ 3. There is a process for obtaining medications during the night or when the pharmacy is closed and for obtaining medications not stocked or not normally available to the hospital.

## *Storage*

## Standard MMU.3

Medications are properly and safely stored. Ⓟ

### Intent of MMU.3

Medications may be stored within a storage area, in a pharmacy or pharmaceutical service, or on the patient care units in unit pharmacies or the nursing station in the clinical unit. Standard MMU.1 provides the oversight mechanism for all locations where medications are stored. There are some types of medications that require special handling; **for example**, radioactive medications and hazardous medications pose a safety risk, and investigational medications may require special storage and/or consent. In all locations where medications are stored, the following is evident:

- Medications stored in the pharmacy are stored under the conditions suitable for product stability as identified by the manufacturers.
- When medications are stored on individual patient care units, ambulances, or other areas outside of the pharmacy, the organization performs a risk assessment to identify the conditions suitable to maintain product stability for the length of time the medications are stored outside of the pharmacy, as applicable. (*Also see* ACC.6)
- Controlled substances are accurately accounted for according to applicable laws and regulations.
- Medications or products requiring special handling, such as radioactive medications, investigational medications, and other similar medications or products, are accurately labeled and safely stored, administered, and monitored.
- Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and warnings. (*Also see* FMS.7)
- Concentrated electrolytes are not stored in care units excluding the exceptions identified in the intent of IPSG.3.2 (scored at IPSG.3.2).
- Medications are protected from loss or theft throughout the hospital.

### Measurable Elements of MMU.3

- ❑ 1. Medications are stored under conditions suitable for product stability, including medications stored on individual patient care units and ambulances, as applicable.
- ❑ 2. Controlled substances are accurately accounted for according to applicable laws and regulations.
- ❑ 3. There is a process for managing medications or products requiring special handling, such as hazardous medications, radioactive medications, and investigational medications.
- ❑ 4. Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and 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.

## Standard MMU.3.1

Emergency medications are available, uniformly stored, monitored, and secure when stored out of the pharmacy. Ⓟ

### Intent of MMU.3.1

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 in these locations. **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.

To ensure access to emergency medications when needed, the hospital establishes a procedure or process to prevent abuse, theft, or loss of the medications. The process ensures 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 understands the balance between ready access and security for locations where emergency medications are stored. **For example**, if access to emergency medications requires a specific individual(s) on the unit to unlock the emergency cart, and the individual(s) is unavailable, the medications are not readily accessible even though they may be secure. (*Also see* FMS.6)

Emergency resuscitation is a highly stressful situation in which time is a crucial element. 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 look-alike product packaging or drug names; disorganized and nonstandard 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; and multiple concentrations of a drug in emergency cart drawers. Therefore, when patient emergencies occur, quick access to appropriate emergency medications is critical. (*Also see* COP.3.3)

Consistency and uniformity in the approach to emergency resuscitation may significantly reduce the risks and improve patient outcomes. **For example**, the hospital can take 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.3.1

- ❑ 1. Emergency medications are immediately available in the units where they will be needed or are readily accessible within the hospital to meet emergency needs.
- ❑ 2. The hospital establishes and implements a process for how emergency medications are uniformly stored; maintained; replaced when used, damaged, or out of date; and protected from loss or theft.
- ❑ 3. Access to emergency medications does not require a specific individual or keys to unlock the emergency cart.
- ❑ 4. Emergency medications are monitored and replaced in a timely manner after use or when expired or damaged.
- ❑ 5. The hospital uses a risk-based approach, as described in the intent, to identify and implement strategies to improve the efficiency and accuracy of medication administration during emergency resuscitation.

## Standard MMU.3.2

The hospital has a medication recall system. Ⓟ

### Intent of MMU.3.2

A medication recall occurs when a drug is removed from the market because it is found to be either defective or potentially harmful. Defects to a medication may be related to incorrect packaging, potential contamination, or poor manufacturing, resulting in impurities or errors in strength/potency. Sometimes, the makers of the drug will identify a problem with their drug and voluntarily recall it. Other times, a government agency will request that the medicine be recalled after receiving reports of problems from the public. Communications of medication recalls may come directly from the manufacturer or from regulatory authorities. 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. The recall process includes any medications compounded within the hospital in which products that have been recalled have been used.

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 expiry date listed on the original packaging from the manufacturer. An outdated medication is one that is opened and is typically safe and effective to use for a short period of time after opening (shelf life). These outdated medications should be marked with a date of expiry based on when they were opened so that staff know the end date of use.

### Measurable Elements of MMU.3.2

- ❑ 1. The hospital establishes and implements a process for receiving and acting on notifications of medication recalls.
- ❑ 2. The process includes identifying, retrieving, and returning, or safely and properly destroying, medications recalled by the manufacturer, supplier, or regulatory agency.
- ❑ 3. The recall process includes medications compounded within the hospital in which products that have been recalled have been used.
- ❑ 4. The hospital establishes and implements a process for use of unopened, expired medications and outdated medications.
- ❑ 5. The hospital establishes and implements a process for the destruction of medications known to be expired or outdated.

## *Ordering and Transcribing*

# Standard MMU.4

The hospital identifies and documents a current list of medications taken by the patient at home and reviews the list against all new medications prescribed or dispensed. Ⓟ

### Intent of MMU.4

Medication reconciliation 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 and may be at risk of an adverse event if an accurate list of those medication is not documented in the patient's record. 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.

The types of information that clinicians use to reconcile medications include, but are not limited to, medication name, dose, frequency, route, and purpose. Organizations should identify the information that needs to be collected to reconcile current and newly ordered medications and to safely prescribe medications in the future. Good medication management includes a review of a proposed new medication against the list of medications the patient is currently taking. (*Also see* ACC.4.3 and AOP.1.1) The goal of this review is 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.4

- ❑ 1. The hospital identifies the information needed to reconcile current and newly ordered medications.
- ❑ 2. The patient's medical records contain 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.
- ❑ 3. Initial medication orders are compared to the list of medications taken prior to admission, according to the hospital's established process.

## Standard MMU.4.1

The hospital identifies those qualified individuals permitted to prescribe or to order medications.

### Intent of MMU.4.1

Selecting a medication to treat a patient requires specific knowledge and experience. 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. (*Also see* COP.2.1; SQE.10; MOI.2; and MOI.9) A hospital may place limits on prescribing or ordering by an individual, such as for controlled substances, chemotherapy agents, or radioactive and investigational medications. (*Also see* SQE.12) 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.4.1

- ❑ 1. Only those permitted by the hospital and by relevant licensure, laws, and regulations prescribe or order medications.
- ❑ 2. The hospital establishes and implements a process to place limits, when appropriate, on the prescribing or ordering practices of individuals.
- ❑ 3. Individuals permitted to prescribe and to order medications are known to the pharmaceutical service or others who dispense medications.

## Standard MMU.4.2

The hospital identifies safe prescribing, ordering, and transcribing practices and defines the elements of a complete order or prescription. Ⓟ

### Intent of MMU.4.2

A common cause of adverse events in the hospital setting is medication errors. One recent study reported that "Medication errors are most common at the ordering or prescribing stage. Typical errors include the healthcare provider 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.

To reduce the variation and improve patient safety, the hospital defines the required elements of a complete order or prescription. (*Also see* MOI.9) All orders and prescriptions contain the name of the drug, the dose, and the frequency and route of administration. Also, the following additional elements are included in the prescription and order when appropriate to the order:

a) The data necessary to accurately identify the patient (*Also see* IPSG.1)
b) When generic or brand names are acceptable or required (*Also see* MMU.2)
c) Specific guidelines for the use of PRN (pro re nata, or "as needed") orders that include indications for use and detailed directions for overlapping orders, such as more than one medication for pain
d) The types of orders that are weight based or otherwise adjusted, such as for children, frail elderly, and oncology patients

e) The types of orders that are 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
f) Rates of administration when intravenous infusions are ordered
g) Other special orders such as titrating, tapering, or range orders

There are processes in place to manage

- medication orders that are incomplete, illegible, or unclear; (*Also see* MOI.10)
- precautions for ordering medications with look-alike or sound-alike names; (*Also see* IPSG.3.1)
- special types of orders, such as emergency, standing, or automatic stop, and any elements unique to such orders; (*Also see* COP.2.1) and
- verbal, telephone, and text medication orders and the process to verify such orders (scored at IPSG.2 and MOI.12).

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. (*Also see* MOI.8)

### Measurable Elements of MMU.4.2

❑ 1. The hospital establishes, implements, and trains staff on a process for the safe prescribing, ordering, and transcribing of medications in the hospital.

❑ 2. All orders and prescriptions contain the name of the drug, the dose, the frequency and route of administration, the indication for prescribing the medication, and the maximum dose.

❑ 3. Additional elements of complete medication orders or prescriptions include at least a) through g) identified in the intent as appropriate to the order.

❑ 4. The hospital develops and implements a process to manage medication orders that are incomplete, illegible, or unclear; including measures to prevent continued occurrence.

❑ 5. The hospital develops and implements a process to manage special types of orders, such as emergency, standing, or automatic stop, and any elements unique to such orders.

❑ 6. Medications prescribed or ordered are documented in the patient's medical record or inserted into the patient's medical record at discharge or transfer.

## *Preparing and Dispensing*

# Standard MMU.5

Medications are prepared and dispensed in a safe and clean environment.

### Intent of MMU.5

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. (*Also see* PCI.4) **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. Some medications and solutions require preparation under very specific guidelines. Staff compounding and preparing these medications are trained in the principles of medication preparation and aseptic technique. Similarly, positive-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, epidurals, and hazardous medications such as

cytotoxic drugs. Due to the need for positive 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. The 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.5

- ❑ 1. Medication preparation and dispensing adhere to laws, regulations, and professional standards of practice.
- ❑ 2. Medications are prepared and dispensed in clean, uncluttered, safe, and functionally separate areas with appropriate medical equipment and supplies.
- ❑ 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. Guidelines for use of single-use and multidose vials are identified and implemented in the medication processes.
- ❑ 5. Medications stored, prepared, and dispensed from areas outside the pharmacy (**for example**, patient care wards) comply with the same cleanliness measures required in the pharmacy.



## Standard MMU.5.1

Medication prescriptions or orders are reviewed for appropriateness. Ⓟ

### Intent of MMU.5.1

Good medication management includes two reviews of each prescription or order:

- The appropriateness of the medication for the patient and his or her 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 (*Also see* MMU.6.1)

Each newly prescribed or ordered medication is reviewed for appropriateness, including a) through g) below. A new appropriateness review should be conducted 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 (the first review) for an order or prescription prior to dispensing includes evaluation of

a) the appropriateness of the drug, dose, frequency, and route of administration;
b) therapeutic duplication;
c) real or potential allergies or sensitivities;
d) real or potential interactions between the medication and other medications or food;
e) variation from hospital criteria for use;
f) patient's weight and other physiological information; and
g) 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 licensed independent 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. (*Also see* SQE.5; SQE.10; SQE.14; and SQE.16) The hospital may choose to use clinical decision support programs associated with medication management to enhance the process. (*Also see* MOI.6) Alternatively, the hospital may choose to use clinical decision support programs to conduct the appropriateness review process. (*Also see* QPS.3) **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. 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. Critical elements of an appropriateness review include at least the following:

h) Allergies
i) Lethal drug-drug interactions
j) Weight-based dosing
k) Potential organ toxicity (**for example**, administration of potassium-sparing diuretics in patients with renal failure)

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. (*Also see* IPSG.2) 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. (*Also see* ACC.3)

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 utilized.

### Measurable Elements of MMU.5.1

- ❑ 1. The hospital defines 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. Apart from exceptions identified in the intent, 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 and includes elements a) through g) in the intent.
- ❑ 3. Individuals permitted to conduct appropriateness reviews are judged competent to do so, are permitted to do so by privileges or job descriptions, and are provided resources to support the review process.
- ❑ 4. When the designated licensed professional is not available to perform the full appropriateness review, a trained individual conducts and documents a review of critical elements h) through k) in the intent for the first dose, and a full appropriateness review is conducted within 24 hours.
- ❑ 5. Review is facilitated by the availability of appropriate patient clinical information for all patients receiving medications, and this clinical information is available at all times when the pharmacy is open or closed.
- ❑ 6. Clinical decision support programs used 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.

## Standard MMU.5.2

A system is used to safely dispense medications in the right dose to the right patient at the right time.

### Intent of MMU.5.2

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 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.

When medications are prepared by someone different from the person administering the medication, 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—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. (*Also see* IPSG.1)

### Measurable Elements of MMU.5.2

- ❑ 1. Medications are dispensed in the most ready-to-administer form available.
- ❑ 2. The system supports accurate and timely dispensing and documentation of dispensing practices.
- ❑ 3. After preparation, medications not immediately administered are labeled with the name of the medication, the dosage/concentration, the date prepared, the expiration date, and two patient identifiers.

## *Administration*

## Standard MMU.6

Qualified individuals permitted to administer medications are identified and document the medications that are administered in the patient's medical record.

### Intent of MMU.6

Administering a medication to treat a patient requires specific knowledge and experience. 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. (*Also see* SQE.3 and SQE.10) 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. (*Also see* COP.2.1) 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.

### Measurable Elements of MMU.6

- ❑ 1. The hospital identifies those individuals, by job description or the privileging process, authorized to administer medications.
- ❑ 2. The hospital places limits, when appropriate, on the medication administration of individuals.
- ❑ 3. Medication administration is recorded for each dose.

## Standard MMU.6.1

Medication administration includes a process to verify the medication is correct based on the medication prescription or order.

### Intent of MMU.6.1

The safe administration of medications includes verifying the

- medication with the prescription or order; (*Also see* MMU.5.1)
- time and frequency of administration with the prescription or order;
- dosage amount with the prescription or order;
- route of administration with the prescription or order; and

- identity of the patient (scored at IPSG.1).

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.5.1 must also be carried out by a qualified individual.

In support of the patient's engagement in all aspects of his or her 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. (*Also see* PCC.2) Medications are administered to the patient on a timely basis and noted in the patient's medical record. (*Also see* COP.2.1)

### Measurable Elements of MMU.6.1

- ❑ 1. Medications are verified with the prescription or order.
- ❑ 2. The dosage amount of the medication is verified with the prescription or order.
- ❑ 3. The route of administration is verified with the prescription or order.
- ❑ 4. Patients are informed about the medications that they are going to be given and have an opportunity to ask questions.
- ❑ 5. Medications are administered as prescribed on a timely basis and noted in the patient's medical record.

## Standard MMU.6.2

Policies and procedures govern medications brought into the hospital by the patient or family and medication prescribed for patient self-administration. Ⓟ

## Standard MMU.6.2.1

Policies and procedures govern medications brought into the hospital as samples. Ⓟ

### Intent of MMU.6.2 and MMU.6.2.1

Overseeing medication use in a hospital requires an understanding of the sources and uses of medications that are not dispensed from the hospital pharmacy, such as medications brought in by the patient or family or medication samples. These types of medications require special processes for labeling, storage, and control of use. The hospital controls the availability and 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. (*Also see* MMU.3.2 and GLD 7.1)

Written documentation of the medications brought in by the patient/family and sample medications must address

a) receipt (denoting how the hospital received the medication from the patient or other source);
b) identification;
c) labeling;
d) storage; and
e) control and distribution.

In addition, the hospital performs a risk assessment for medications brought in by the patient that addresses where the patient obtained the medication, when the medication was obtained, and how the medication was stored at home. Medications brought into the hospital by the patient or his or her family or prescribed within the hospital for self-administration are known to the patient's physician and noted in the patient's medical record.

### Measurable Elements of MMU.6.2

- ❑ 1. The hospital establishes and implements a process that includes a) through e) of the intent for medications brought in by the patient/family.
- ❑ 2. The hospital performs a risk assessment for medications brought in by the patient/family that addresses where and when the medication was obtained and how the medication was stored at home.
- ❑ 3. The hospital establishes and implements a process to govern patient self-administration of medications.
- ❑ 4. The hospital establishes and implements a process to govern the management, use, and documentation of medication brought in by the patient/family.

### Measurable Elements of MMU.6.2.1

- ❑ 1. The hospital establishes and implements a process that includes a) through e) of the intent for medication samples.
- ❑ 2. The hospital performs a risk assessment for sample medications brought in by the patient or provided by other sources that addresses where and when the medication was obtained and how the medication was stored prior to arrival.
- ❑ 3. The hospital establishes and implements a process to govern the availability, management, use, and documentation of medication samples.

## *Monitoring*

# Standard MMU.7

Medication effects on patients are monitored. Ⓟ

### Intent of MMU.7

Patients, their physicians, nurses, and other health care practitioners work together to monitor patients on medications. 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 monitoring with select medications, and to evaluate the patient for adverse effects. (*Also see* AOP.2) 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 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. (*Also see* QPS.7.1)

### Measurable Elements of MMU.7

- ❑ 1. Medication effects on patients are monitored and documented when appropriate.
- ❑ 2. Medication adverse effects on patients are monitored and documented.
- ❑ 3. The hospital utilizes a standardized process for recording in the patient medical record, adverse effects related to medication use and reporting adverse effects to the hospital.
- ❑ 4. The hospital utilizes a standardized process for reporting adverse medication effects as part of the hospital quality program.
- ❑ 5. Adverse effects are reported as identified by the process in the time frame required.

## Standard MMU.7.1

The hospital establishes and implements a process for reporting and acting on medication errors and near misses (or close calls). Ⓟ

### Intent of MMU.7.1

The hospital has a process to identify and to report medication errors and near misses. (*Also see* QPS.7.1 and QPS.8) The process includes defining a medication error and near miss, using a standardized format for reporting, and educating staff on the process and importance of reporting. Definitions and processes are developed through a collaborative process that includes all those involved in the different steps in medication management. 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 for taking 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. (*Also see* IPSG.3) Improvements in medication processes and staff training are used to prevent errors in the future. The pharmacy participates in such staff training.

### Measurable Elements of MMU.7.1

- ❑ 1. The hospital establishes a definition for a medication error and near miss.
- ❑ 2. The hospital establishes and implements a process for reporting and acting on medication errors and near misses.
- ❑ 3. Those accountable for acting on the reports are identified.
- ❑ 4. The hospital uses medication errors and near misses reporting information to improve medication use processes.

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# Section III: Health Care Organization Management Standards

# Quality Improvement and Patient Safety (QPS)

## Overview

It is essential that organizations have a framework to support ongoing quality improvement and patient safety. This chapter describes a comprehensive approach to quality improvement and patient safety that impacts all aspects of the facility's operation. This approach includes

- department-level input and participation into the quality improvement and patient safety program;
- use of objective, validated data to measure how well processes work;
- effectively using data and benchmarks to focus the program; and
- implementing and sustaining changes that result in improvement.

Both quality improvement and patient safety programs

- are leadership driven;
- seek to change the culture and environment of an organization;
- proactively identify and reduce variation;
- use data and evidence-based methodology to focus on priority issues; and
- seek to demonstrate sustainable improvements.

Quality and safety are rooted in the daily work of all staff at the facility. As clinical staff assess patient needs and provide care, this chapter can help them understand how to make real improvements that help patients and reduce risks. Similarly, nonclinical staff can apply the standards to their daily work to understand how processes can be more efficient, resources can be used more wisely, and physical risks can be reduced.

These international accreditation standards address the full spectrum of activities of a health care organization, including the framework for improving those activities and reducing the risks associated with variation in processes.

Thus, the framework presented in these standards is suitable for a wide variety of structured programs and less formal approaches to quality improvement and patient safety. This framework can also incorporate traditional measurement programs, such as those related to unanticipated events (*risk management*) and resource use (*utilization management*).

Over time, organizations that follow this framework will

- develop greater leadership support for an organizationwide program;
- train and involve more staff;
- set clearer priorities for what to measure;
- base decisions on measurement data; and
- make improvements based on comparison to other organizations, nationally and internationally.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

# 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.1** A qualified individual(s) guides the implementation of the hospital's program for quality improvement 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.2** Quality and patient safety program staff support the measure selection process throughout the hospital and provide coordination and integration of measurement activities throughout the hospital.

**QPS.3** Hospital leadership builds a culture and environment that supports implementation of evidence-based care through the use of current scientific knowledge and information to support patient care, health professional education, clinical research, and management.

### Analysis and Validation of Measurement Data

**QPS.4** The quality and patient safety program includes the aggregation and analysis of data to support patient care, hospital management, and the quality management program and participation in external databases.

**QPS.4.1** Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the hospital.

**QPS.5** The data analysis process includes at least one determination per year of the impact of hospitalwide priority improvements on cost and efficiency.

**QPS.6** The hospital uses an internal process to validate data. Ⓟ

**QPS.7** The hospital uses a defined process for identifying and managing sentinel events. Ⓟ

**QPS.7.1** The hospital uses a defined process for identifying and managing adverse, no-harm, and near miss events. Ⓟ

**QPS.8** Data are always analyzed when undesirable trends and variation are evident from the data. Ⓟ

### Gaining and Sustaining Improvement

**QPS.9** Improvement in quality and safety is achieved and sustained.

**QPS.10** An ongoing program of risk management is used to identify and to proactively reduce unanticipated adverse events and other safety risks to patients and staff. Ⓟ

# Standards, Intents, and Measurable Elements

**Note:** In all QPS standards, leaders are individuals, and leadership is the collective group. Accountabilities are described at the individual or collective level. (*Also see* the "Governance, Leadership, and Direction" [GLD] chapter for other related requirements.)

## Management of Quality and Patient Safety Activities

The overall program for quality and patient safety in a hospital is approved by the governing entity, with the hospital's leadership defining the structure and allocating resources required to implement the program. (*Also see* GLD.2 and GLD.4) Leadership also identifies the hospital's overall priorities for measurement and improvement, with the department/service leaders identifying the priorities for measurement and improvement within their department/service. (*Also see* GLD.5; GLD.11; and GLD.11.1)

The standards in this QPS chapter identify the structure, leadership, and activities to support the data collection, data analysis, and quality improvement for the identified priorities—hospitalwide, as well as department- and service-specific. This includes the collection and analysis on, and the response to, hospitalwide sentinel events, adverse events, and near miss (or close call) events. The standards also describe the central role of coordinating all the quality improvement and patient safety initiatives in the hospital and providing guidance and direction for staff training and communication of quality and patient safety information. The standards do not identify an organizational structure, such as a department, as this is up to each hospital to determine.

# Standard QPS.1

A qualified individual(s) guides the implementation of the hospital's program for quality improvement 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.1

The continuous improvement in quality and patient safety in a hospital requires a well-implemented program. (*Also see* GLD.9) While the governing entity approves the program and leadership provides resources to implement the program, it takes daily capable guidance and management to carry out the program and make continuous improvement part of the fabric of how the hospital meets its mission and strategic priorities. (*Also see* GLD.4)

One or more qualified individuals see that the program is put into operation. This takes knowledge and experience in the many facets of data collection, data validation, and data analysis, and in implementing sustainable improvements. The individual(s) with oversight for the quality program also selects quality program staff with those capabilities needed for the program. (*Also see* SQE.1) At times, some of the key quality individuals may be located within a department/service in the hospital. These individuals need to be supported with information and assistance. The quality 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 program staff coordinate and organize like measures throughout the organization and provide support with measurement activities related to hospital priorities. (*Also see* GLD.11)

Training and communication are also essential. The quality 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, and how to validate data. Staff throughout the hospital may need assistance in data validation and analysis, implementing improvements, and evaluating if the improvements were sustained. The quality program staff are thus constantly involved in training and communicating quality and patient safety issues throughout the hospital. (*Also see* GLD.4.1)

### Measurable Elements of QPS.1

- ❑ 1. An individual(s) who is experienced in the methods and processes of improvement is selected to guide the implementation of the hospital's quality and patient safety program.
- ❑ 2. The individual(s) with oversight for the quality program selects and supports qualified staff for the program and supports those staff with quality and patient safety responsibilities throughout the hospital.
- ❑ 3. The quality program provides support and coordination to department/service leaders for like measures across the hospital and for the hospital's priorities for improvement.
- ❑ 4. The quality program implements a training program for all staff that is consistent with staff's roles in the quality improvement and patient safety program.
- ❑ 5. The quality program is responsible for the regular communication of quality issues to all staff.

## *Measure Selection and Data Collection*

## Standard QPS.2

Quality and patient safety program staff support the measure selection process throughout the hospital and provide coordination and integration of measurement activities throughout the hospital.

### Intent of QPS.2

Measure selection is a leadership responsibility. GLD.5 describes how the leadership of the hospital decides the priority areas to measure for the entire hospital, and GLD.11 and GLD.11.1 describe the measure selection process for each department/service. All departments and services—clinical and managerial—select measures related to their priorities. 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 antibiotic use in the hospital. 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 quality and patient safety program is also 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. (*Also see* GLD.4)

### Measurable Elements of QPS.2

- ❑ 1. The quality and patient safety program supports the selection of measures throughout the hospital at the hospitalwide level and at the hospital department or service level.
- ❑ 2. The quality and patient safety program provides coordination and integration of measurement activities throughout the hospital.
- ❑ 3. The quality and patient safety program provides for the integration of event reporting systems, safety culture measures, and others to facilitate integrated solutions and improvements.
- ❑ 4. The quality and patient safety program tracks the progress on the planned collection of measure data for the priorities selected.

## Standard QPS.3

Hospital leadership builds a culture and environment that supports implementation of evidence-based care through the use of current scientific knowledge and information to support patient care, health professional education, clinical research, and management.

### Intent of QPS.3

A culture and environment that supports implementation and sustainability of evidence-based care has been shown to improve patient outcomes. Health care practitioners, researchers, educators, and managers often need information to assist with their responsibilities. Such information may include scientific and management literature, clinical practice guidelines, research findings, historical information, and educational methodologies. The Internet print materials in a library, online search sources, personal materials, and, more recently, clinical decision support programs associated with electronic medical records, are all valuable sources of current information. (*Also see* MOI.6) Developing and implementing the right tools, culture, education, and patient engagement skills in the overall care process enables health care providers to make better informed decisions. Using evidence-based practices in delivering patient care can provide better opportunities to enhance patient care and improve clinical outcomes. (*Also see* COP.3.1 and MMU.5.1)

### Measurable Elements of QPS.3

- ❑ 1. Hospital leadership builds a culture and environment that supports implementation of evidence-based care.
- ❑ 2. Current scientific knowledge and information supports patient care.
- ❑ 3. Current scientific knowledge and information supports clinical education.
- ❑ 4. Current scientific knowledge and information supports research.
- ❑ 5. Current professional knowledge and information supports management.
- ❑ 6. Information is provided in a time frame that meets user expectations.

## *Analysis and Validation of Measurement Data*

## Standard QPS.4

The quality and patient safety program includes the aggregation and analysis of data to support patient care, hospital management, and the quality management program and participation in external databases.

### Intent of QPS.4

Data help hospitals make the right decisions. When decisions are supported by data, hospitals are more likely to move in directions that help them achieve their goals. Successful hospitals measure, analyze, and validate their performance data. 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.

The quality and patient safety program identifies, collects, and analyzes aggregate data to support patient care and hospital management. Aggregate data provide a profile of the hospital over time and allow the comparison of the hospital's performance with other organizations, particularly on the hospitalwide measures selected by leadership. Thus, aggregate data are an important part of the hospital's performance improvement activities. In particular, aggregate data from risk management, utility system management, infection prevention and control,

and utilization review can help the hospital understand its current performance and identify opportunities for improvement. (*Also see* MOI.1)

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. (*Also see* PCI.5 and PCI.5.1) Hospitals may be required by laws or regulations to contribute to some external databases. In all cases, the security and confidentiality of data and information are maintained. (*Also see* MOI.2)

### Measurable Elements of QPS.4

- ❑ 1. The quality and patient safety program has a process to aggregate data.
- ❑ 2. Aggregate data and information support patient care, hospital management, professional practice review, and the overall quality and patient safety program.
- ❑ 3. Aggregate data and information are provided to agencies outside the hospital when required by laws or regulations.
- ❑ 4. There is a process to contribute to and learn from external databases for comparison purposes.
- ❑ 5. Security and confidentiality are maintained when contributing to or using external databases.

## Standard QPS.4.1

Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the hospital.

### Intent of QPS.4.1

To reach conclusions and to make decisions, data must be aggregated, analyzed, and transformed into useful information. Data analysis involves individuals who understand information management, have skills in data aggregation methods, and know how to use various statistical tools. Results of data analysis need to be reported to those individuals responsible for the process or outcome being measured and who can take action on the results. These individuals may be clinical, managerial, or a combination. Thus, data analysis provides continuous feedback of quality management information to help those individuals make decisions and continuously improve clinical and managerial processes. (*Also see* GLD.1.2)

Understanding statistical techniques is helpful 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 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. (*Also see* QPS.8) **For example**, clinical laboratory quality control data may be analyzed weekly to meet local regulations, and patient fall data may be analyzed monthly if falls are infrequent. Thus, aggregation of data at points in time enables the hospital to judge a particular process's stability or a particular outcome's predictability in relation to expectations.

The goal of data analysis is to be able to compare a hospital in four ways:

1) With itself over time, such as month to month, or one year to the next
2) With other similar organizations, such as through reference databases
3) With standards, such as those set by accrediting and professional bodies or those set by laws or regulations

4) 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. (*Also see* GLD.5)

### Measurable Elements of QPS.4.1

- ❑ 1. Data are aggregated, analyzed, and transformed into useful information to identify opportunities for improvement.
- ❑ 2. Individuals with appropriate clinical or managerial experience, knowledge, and skills participate in the process.
- ❑ 3. Statistical tools and techniques are used in the analysis process when suitable.
- ❑ 4. The frequency of data analysis is appropriate to the process or outcome being studied.
- ❑ 5. Results of analysis are reported to those accountable for taking action.
- ❑ 6. Data analysis supports comparisons internally over time, including comparisons with databases of like organizations, with best practices, and with objective scientific professional sources.

## Standard QPS.5

The data analysis process includes at least one determination per year of the impact of hospitalwide priority improvements on cost and efficiency.

### Intent of QPS.5

The quality and patient safety program includes an analysis of the impact of priority improvements as supported by leadership. (*Also see* GLD.5) **For example**, there is evidence to support that the use of clinical practice guidelines to standardize care has a significant impact on efficiency of care and a reduction in the length of stay, which ultimately reduces costs. The quality and patient safety program staff develop 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 analysis will provide useful information on which improvements impact efficiency and therefore cost.

### Measurable Elements of QPS.5

- ❑ 1. Data on the amount and type of resource use are collected on at least one hospitalwide priority improvement project per year before and following the improvement.
- ❑ 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 results of the analysis are used to refine the process and are reported through the quality coordination mechanism to leadership.

## Standard QPS.6

The hospital uses an internal process to validate data. Ⓟ

### Intent of QPS.6

A quality improvement program is only as valid as the data that are collected. If 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 or external data validation process needs to be in place. Data validation is most important when

a) 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);
b) data will be made public on the hospital's website or in other ways;
c) a change has been made to an existing measure, such as the data collection tools have changed or the data abstraction process or abstractor has changed;
d) the data resulting from an existing measure have changed in an unexplainable way;
e) the data source has changed, such as when part of the patient medical record has been turned into an electronic format and thus the data source is now both electronic and paper; or
f) 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.

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. Data validation becomes one of the steps in the process of setting priorities for measurement, selecting what is to be measured, extracting or collecting the data, analyzing the data, 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 leadership is accountable for ensuring that the data are valid. (*Also see* GLD.3.1) 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. (*Also see* GLD.6)

### Measurable Elements of QPS.6

❑ 1. Data validation is used by the quality program as a component of the improvement process selected by leadership.

❑ 2. Data are validated when any of the conditions noted in a) through f) in the intent are met.

❑ 3. An evidence-based methodology for data validation is used.

❑ 4. Hospital leadership assumes accountability for the validity of the quality and outcome data made public.

## Standard QPS.7

The hospital uses a defined process for identifying and managing sentinel events. Ⓟ

## Standard QPS.7.1

The hospital uses a defined process for identifying and managing adverse, no-harm, and near miss events. Ⓟ

### Intent of QPS.7 and QPS.7.1

In order to address system issues that can lead to patient, staff, or visitor harm, the hospital must have a process for identifying and managing sentinel, adverse, no-harm, and near miss events. In response to these events it is important that the hospital focuses not on individual error, but on the system factors that contributed to the event.

*A sentinel event* is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following:

a) Death
b) Permanent harm
c) Severe temporary harm

*Severe temporary harm* is defined as critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. An event is also considered sentinel if it is one of the following:

d) Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)
e) Unanticipated death of a full-term infant
f) Discharge of an infant to the wrong family
g) Abduction of any patient receiving care, treatment, and services
h) 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 temporary harm to the patient
i) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
j) Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital
k) Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital (*Also see* SQE.8.2)
l) Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
m) Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
n) Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)
o) Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose
p) Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
q) Any intrapartum (related to the birth process) maternal death
r) Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm

Sentinel events are one category of patient safety events. A *patient safety event* is 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. Patient safety events also include adverse events, no-harm events, near misses, and hazardous conditions, which are defined as follows:

- An *adverse event* is a patient safety event that resulted in harm to a patient.
- A *no-harm event* is a patient safety event that reaches the patient but does not cause harm.
- A *near miss* (or close call) is a patient safety event that did not reach the patient.
- A *hazardous* (or "unsafe") *condition(s)* is a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event

The hospital's definition of a sentinel event includes a) through r) above and may include other events as required by laws or regulations or viewed by the hospital as appropriate to add to its list of sentinel events. All events that meet the definition of sentinel event must be assessed by performing a comprehensive systematic analysis; **for example**, a thorough and credible root cause analysis (RCA). Accurate details of the event are

essential to a thorough and credible RCA; thus, the RCA needs to be performed as soon after the event as possible. The analysis and action plan are completed within 45 days of the event or becoming aware of the event. For the RCA to be considered thorough, the team must determine the causal factors in the system that contributed to the event and identify potential opportunities for improvement. For the RCA to be considered credible, the team involves key stakeholders in every step of the process, works with patients/family/staff involved in the event to better understand the circumstances, and seeks the final plan approval of the CEO or other high-level leadership. The goal of performing an RCA is for the hospital to better understand the origins of the event. When the RCA reveals that systems improvements or other actions can prevent or reduce the risk of such sentinel or adverse events recurring, the hospital redesigns the processes and takes whatever other actions are appropriate to do so. Note that the terms *sentinel event* and *medical error* are not synonymous. Not all errors result in a sentinel event, nor does a sentinel event occur only as a result of an error. Identifying an incident as a sentinel event is not an indicator of legal liability.

While not all patient safety events will meet the definition of a sentinel event, those that meet the definition of an adverse event require analysis in order to identify corrective actions. In addition, in an attempt to proactively learn where systems may be vulnerable, no-harm events, near misses, and hazardous conditions are tracked and used as opportunities to prevent harm, in accordance with the hospital's process for responding to patient safety events that do not meet the definition of sentinel event. (*Also see* MMU.7.1) The hospital's process for managing these events includes a mechanism for blame-free reporting. (*Also see* GLD.12.2 and GLD.13.1) The data from these reports are aggregated and analyzed to learn where proactive process changes will reduce or prevent their occurrence.

## Measurable Elements of QPS.7

- ❑ 1. Hospital leadership establishes a definition of a sentinel event that includes at least a) through r) found in the intent.
- ❑ 2. Hospital leaders complete a credible and thorough comprehensive systematic analysis (**for example**, root cause analysis) of all sentinel events within a time period specified by hospital leadership that does not exceed 45 days from the date of the event or when made aware of the event.
- ❑ 3. The root cause analysis identifies all system and process origins that may have contributed to the event.
- ❑ 4. Hospital leadership considers each identified contributing factor and takes corrective actions for improvement to prevent or reduce the risk of the adverse event from recurring.
- ❑ 5. The hospital monitors the implemented corrective actions for potential process failures (unintended consequences), effectiveness, and sustainability over time.

## Measurable Elements of QPS.7.1

- ❑ 1. Hospital leadership establishes a definition of adverse event, no-harm event, and near miss event as defined in the intent.
- ❑ 2. Hospital leadership has a mechanism for blame-free reporting of adverse events, no-harm events, and near miss events
- ❑ 3. Hospital leadership defines a process for managing adverse events that includes an analysis of the events to identify corrective actions.
- ❑ 4. Hospital leadership defines a process for managing near miss events and no-harm events that includes an analysis of the events to identify corrective actions.
- ❑ 5. Hospital leaders implement corrective actions, when appropriate, on the results of the analysis.
- ❑ 6. Hospital leaders monitor the implemented corrective actions for potential process failures (unintended consequences), effectiveness, and sustainability over time.

## Standard QPS.8

Data are always analyzed when undesirable trends and variation are evident from the data. Ⓟ

### Intent of QPS.8

The hospital collects data on diverse and different areas of patient care services periodically and reports results to the governing body as part of the quality improvement and patient safety program. (*Also see* GLD.4.1) In order to do so there must be reliable mechanisms of reporting outcomes to ensure quality services. Those that pose patient safety risk are identified and monitored. Data collection should be sufficient to detect trends and patterns and will vary depending on the service frequency and/or the risk for patients. (*Also see* MMU.7.1; QPS.4.1; and QPS.10)

Data gathering and analysis are conducted for at least the following:

a) All confirmed transfusion reactions, if applicable to the hospital (*Also see* COP.3.4)
b) All serious adverse drug events, if applicable and as defined by the hospital (*Also see* MMU.7)
c) All significant medication errors, if applicable and as defined by the hospital (*Also see* MMU.7.1)
d) 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)
e) Adverse events or patterns of adverse events during procedural sedation regardless of administration site (*Also see* ASC.3.2 and ASC.5)
f) Adverse events or patterns during anesthesia regardless of administration site
g) Adverse events related to patient identification (*Also see* IPSG.1)
h) Other adverse events; **for example**, health care–associated infections and infectious disease outbreaks (*Also see* PCI.6.1 and PCI.8.1)

### Measurable Elements of QPS.8

❑ 1. Defined data gathering processes are developed and implemented to ensure accurate data gathering, analysis, and reporting.

❑ 2. Intense analysis of data takes place when adverse levels, patterns, or trends occur.

❑ 3. Data gathering and analysis are performed on items a) through h) of the intent.

❑ 4. Results of analyses are used to implement actions to improve the quality and safety of the service, treatment, or function.

❑ 5. Outcome data are reported to the governing entity as part of the quality improvement and patient safety program.

## *Gaining and Sustaining Improvement*

## Standard QPS.9

Improvement in quality and safety is achieved and sustained.

### Intent of QPS.9

The information from data analysis is used to identify potential improvements or to reduce (or prevent) 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. In particular, improvements are planned for the priority data collection areas identified by hospital leadership.

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 procedure, and any necessary staff education is carried out. The hospital documents those improvements achieved and sustained as part of its quality management and improvement program. (*Also see* GLD.11)

### Measurable Elements of QPS.9

- ❑ 1. Improvements in quality and patient safety are planned, tested, and implemented.
- ❑ 2. Data are available to demonstrate that improvements are effective and sustained.
- ❑ 3. Policy changes necessary to plan, to carry out, and to sustain the improvement are made.
- ❑ 4. Successful improvements are documented.

## Standard QPS.10

An ongoing program of risk management is used to identify and to proactively reduce unanticipated adverse events and other safety risks to patients and staff. Ⓟ

### Intent of QPS.10

Proactive risk management is essential to the quality and safety of patient care, treatment, and services within an organization. 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 need to adopt a proactive approach to risk management that includes developing 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 whose essential components include

a) risk identification;
b) risk prioritization;
c) risk reporting;
d) scope, objectives, and criteria for assessing risk;
e) risk management, to include risk analysis; (*Also see* MMU.7.1; QPS.7; QPS.7.1; and QPS.8) and
f) management of related claims.

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 a critical, high-risk processes. **For example**, failure mode and effects analysis (FMEA) and hazard vulnerability analysis (HVA) are two common tools.

To use these or similar tools effectively, leadership needs to 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. This information should be used to prioritize the allocation of resources to analyze the areas of highest risks and take action to 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 documented.

## Measurable Elements of QPS.10

- ❑ 1. The hospital's risk management framework includes a) through f) in the intent.
- ❑ 2. Hospital leadership identifies and prioritizes the potential risks that could have the greatest impact on patient and staff safety and on the quality of patient care.
- ❑ 3. At least annually, a proactive risk reduction exercise is conducted on at least one of the priority risk processes.
- ❑ 4. High-risk processes are redesigned and implemented based on the results of the analysis of the risk reduction exercise.
- ❑ 5. Hospital leadership develops and implements communication strategies to staff, governance, and stakeholders as appropriate.

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# Prevention and Control of Infections (PCI)



## Overview

The goal of an organization's infection prevention and control program is to identify and to reduce or eliminate the risks of acquiring and transmitting infections among patients, staff, health care practitioners, contract workers, volunteers, students, visitors, and the community. In addition, developing hospitalwide initiatives related to evolving health care practices and/or concerns, such as an antibiotic stewardship program and a program for response to global communicable diseases, is an essential component of the infection prevention and control program.

The infection risks and program activities will differ from organization to organization, depending on the organization's clinical activities and services, patient population(s) served, geographic location, patient volume, and number of staff. The program's priorities should reflect the identified risks in the organization, global and community developments, and the complexity of services provided.

Effective infection prevention and control programs have in common identified 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.1** One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training, experience, certification, and/or clinical authority.

**PCI.2** There is a designated coordination mechanism for all infection prevention and control activities that involves physicians, nurses, and others based on the size and complexity of the hospital.

### Resources

**PCI.3** Hospital leadership provides resources to support the infection prevention and control program.

### Goals of the Infection Prevention and Control Program

**PCI.4** The hospital designs and implements a comprehensive infection prevention and control program that identifies the procedures and processes associated with the risk of infection and implements strategies to reduce infection risk. Ⓟ

**PCI.5** The hospital uses a risk-based data-driven approach in establishing the focus of the health care–associated infection prevention and control program. Ⓟ

**PCI.5.1** The hospital identifies areas at high risk for infections by conducting a risk assessment, develops interventions to address these risks, and monitors the effectiveness.

## Medical Equipment, Devices, and Supplies

**PCI.6** The hospital reduces the risk of infections associated with medical/surgical equipment, devices, and supplies by ensuring adequate cleaning, disinfection, sterilization, and storage. Ⓟ

**PCI.6.1** The hospital identifies and implements a process for managing the reuse of single-use devices consistent with regional and local laws and regulations and implements a process for managing expired supplies. Ⓟ



## Environmental Cleanliness

**PCI.7** The infection prevention and control program identifies and implements standards from recognized infection prevention and control programs to address cleaning and disinfection of the environment and environmental surfaces. Ⓟ

**PCI.7.1** The infection prevention and control program identifies standards from recognized infection control health agencies related to cleaning and disinfection of laundry, linens, and scrub attire provided by the hospital.

## Infectious Human Tissues and Waste

**PCI.8** The hospital reduces the risk of infections through proper disposal of waste, proper management of human tissues, and safe handling and disposal of sharps and needles. Ⓟ

**PCI.8.1** The hospital has a process to protect patients and staff from bloodborne pathogens related to exposure to blood and body fluids. Ⓟ

## Food Services

**PCI.9** The hospital reduces the risk of infections associated with the operations of food services.

## Engineering Controls

**PCI.10** The hospital reduces the risk of infection in the facility through the use of mechanical and engineering controls.

## Construction and Renovation Risks

**PCI.11** The hospital reduces the risk of infection in the facility associated with demolition, construction, and renovation.

## Transmission of Infections

**PCI.12** The hospital provides barrier precautions and isolation procedures that protect patients, visitors, and staff from communicable diseases and protects immunosuppressed patients from acquiring infections to which they are uniquely prone. Ⓟ

**PCI.12.1** The hospital develops and implements a process to manage a sudden influx of patients with airborne infections and when negative-pressure rooms are not available. Ⓟ

**PCI.12.2** The hospital develops, implements, and evaluates an emergency preparedness program to respond to the presentation of global communicable diseases. Ⓟ

**PCI.13** Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required. Ⓟ

### Quality Improvement and Program Education

**PCI.14** The infection prevention and control process is integrated with the hospital's overall program for quality improvement and patient safety, using measures that are epidemiologically important to the hospital.

**PCI.15** The hospital provides education on infection prevention and control practices to staff, physicians, patients, families, and other caregivers when indicated by their involvement in care. Ⓟ

# Standards, Intents, and Measurable Elements

## *Responsibilities*



## Standard PCI.1

One or more individuals oversee all infection prevention and control activities. This individual(s) is qualified in infection prevention and control practices through education, training, experience, certification, and/or clinical authority.

### Intent of PCI.1

The goal of a hospital's infection prevention and control program is to identify and to reduce the risks of acquiring and transmitting infections among patients, staff, health care practitioners, contract workers, volunteers, students, and visitors.

The infection risks and program activities may differ from hospital to hospital, depending on the hospital's clinical activities and services, patient population(s) served, geographic location, patient volume, and number of staff. Thus, the oversight of the infection prevention and control program corresponds to the hospital's size, complexity of activities, and level of risks, as well as the program's scope. One or more individuals, acting on a full-time or part-time basis, provide that oversight as part of their assigned responsibilities or job descriptions. (*Also see* GLD.9 and SQE.3) The infection prevention and control program is supported by a team of individuals, as necessary, to ensure that the program is led by an individual(s) with the clinical and leadership experience to direct, implement, and measure change. The individual(s) leading the infection prevention and control program has experience in both infection prevention and control and leadership. The needed qualifications for this individual(s) will depend on the activities he or she will carry out, and the qualifications may be met through

- education;
- training;
- experience;
- certification or licensure; and/or
- demonstrated leadership ability.

This individual(s) is responsible for the organization's progressive improvement in infection prevention and control activities, including setting priorities and ensuring incremental progress toward meeting these priorities. This individual(s) identifies high-risk areas for infection prevention and control, including the Central Sterile Supply Department and operating theatres, and provides oversight or designates an appointee to provide oversight of these areas. A team approach supports coordination with the hospital's facility management and safety program to incorporate infection prevention and control practices.

This individual(s) is accountable for coordination with hospital leadership regarding priorities, resources, and quality improvement related to the infection prevention and control program. The results and other data are reported to local, national, regional, and/or global public health agencies as required. The hospital also takes

appropriate actions to respond to reports issued by public health agencies, as appropriate to the hospital and its patient population.

### Measurable Elements of PCI.1

- ❑ 1. One or more individuals oversee the infection prevention and control program and ensure that the program complies with local and national laws and regulations.
- ❑ 2. The individual(s) is qualified for the hospital's size, complexity of activities, and level of risks, as well as the program's scope.
- ❑ 3. The individual(s) fulfills program oversight responsibilities as assigned or described in a job description.
- ❑ 4. This individual(s) coordinates with hospital leadership regarding priorities, resources, and quality improvement opportunities related to the infection prevention and control program.
- ❑ 5. The hospital reports infection prevention and control program results to public health agencies as required.
- ❑ 6. The hospital takes appropriate action on reports from relevant public health agencies.



## Standard PCI.2

There is a designated coordination mechanism for all infection prevention and control activities that involves physicians, nurses, and others based on the size and complexity of the hospital.

### Intent of PCI.2

Infection prevention and control activities reach into every part of a hospital and involve individuals in multiple departments and services (**for example**, clinical departments, facility maintenance, food services [catering], housekeeping, laboratory, pharmacy, and sterilization services). (*Also see* AOP.5.3; AOP.6.2; and FMS.5) In addition, hospitals are at risk for infections that can enter the hospital via patients, families, staff, volunteers, visitors, vendors, independent entities, and other individuals. Thus, all physical areas of the hospital, including staff-only areas, where these individuals are found must be included in the program of infection surveillance, prevention, and control.

There is a designated mechanism to coordinate the overall program. **For example**, the mechanism may be a small work group, a coordinating committee, a task force, or some other mechanism. The functions and actions of this mechanism must be recorded or documented to review the effectiveness of program coordination and to monitor progressive improvement in the prevention and control of infections. There must also be leadership representation in this mechanism; hospital leadership must have an active role in the prevention and control of infections and be accountable for the status of the program. Responsibilities of this designated coordination mechanism include, **for example**, setting criteria to define health care–associated infections, establishing data collection (surveillance) methods, designing strategies to address infection prevention and control risks, and reporting processes. Coordination involves communicating with all parts of the hospital to ensure that the program is continuous and proactive.

Whatever the mechanism chosen by the hospital to coordinate the infection prevention and control program, physicians and nurses are represented and engaged in the activities with the infection prevention and control professionals. (*Also see* MMU.1.1) Others may be included as determined by the hospital's size and complexity of services (**for example**, epidemiologist, data collection expert, statistician, central sterilization manager, microbiologist, pharmacist, housekeeping services, environmental or facilities services, operating theatre supervisor).

### Measurable Elements of PCI.2

- ❑ 1. The designated mechanism, as described in the intent, coordinates the infection prevention and control program and involves infection prevention and control professionals.
- ❑ 2. Infection prevention and control activities involve physicians, nurses, and others based on the size and complexity of the hospital.
- ❑ 3. All areas of the hospital are included in the infection prevention and control program.

## *Resources*

# Standard PCI.3

Hospital leadership provides resources to support the infection prevention and control program.

### Intent of PCI.3

The infection prevention and control program requires adequate staff to meet the program goals and the needs of the hospital and to meet or exceed local laws and regulations related to infection prevention and control. The number of staff is determined by the hospital's size, complexity of activities, and level of risks, as well as the program's scope. Staffing levels are approved and assigned by the hospital's leadership. (*Also see* SQE.6) Hospital leadership ensures that human resources are available to support the infection prevention and control program. (*Also see* GLD.1.1) This includes the appointment of a qualified individual(s) to oversee the program and to provide oversight of high-risk areas (**for example**, the Central Sterile Supply Department and operating theatres), staff to provide education about the infection prevention and control program, and clinical staffing numbers that allow for safe practice, including infection prevention and control practices.

In addition, the infection prevention and control program requires resources to provide education to all staff and to purchase supplies, such as alcohol-based hand rub for hand hygiene. Hospital leadership ensures that the program has adequate resources to effectively carry out the program. Hospital leadership approves and allocates the resources and then ensures that they are provided to the infection prevention and control program as intended and meet the specific needs of the hospital.

Information management systems are important resources to support the tracking 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. (*Also see* MOI.1) In addition, infection prevention and control program data and information are managed with those of the hospital's quality management and improvement program.

### Measurable Elements of PCI.3

- ❑ 1. The infection prevention and control program is staffed according to the hospital's size, complexity of activities, and level of risks, as well as the program's scope.
- ❑ 2. Hospital leadership approves and assigns staff required for the infection prevention and control program.
- ❑ 3. Hospital leadership approves and allocates resources required for the infection prevention and control program.
- ❑ 4. Information management systems support the infection prevention and control program.

## Goals of the Infection Prevention and Control Program

# Standard PCI.4

The hospital designs and implements a comprehensive infection prevention and control program that identifies the procedures and processes associated with the risk of infection and implements strategies to reduce infection risk. Ⓟ

### Intent of PCI.4

Hospitals assess and care for patients using many simple and complex processes, each associated with a level of infection risk to patients and staff. It is important for a hospital to measure and review those processes and to implement needed policies, procedures, education, and evidence-based activities designed to reduce the risk of infection. (*Also see* ACC.6; COP.4; and COP.4.1)

An infection prevention and control program must be comprehensive, encompassing both patient care and staff health. The program identifies and addresses the infection issues that are epidemiologically important to the hospital and that may impact patients, staff, visitors, and vendors. In addition, the program requires a range of strategies that cross all levels of the hospital based on the hospital's size, geographic location, services, and patients. The program includes hand hygiene, oversight for improving the safe use of antimicrobials and ensuring safe medication preparation, systems to identify infections and to investigate outbreaks of infectious diseases, and implementation of a vaccine program for staff and patients. (*Also see* IPSG.5; MMU.1.1; MMU.5; PCI.12; PCI.12.1; PCI.12.2; and SQE.8.3) The periodic assessment of risk and the setting of risk reduction goals guide the program.

### Measurable Elements of PCI.4

- ❑ 1. The infection prevention and control program is comprehensive and crosses all levels of the hospital, to reduce the risk of health care–associated infections in patients.
- ❑ 2. The infection prevention and control program is comprehensive and crosses all levels of the hospital to reduce the risk of health care–associated infections in hospital staff.
- ❑ 3. The hospital identifies those processes associated with infection risk.
- ❑ 4. The hospital implements strategies, education, and evidence-based activities to reduce infection risk in those processes.

# Standard PCI.5

The hospital uses a risk-based data-driven approach in establishing the focus of the health care–associated infection prevention and control program. Ⓟ

# Standard PCI.5.1

The hospital identifies areas at high risk for infections by conducting a risk assessment, develops interventions to address these risks, and monitors the effectiveness.

### Intent of PCI.5 and PCI.5.1

Each hospital must identify those epidemiologically important infections, infection sites, and associated devices, procedures, and practices that will provide the focus of efforts to prevent and to reduce the risk and incidence of health care–associated infections. A risk-based approach helps hospitals identify those practices

and infections on which they should focus their programs. A risk-based approach uses surveillance as an important component for gathering and analyzing the data that guide the risk assessment.

Hospitals collect and evaluate data on the following relevant infections and sites:

a) Respiratory tract—such as the procedures and medical equipment associated with intubation, mechanical ventilatory support, tracheostomy, and so on
b) Urinary tract—such as the invasive procedures and medical equipment associated with indwelling urinary catheters, urinary drainage systems, their care, and so on
c) Intravascular invasive devices—such as the insertion and care of central venous catheters, peripheral venous lines, and so on
d) Surgical sites—such as their care and type of dressing and associated aseptic procedures
e) Epidemiologically significant diseases and organisms—multidrug-resistant organisms, highly virulent infections (*Also see* PCI.12.2 and SQE.8.3)
f) Emerging or reemerging infections with the community

In addition, applying the scientific knowledge related to the control of infections through such strategies as the use of clinical practice guidelines (*also see* GLD.11.2), antibiotic stewardship programs (*also see* MMU.1.1), programs to reduce community- and hospital-associated infections, and initiatives to decrease the use of unnecessary invasive devices can significantly reduce the rates of infection.

The infection prevention and control process is designed to lower the risk of infection for patients, staff, and others. To reach this goal, the hospital must proactively identify and track risks, rates, and trends in health care–associated infections. The hospital uses measurement information to improve infection prevention and control activities and to reduce health care–associated infection rates to the lowest possible levels. A hospital can best use measurement data and information by understanding rates and trends in other similar hospitals and contributing data to infection-related databases. (*Also see* QPS.4 and GLD.5)

The infection prevention and control program identifies other high-risk areas for infection through a risk assessment. Goals for the infection prevention and control program are established based on this risk assessment throughout the hospital. Risk assessments may also be completed when there are questions about risks related to current practices; **for example**, the use of cardboard boxes, transportation paths for clean and dirty linens, installation of new positive or negative pressure systems, and so on. Program leaders implement evidence-based interventions to minimize these infection risks. Ongoing monitoring of identified risks and risk reduction interventions are monitored for effectiveness of these interventions, including progressive and sustained improvement, and what changes may be required to the program goals based on the successes and challenges apparent in monitoring data.

## Measurable Elements of PCI.5

- ❑ 1. The hospital establishes the focus of the program through the collection and tracking of data related to a) through f) in the intent.
- ❑ 2. The data collected in a) through f) are analyzed to identify priorities for reducing rates of infection.
- ❑ 3. The hospital implements infection prevention and control strategies to reduce the rates of infection for the identified priorities.
- ❑ 4. Processes are redesigned based on risk, rate, and trend data and information.

### Measurable Elements of PCI.5.1

- ❑ 1. The hospital completes and documents a risk assessment, at least annually, to identify and prioritize areas at high risk for infections.
- ❑ 2. The hospital identifies and implements interventions to address infection risks identified through the risk assessment.
- ❑ 3. The hospital evaluates the effectiveness of the interventions and makes appropriate changes to the infection prevention and control program as needed.
- ❑ 4. The hospital performs ongoing data monitoring to ensure that risks are reduced or eliminated.

## *Medical Equipment, Devices, and Supplies*



# Standard PCI.6

The hospital reduces the risk of infections associated with medical/surgical equipment, devices, and supplies by ensuring adequate cleaning, disinfection, sterilization, and storage. Ⓟ

### Intent of PCI.6

Procedures that involve contact with medical/surgical equipment, devices, and supplies can be a major source for introducing pathogens that lead to infection. Failure to properly clean, disinfect, or sterilize, and improper use or storage of equipment, devices, and supplies, not only poses risks to patients, but also carries a risk for person-to-person transmission of infections. It is critical that health care staff follow standard practices to clean, disinfect, and sterilize. Infection risk is minimized with proper *cleaning*, *disinfection*, and *sterilization* processes.

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. . . ." The 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."

Manufacturer guidelines and professional practice standards are consulted to determine the level of disinfection or sterilization required for items. (*Also see* GLD.7) The level of disinfection or sterilization also depends on the category of the item—noncritical, semi-critical, and critical.

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—Semi-critical: Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores
- Level 3—Non-critical: Objects that contact intact skin but not mucous membranes, and require low-level disinfection

Disinfection of medical equipment and devices involves both low- and high-level techniques. Low-level disinfection is used for noncritical items such as stethoscopes, blood glucose meters, and other noninvasive equipment. Low-level disinfection is also appropriate for items such as computer keyboards, telephones, and television remotes. Disinfection agents that may be used for low-level disinfection include phenols and quaternary ammonium compounds. High-level disinfection is used on semi-critical items, which are items that

come in contact with mucus membranes or nonintact skin (**for example**, speculums that may be used in ear, nose, and throat departments, obstetrics/gynecology departments, or ophthalmology departments).

Disinfection agents that may be used for high-level disinfection include ortho-phthalaldehyde and hydrogen peroxide. Sterilization is required for critical items, which are those that come into contact with sterile parts of the body or the vascular system, such as many dental instruments, surgical instruments, and cardiac catheters. To properly sterilize critical hinged instruments, they must be processed in their open position. Sterilization may not be possible for some critical items, such as flexible endoscopes, so manufacturers' guidelines may require the use of high-level disinfection instead.

Sterilization of medical/surgical supplies and other invasive devices and equipment includes several different methods, and there are advantages and disadvantages to each method. The type of sterilization used is dependent on the situation in which sterilization occurs and on what is being sterilized, and manufacturer guidelines. **For example**, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. However, steam sterilization can only be used on items that are heat and moisture resistant. Low-temperature sterilization is most commonly used for sterilizing temperature- and moisture-sensitive medical devices and supplies. Flash sterilization (also known as immediate-use steam sterilization) is used in situations in which there is insufficient time to sterilize an item using the packaged method of saturated steam under pressure. Hospitals follow manufacturer guidelines and professional practice guidelines for sterilization techniques that best fit the type of situations for sterilization and devices and supplies being sterilized. Additional cleaning and disinfection is required for medical/surgical equipment, devices, and supplies used with patients who are isolated as part of implementing transmission-based precautions.

Cleaning, disinfection, and sterilization can take place in a centralized sterilization area or, with proper oversight, in other areas of the hospital, such as a gastroenterology lab or an endoscopy lab. Cleaning, disinfection, and sterilization methods maintain the same standards wherever they are performed in the hospital. (*Also see* ACC.6) It is critical that staff follow standard practices to minimize infection risks. Staff processing medical/surgical equipment, devices, and supplies are oriented to and trained in the practices of cleaning, disinfection, and sterilization; demonstrate competency in the practices; and receive proper supervision. Staff processing equipment, devices, and supplies must demonstrate competency as part of their initial and ongoing training.

In order to prevent contamination, clean and sterile supplies are properly stored in designated storage areas that are clean and dry and protected from dust, moisture, and temperature extremes. Ideally, sterile supplies are stored separately from clean supplies, and sterile storage areas have limited access. Hospital leaders conduct risk assessments and consult professional standards to identify risks related to specific storage processes and to identify interventions to mitigate those risks; **for example**, the use of cardboard or plastic storage boxes in clean storage areas. Some disinfected items require specific drying and storage principles to ensure complete and thorough disinfection. **For example**, following disinfection, endoscopes must be able to hang freely without coming into contact with the floor in order to prevent fluid from accumulating in the bottom of the scope.

### Measurable Elements of PCI.6

- ❑ 1. The hospital follows professional practice guidelines and manufacturer guidelines for sterilization techniques that best fit the type of situations for sterilization and devices and supplies being sterilized.
- ❑ 2. The hospital follows professional practice guidelines and manufacturer guidelines for low- and high-level disinfection that best fit the type of devices and equipment being disinfected.
- ❑ 3. Staff processing medical/surgical equipment, devices, and supplies are oriented to, trained in, and demonstrate competency in cleaning, disinfection, and sterilization, and they receive proper supervision.
- ❑ 4. Methods for medical/surgical cleaning, disinfection, and sterilization are coordinated and uniformly applied throughout the hospital.
- ❑ 5. Clean and sterile supplies are properly stored in designated storage areas that are clean and dry and protected from dust, moisture, and temperature extremes.



## Standard PCI.6.1

The hospital identifies and implements a process for managing the reuse of single-use devices consistent with regional and local laws and regulations and implements a process for managing expired supplies. Ⓟ

### Intent of PCI.6.1

Certain single-use devices may be reused under specific circumstances when permitted by local and national laws and regulations. This standard addresses types of single-use critical and semi-critical [medical] devices listed in the Spaulding Classification; it is not meant to include non-critical devices.

There are two risks associated with the reuse of reprocessed single-use devices: There is the potential for an increased risk of infection, and there is the risk that the performance of the device may be inadequate or unacceptable after it is reprocessed. The reuse of reprocessed single-use devices carries significant risk, as many devices are complex in design and therefore difficult to clean, disinfect, or sterilize. Reprocessing must meet the same criteria as the original manufacturer to ensure that the device is safe for reuse, in both function and cleanliness, following reprocessing. Despite these requirements, reprocessing can also impact the effectiveness or function of the device, leading to increased risk of the device breaking or failing during use. Most single-use devices are not designed for reprocessing, leading to increased risk of cross-infection. In addition, chemicals used for reprocessing may corrode the device, and the process itself may damage the device.

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." If the hospital permits the reuse of reprocessed single-use devices, there is a hospital policy that guides such reuse. The policy is consistent with national laws and regulations and professional standards and includes identification of

a) single-use devices and materials that may be reused;
b) a process for identifying when a single-use device is no longer safe or suitable for reuse;
c) the cleaning process for each device that starts immediately after use and follows a clear protocol;
d) identification of patients on whom reusable medical devices have been used; and
e) a proactive evaluation of the safety of reusing single-use items.

The hospital collects and analyzes data on adverse events related to reused devices and materials to identify risks and implements actions to reduce risks and improve processes. (*Also see* QPS.8) There is oversight of the process to grant or revoke approvals for the reuse of reprocessed single-use devices based on these data, hospital needs, and alternatives to reuse. The list of single-use devices approved for reuse is routinely reviewed to ensure that it is accurate and current.

Most medical materials (IV fluids, catheters, sutures, and other medical materials) are imprinted with an expiration date. When the expiration date on these materials has passed, the manufacturer does not guarantee the sterility, safety, or stability of the item. Some materials contain a statement indicating that the contents are sterile as long as the packaging is intact. A policy identifies the process for ensuring proper management of expired supplies.

### Measurable Elements of PCI.6.1

- ❑ 1. The hospital identifies single-use devices and materials that may be reused in accordance with local and national laws and regulations.
- ❑ 2. The hospital utilizes a standardized process for identifying when a single-use device is no longer safe or suitable for reuse.
- ❑ 3. The hospital has a clear protocol for the cleaning, disinfecting, and sterilization as appropriate, for each reusable, single-use device.
- ❑ 4. The cleaning process for each device is followed as per protocol.
- ❑ 5. The hospital identifies patients on whom reusable medical devices have been used.
- ❑ 6. When adverse events resulting from reuse of single-use devices occur, patients using these devices are tracked and an analysis is performed, with results used to identify and implement improvements.

## *Environmental Cleanliness*

## Standard PCI.7

The infection prevention and control program identifies and implements standards from recognized infection prevention and control programs to address cleaning and disinfection of the environment and environmental surfaces. Ⓟ

### Intent of PCI.7

Pathogens on surfaces and throughout the environment contribute to hospital-acquired illnesses in patients, staff, and visitors. Effective environmental cleaning and disinfection practices contribute to the prevention of hospital-acquired infections. Routine cleaning of the environment includes daily cleaning of patient rooms and care areas, waiting areas and other public spaces, staff workspaces, kitchens, and so on. The hospital defines its routine cleaning practices, including frequency of cleanings, cleaning equipment and agents used, which staff members are responsible for cleaning tasks, and when areas require more frequent cleaning. Terminal cleaning is completed following discharge; this process may be further enhanced if the patient had a known or suspected contagious infection. Terminal cleaning requires further attention to the environment and may include laundering of privacy curtains, removal and cleaning of all detachable items in the room, and disinfecting surfaces with multiple cleaning agents, as indicated by infection prevention and control standards.

Certain areas of the hospital require particular attention during environmental cleaning and disinfection due to their high-risk nature. Hospital leaders conduct risk assessments to determine which areas of the hospital require additional cleaning and disinfection; areas such as operating theatres, the Central Sterile Supply Department, neonatal intensive care units, burn units, and others are often considered high risk. Hospital leaders identify appropriate clinical guidelines and practice recommendations for staff to use when cleaning and disinfecting high-risk areas or situations.

Environmental cleaning and disinfections are monitored through a variety of ways. **For example**, hospital leaders may collect patient and family compliments and complaints, or fluorescent markers may be used to

check for residual pathogens. These data are used during ongoing education for environmental cleaning staff and to evaluate and change the cleaning and disinfection process when indicated.

### Measurable Elements of PCI.7

- ❑ 1. The hospital selects cleaning and disinfection standards and procedures from recognized infection prevention and control programs to maintain environmental cleanliness.
- ❑ 2. Hospital leaders identify areas and situations that are high risk for infection transmission and implement additional cleaning and disinfection procedures as indicated.
- ❑ 3. Cleaning of infectious rooms during the patient's hospitalization and after discharge follows infection prevention and control guidelines.
- ❑ 4. The hospital monitors environmental cleaning and disinfection processes, and data are used to make changes to the process when applicable.



## Standard PCI.7.1

The infection prevention and control program identifies standards from recognized infection control health agencies related to cleaning and disinfection of laundry, linens, and scrub attire provided by the hospital.

### Intent of PCI.7.1

Handling of laundry, linens and hospital-issued scrub attire includes the collection, sorting, washing, drying, folding, distribution, and storage of these items. 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 these items.

Staff handling laundry, linens, and scrub attire follow standard precautions and use appropriate transmission-based precautions when handling laundry and linens from isolation rooms. **For example**, staff handling linens from a contact isolation room use gloves and gowns to protect themselves from exposure. 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 processing contaminated items of the increased infection risk. Laundering consists of flushing, washing, bleaching, rinsing, and souring the items and follows guidelines from infection control agencies, including water temperatures, length of wash cycles, and use of cleaning agents. Laundry, linens, and hospital-issued scrub attire are processed, transported, and stored in a manner that prevents cross contamination of soiled and clean items; **for example**, soiled and clean items may enter and exit the laundry facilities through designated doors, and clean linens may be stored in covered linen carts.

The hospital identifies areas in which staff will be required to wear hospital-issued scrub attire, including white coats or jackets, due to increased infection risks; **for example**, the Central Sterile Supply Department, operating theatres, and the neonatal intensive care unit. The hospital also implements practices that decrease the risk of infection related to white coats and laboratory jackets, as these items can harbor and transport microorganisms between patients. Staff will be 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.7.1

- ❑ 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.
- ❑ 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 hospital-issued scrub attire where required.

## *Infectious Human Tissues and Waste*



# Standard PCI.8

The hospital reduces the risk of infections through proper disposal of waste, proper management of human tissues, and safe handling and disposal of sharps and needles. Ⓟ

### Intent of PCI.8

Hospitals produce considerable waste each day. Frequently that waste is or could be infectious. Thus, the proper disposal of waste contributes 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.

One of the dangers of needlestick 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. (*Also see* SQE.8.2)

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 in a manner that warns of the potential hazard for injury and must be stored in a manner that prevents the sharps from spilling out of the container. (*Also see* ACC.6)

Improper disposal of discarded needles, scalpels, and other sharps can pose a health risk to the general public and to those who work in waste management. Disposing 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 and that do so in accordance with laws and regulations. (*Also see* FMS.7 through FMS.7.2)

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 on respectful, safe handling procedures.

### Measurable Elements of PCI.8

- ❑ 1. The handling and disposal of infectious waste, blood and blood components, body fluids, and body tissues is managed to minimize infection transmission risk.
- ❑ 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 sources 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 operates 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 on preventing cross contamination, maintaining chain of custody when needed, and respectful, safe handling procedures.



## Standard PCI.8.1

The hospital has a process to protect patients and staff from bloodborne pathogens related to exposure to blood and body fluids. Ⓟ

### Intent of PCI.8.1

Exposures to blood and body fluid 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. (*Also see* SQE.8.3) Body fluids include cerebrospinal, synovial, pleural, peritoneal, pericardial, 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 establishes a process for handling staff, patient, and visitor blood and body fluid exposures. (*Also see* PCI.4 and SQE.8.2) 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. 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 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. (*Also see* PCC.2) This process also includes steps for notifying any patient involved in the exposure.

Data from exposure incidents are tracked and monitored, and exposure incident reports are reviewed. 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. (*Also see* QPS.8)

### Measurable Elements of PCI.8.1

- ❑ 1. The hospital identifies processes that could result in patient or staff exposure to blood and body fluids and implements practices to reduce the risk of exposure.
- ❑ 2. The hospital utilizes a process for reporting patient and staff exposures to blood and body fluids.
- ❑ 3. The hospital utilizes a process for acting upon patient and staff exposures to blood and body fluids.
- ❑ 4. Staff are educated on the process for reporting an exposure incident.
- ❑ 5. The hospital tracks and monitors incidents of patient and staff exposures to blood and body fluids.
- ❑ 6. 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.9

The hospital reduces the risk of infections associated with the operations of food services.

### Intent of PCI.9

Improperly stored and prepared food can cause illnesses, such as food poisoning or food infections. Food illnesses can be particularly 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 at temperatures that prevent the risk of bacterial growth.

Hospital leaders must understand the food supply chain from start to finish in order to ensure safe operations of food services. This includes careful selection of food sources and suppliers. 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 monitor the temperature of prepared food during transport of prepared foods from the kitchen to patient care areas. 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 is also a process to ensure that food served is not left out for an amount of time that would make it unsuitable for consumption. Safe food storage 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, countertops, cutting boards, or cloths used to wipe countertops or dry dishes. In addition, the surfaces on which the food is prepared; 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. 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.

### Measurable Elements of PCI.9

- ❑ 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 utilizes 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.



## *Engineering Controls*

# Standard PCI.10

The hospital reduces the risk of infection in the facility through the use of mechanical and engineering controls.

### Intent of PCI.10

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. Positive pressure ventilation systems in operating theatres must be active when occupied but do not need to be active during cleaning or maintenance. Positive pressure ventilation must remain active at all times in sterile supply storage areas to prevent contamination of sterile supplies. 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. Cold water and hot water must be stored and distributed at temperatures that minimize growth of waterborne microorganisms. 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, ventilation, and air-conditioning (HVAC) systems in a manner that minimizes infection risks to patients, staff, and visitors. Airborne contaminants can be spread through exhaust, 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. (*Also see* FMS.10; FMS.10.1; and FMS.10.2)

### Measurable Elements of PCI.10

- ❑ 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.

## *Construction and Renovation Risks*

# Standard PCI.11

The hospital reduces the risk of infection in the facility associated with demolition, construction, and renovation.

### Intent of PCI.11

Demolition, construction, renovation, and routine maintenance projects anywhere within the hospital can be a major infection control risk. Exposure to construction dust and debris, noise, vibration, and other hazards can be potentially dangerous to lung function and to the safety of staff and visitors. The hospital uses risk criteria that address the impact of the renovation or new construction on air-quality requirements, infection prevention and control, utility requirements, noise, vibration, and emergency procedures. The hospital also determines how construction or renovation projects in one area of the hospital may affect other areas; **for example**, if renovations are being completed in the water pump room, construction may inadvertently affect the water pressure in the dialysis unit, leading to stagnant water in pipes. (*Also see* FMS.12)

### Measurable Elements of PCI.11

- ❑ 1. The hospital has a program that uses risk criteria to assess the impact of renovation or new construction and implements the program when demolition, construction, or renovation take place.
- ❑ 2. The hospital assesses the risks and impact of demolition, renovation, or construction activities on air quality and infection prevention and control activities throughout the hospital.
- ❑ 3. The risks and impact of the demolition, renovation, or construction are managed to protect patients, staff, and visitors from infection.

## Transmission of Infections

# Standard PCI.12

The hospital provides barrier precautions and isolation procedures that protect patients, visitors, and staff from communicable diseases and protects immunosuppressed patients from acquiring infections to which they are uniquely prone. Ⓟ

# Standard PCI.12.1

The hospital develops and implements a process to manage a sudden influx of patients with airborne infections and when negative-pressure rooms are not available. Ⓟ

### Intent of PCI.12 and PCI.12.1

The hospital develops policies and procedures that establish the isolation and barrier procedures for the hospital. These policies and procedures are based on the method of disease transmission and address individual patients who may be infectious as well as the physical environment. (*Also see* ACC.6 and COP.3)

In addition to the use of standard precautions, transmission-based precautions must be used to prevent infection transmission. (*Also see* ACC.1) 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 infections that other patients or staff may be carrying

Airborne infection isolation room precautions are necessary to prevent the transmission of infectious agents that can remain suspended in the air for long periods of time. The preferred placement for a patient with an airborne infection is in a negative-pressure room. When the structure of the building prevents the immediate construction of a negative-pressure room, the hospital may construct temporary negative-pressure isolation when airborne infection isolation is needed and there are no available or insufficient airborne infection isolation rooms. This may occur when there is an outbreak of an airborne infectious disease with large numbers of communicable patients. The two most effective systems for creating temporary negative-pressure isolation involve using a high-efficiency particulate air (HEPA) filtration system that either discharges air to the outside or discharges air to the return air system. **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 acceptable guidelines and must adhere to all building and fire codes, and 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 utilize 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.

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. (*Also see* PCI.12.2)

### Measurable Elements of PCI.12

- ❑ 1. The hospital utilizes a process to isolate patients with infectious diseases, and staff use transmission-based precautions, in accordance with recommended guidelines.
- ❑ 2. The hospital protects patients with immunosuppression or other increased risks for contracting a communicable disease through isolation and the use of reverse/protective isolation in accordance with recommended guidelines.
- ❑ 3. The hospital routinely monitors and makes available negative-pressure rooms for infectious patients who require isolation for airborne infections.
- ❑ 4. When negative-pressure rooms are not immediately available, temporary negative-pressure rooms that follow acceptable guidelines as described in the intent and adhere to building and fire codes may be created.

### Measurable Elements of PCI.12.1

- ❑ 1. The hospital develops and implements a process to address managing patients with airborne infections for short periods of time when negative-pressure rooms are not available.
- ❑ 2. The hospital develops and implements a process for managing an influx of patients with contagious diseases.
- ❑ 3. 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.12.2

The hospital develops, implements, and evaluates an emergency preparedness program to respond to the presentation of global communicable diseases. Ⓟ

### Intent of PCI.12.2

The globalization of society has increased the likelihood of the rapid spread of communicable diseases from one country to another. Infectious diseases that were previously endemic to a particular area are now found all over the world. WHO has identified the importance of detecting communicable disease outbreaks early and stopping the mortality, spread, and potential impact. An important 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.

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.

To respond effectively to the presentation of global communicable diseases, the hospital develops a program to manage these potential emergencies. The program provides processes for

a) communication with organizations participating in worldwide surveillance activities;
b) development and implementation of segregation and isolation strategies; (*Also see* ACC.1; PCI.12; and PCI.12.1)
c) training, including demonstration, on the use of personal protective equipment appropriate to infectious disease;
d) development and implementation of communication strategies;
e) identification and assignment of staff roles and responsibilities; and
f) response to emerging or reemerging infections within the community.

The program is evaluated at least annually to ensure proper response when an actual event occurs. Evaluation involves local, regional, and/or national authorities, when applicable; **for example**, a community-wide 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. (*Also see* FMS.11)



### Measurable Elements of PCI.12.2

- ❑ 1. Hospital leaders, along with the individual(s) responsible for the infection prevention and control program, develop and implement an emergency preparedness program to respond to global communicable diseases that includes at least a) through f) in the intent.
- ❑ 2. The hospital identifies the first points of patient entry into the hospital system and targets education on early recognition and prompt action.
- ❑ 3. The hospital evaluates the entire program at least annually and, when applicable, involves local, regional, and/or national authorities.
- ❑ 4. At the conclusion of every drill or tabletop exercise, debriefing of the evaluation is conducted.
- ❑ 5. Follow-up actions identified from the evaluation process and debriefing are developed and implemented.

## Standard PCI.13

Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required. Ⓟ

### Intent of PCI.13

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. (*Also see* IPSG.5; AOP.5.7; PCI.7; PCI.7.1; PCI.8.1; and PCI.9) The hospital identifies those situations in which personal protective equipment such as masks, eye protection, gowns, or gloves are required and provides training in their correct use. **For example**, wearing gloves and a face shield when suctioning a patient, or using gloves, gown, face shield, and appropriate face mask for patients in isolation due to a communicable disease. Liquid soap, disinfectants, and towels or other

means of drying are located in those areas where hand-washing and hand-disinfecting procedures are required. It is important to follow guidelines for ensuring that liquid soap dispensers are thoroughly and properly cleaned before refilling. Staff are educated in proper hand-washing, hand-disinfection, and surface-disinfection procedures as well as 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. (*Also see* PCI.12)

### Measurable Elements of PCI.13

- ❑ 1. The hospital identifies situations in which personal protective equipment is required and ensures that it is available at any site of care at which it could be needed.
- ❑ 2. Staff are trained and correctly use personal protective equipment in each identified situation.
- ❑ 3. The hospital implements surface disinfecting procedures for areas and situations in the hospital identified as at risk for infection transmission.
- ❑ 4. Liquid soap, disinfectants, and towels or other means of drying are located in areas where hand-washing and hand-disinfecting procedures are required.
- ❑ 5. Patients and visitors are educated on when they are required to disinfect their hands and how to correctly use personal protective equipment.

## *Quality Improvement and Program Education*

# Standard PCI.14

The infection prevention and control process is integrated with the hospital's overall program for quality improvement and patient safety, using measures that are epidemiologically important to the hospital.

### Intent of PCI.14

The hospital uses measurement information to improve infection prevention and control activities and to reduce health care–associated infection rates to the lowest possible levels. A hospital can best use measurement data and information by understanding similar rates and trends in other similar hospitals and contributing data to infection-related databases. All departments/services are required to participate in relevant hospitalwide priorities for measurement and also select measures for department/service-specific priorities for the infection prevention and control program. (*Also see* GLD.4 and GLD.11) Monitoring data include benchmarking infection rates internally and with external organizations and/or databases.

### Measurable Elements of PCI.14

- ❑ 1. The hospital integrates infection prevention and control activities into the quality improvement and patient safety program.
- ❑ 2. The hospital collects and analyzes data for the infection prevention and control activities, and the data include epidemiologically important infections.
- ❑ 3. The hospital uses monitoring data to evaluate and support improvements to the infection prevention and control program at least annually.
- ❑ 4. Monitoring data include benchmarking infection rates.
- ❑ 5. The infection prevention and control program documents monitoring data and provides reports of data analysis to leadership on a quarterly basis.

# Standard PCI.15

The hospital provides education on infection prevention and control practices to staff, physicians, patients, families, and other caregivers when indicated by their involvement in care. Ⓟ

## Intent of PCI.15

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. (*Also see* SQE.7) In addition, staff receive ongoing education and training related to emerging trends in infection prevention and control. (*Also see* SQE.8) 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.

## Measurable Elements of PCI.15

- ❑ 1. The hospital provides education about infection prevention and control to all staff and other professionals when they begin work in the hospital.
- ❑ 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.
- ❑ 3. The hospital provides education about infection prevention and control to patients and families.
- ❑ 4. The hospital communicates findings and trends from quality improvement activities to all staff and included as part of staff education.

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# 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.

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.

**Note:** In all GLD standards, the term *leaders* is used to indicate that one or more individuals are accountable for the expectation(s) found in the standard. *Leadership* is used to indicate that a group of leaders is collectively accountable for the expectation(s) found in the standard.

Standards in this chapter are grouped using the following leadership hierarchy (and illustrated in the figure below):

## 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, or in the case of public hospitals, the Ministry of Health. Any individual(s) or group responsible for the requirements found in GLD.1.1 is considered the governing entity of the hospital. Other standards that include the requirements and expectations of the governing entity are GLD.1 and GLD.1.2.

## 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. This position is most commonly occupied by a physician, an administrator, or both working together. In academic medical centers, the dean of the medical school may be at this executive level in the hospital. GLD.2 describes the accountabilities and expectations of the Chief Executive.

## Level III: Hospital Leadership

The standards assign to hospital leadership 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 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.3 through GLD.7.1 describe the accountabilities of this group.

**Note:** GLD.8 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.8 through GLD.11.2 describe the expectations of these department/service leaders. Typically, the subgroups consist of clinical departments such as medicine, surgery, obstetrics, pediatrics, and others; one or more nursing subgroups; diagnostic services or departments such as 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 of the levels described above. These requirements are found in GLD.12 through GLD.19 and include the culture of safety, ethics, and health professional education and research when present.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

# 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 of the Hospital

**GLD.1** The structure and authority of the hospital's governing entity are described in bylaws, policies and procedures, or similar documents. Ⓟ

**GLD.1.1** The operational responsibilities and accountabilities of the governing entity are described in a written document(s). Ⓟ

**GLD.1.2** The governing entity approves the hospital's program for quality and patient safety and regularly receives and acts on reports of the quality and patient safety program. Ⓟ

## Chief Executive(s) Accountabilities

**GLD.2** A chief executive(s) is responsible for operating the hospital and complying with applicable laws and regulations. Ⓟ

## Hospital Leadership Accountabilities

**GLD.3** Hospital leadership is identified and is collectively responsible for defining the hospital's mission and creating the programs and policies needed to fulfill the mission.

**GLD.3.1** Hospital leadership identifies and plans for the type of clinical services required to meet the needs of the patients served by the hospital. Ⓟ

**GLD.3.2** Hospital leadership ensures effective communication throughout the hospital. Ⓟ

**GLD.3.3** Hospital leadership ensures that there are uniform programs for the recruitment, retention, development, and continuing education of all staff.

## Hospital Leadership for Quality and Patient Safety

**GLD.4** Hospital leadership plans, develops, and implements a quality improvement and patient safety program.

**GLD.4.1** Hospital leadership communicates quality improvement and patient safety information to the governing entity and hospital staff on a regular basis.

**GLD.5** The chief executive and hospital leadership 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.

## Hospital Leadership for Contracts

**GLD.6** Hospital leadership is accountable for the review, selection, and monitoring of clinical and nonclinical contracts and inspects compliance with contracted services as needed. Ⓟ

**GLD.6.1** Hospital leadership ensures that contracts and other arrangements are included as part of the hospital's quality improvement and patient safety program.

**GLD.6.2** Hospital leadership ensures that licensed health care professionals and independent health care practitioners not employed by the hospital have the right credentials and are competent and/or privileged for the services provided to the hospital's patients. Ⓟ

## Hospital Leadership for Resource Decisions

**GLD.7** Hospital leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.

**GLD.7.1** Hospital leadership seeks and uses data and information on the safety of the supply chain to protect patients and staff from unstable, contaminated, defective, and counterfeit supplies.

## Clinical Staff Organization and Accountabilities

**GLD.8** Medical, nursing, and other leaders of departments and clinical services plan and implement a professional staff structure to support their responsibilities and authority. Ⓟ

## Direction of Hospital Departments and Services

**GLD.9** One or more qualified individuals provide direction for each department or service in the hospital. Ⓟ

**GLD.10** 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. Ⓟ

**GLD.11** Department/service leaders improve quality and patient safety by participating in hospitalwide improvement priorities and in monitoring and improving patient care specific to the department/service.

**GLD.11.1** Measures selected by the department/service leaders that are applicable to evaluating the performance of physicians, nurses, and other professional staff participating in the clinical care processes are used in the staff's performance evaluation.

**GLD.11.2** Department/service leaders select and implement clinical practice guidelines, and related clinical pathways and/or clinical protocols, to guide clinical care. Ⓟ

## Organizational and Clinical Ethics

**GLD.12** Hospital leadership establishes 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.12.1** The hospital's framework for ethical management addresses operational and business issues, including marketing, admissions, transfer, discharge, and disclosure of ownership and any business and professional conflicts that may not be in patients' best interests. Ⓟ

**GLD.12.2** The hospital's framework for ethical management addresses ethical issues and decision making in clinical care. Ⓟ

**GLD.13** Hospital leadership creates and supports a culture of safety program throughout the hospital. Ⓟ

**GLD.13.1** Hospital leadership implements, monitors, and takes action to improve the program for a culture of safety throughout the hospital.

## Health Professional Education

**GLD.14** Health professional education, when provided within the hospital, is guided by the educational parameters defined by the sponsoring academic program and the hospital's leadership.

### Human Subjects Research

**GLD.15** Human subjects research, when provided within the hospital, is guided by laws, regulations, and hospital leadership. Ⓟ

**GLD.16** Patients and families are informed about how to gain access to clinical research, clinical investigations, or clinical trials involving human subjects. Ⓟ

**GLD.17** Patients and families are informed about how patients who choose to participate in clinical research, clinical investigations, or clinical trials are protected.

**GLD.18** Informed consent is obtained before a patient participates in clinical research, clinical investigations, or clinical trials. Ⓟ

**GLD.19** The hospital has a committee or another way to oversee all research in the hospital involving human subjects. Ⓟ

# Standards, Intents, and Measurable Elements

**Note:** In all GLD standards, leaders are individuals and leadership is the collective group. Accountabilities are described at the individual or collective level. (*Also see* the "Quality Improvement and Patient Safety" [QPS] chapter for other related requirements.)

## *Governance of the Hospital*

## Standard GLD.1

The structure and authority of the hospital's governing entity are described in bylaws, policies and procedures, or similar documents. Ⓟ

### Intent of GLD.1

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, or in the case of many public hospitals, the Ministry of Health—that is responsible for overseeing the hospital's operations and accountable for the health care services the hospital provides. This governing entity is responsible for the requirements found in GLD.1.1. The structure and authority of this entity are described in bylaws, policies and procedures, or similar documents that identify how they are to be carried out.

There is an annual evaluation of the governing entity. The annual evaluation can be simple; **for example**, three or four questions related to whether or not the governing entity is fulfilling its responsibilities, such as those described in GLD.1.1—approving the mission, the strategic and operational plans, the budget, and so on. An online survey can be developed, or the questions can be sent through e-mail or by postal mail to the members of the governing entity.

When the hospital is one of many organizations reporting to a governing entity, such as in the case of some Ministries of Health (MOH) serving as the governing entity, obtaining results from the annual evaluation may be a challenge. In these circumstances, the hospital makes a credible effort to obtain the necessary input and actions from the governing entity. A credible effort is characterized by multiple attempts by various methods (**for example**, phone, e-mail, and/or letter) with documentation of the attempts and outcome(s) of the communications. (*Also see* GLD.1.2)

The hospital's governing entity is represented or displayed in an organizational chart or other document that shows lines of authority and accountability.

### Measurable Elements of GLD.1

❑ 1. The structure and authority of the hospital's governing entity is described in a written document, bylaws, and/or policies and procedures with those responsible for governance of the hospital identified.

❑ 2. The document(s) describes when and how the authority of the governing entity and the chief executive can be delegated.

❑ 3. The governing entity is evaluated annually, and the results are documented.

## Standard GLD.1.1

The operational responsibilities and accountabilities of the governing entity are described in a written document(s). Ⓟ

### Intent of GLD.1.1

The governing entity's responsibilities and accountabilities are described in a written document(s) that identifies how they are to be carried out. In order for the hospital to have clear leadership, operate efficiently, and provide high-quality health care services, the governing entity must fulfill their responsibilities. These responsibilities are primarily at the approval level and include

- 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 on a daily basis;
- approving the hospital's participation in health care professional education and in research and the oversight of the quality of such programs; (*Also see* GLD.14 and GLD.15)
- approving or providing a capital and operating budget(s) and other resources required to operate the hospital and to meet the hospital's mission and strategic plan; (*Also see* COP.8; PCI.3; GLD.9; and FMS.1) and
- appointing or approving the hospital's chief executive(s) and providing for an annual evaluation of the individual's(s') performance, which is documented.

### Measurable Elements of GLD.1.1

❑ 1. The governing entity approves the hospital's strategic plans, operational plans, policies, and procedures, and approves, periodically reviews, and makes public the hospital's mission statement.

❑ 2. The governing entity approves the hospital's capital and operating budget(s) and allocates other 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.

## Standard GLD.1.2

The governing entity approves the hospital's program for quality and patient safety and regularly receives and acts on reports of the quality and patient safety program. Ⓟ

### Intent of GLD.1.2

The governing entity approves or provides for all of the hospital's programs and policies and allocates resources to meet the hospital's mission. One important accountability is to carry out all responsibilities in a manner that supports the continual improvement in quality and patient safety. This important investment in quality needs to be planned, provided adequate resources, and monitored for progress. Thus, the governing entity approves the quality program on an annual basis, and on a regular 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 program, including adverse events and sentinel events, are presented to the governing entity for their information and discussion. (*Also see* QPS.4.1) 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. (*Also see* GLD.1)

### Measurable Elements of GLD.1.2

- ❑ 1. The governing entity annually approves the hospital's program for quality and patient safety.
- ❑ 2. The governing entity at least quarterly receives and acts on reports of the quality and patient safety program, including reports of adverse and sentinel events.
- ❑ 3. Minutes reflect actions taken and any follow-up on those actions.

## *Chief Executive(s) Accountabilities*

## Standard GLD.2

A chief executive(s) is responsible for operating the hospital and complying with applicable laws and regulations. Ⓟ

### Intent of GLD.2

Effective leadership is essential for a hospital to be able to operate efficiently and to fulfill its mission. Leadership is what individuals provide together and individually to the hospital and can be carried out by any number of individuals.

The chief executive(s) is responsible for the hospital's overall, day-to-day operations. This includes the procurement and inventory of essential supplies, maintenance of the physical facility, financial management, quality management, and other responsibilities. The education and experience of the individual(s) match the requirements in the position description. The chief executive(s) cooperates with hospital leadership 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 responsible for implementing all policies and ensuring that all policies are complied with by the hospital's staff.

The chief executive(s) is responsible for the hospital's

- compliance with applicable laws and regulations;
- response to any reports from inspecting and regulatory agencies; (*Also see* PCI.1 and FMS.1) and
- processes to manage and to control human, financial, and other resources.

### Measurable Elements of GLD.2

- ❑ 1. The education and experience of the chief executive(s) match the requirements in the position description.
- ❑ 2. The chief executive(s) manages the hospital's day-to-day operations, including those responsibilities described in the position description.
- ❑ 3. The chief executive(s) recommends policies, strategic plans, and budgets to the governing entity.
- ❑ 4. The chief executive(s) ensures compliance with approved policies.
- ❑ 5. The chief executive(s) ensures compliance with applicable laws and regulations.
- ❑ 6. The chief executive(s) responds to any reports from inspecting and regulatory agencies.

## *Hospital Leadership Accountabilities*

## Standard GLD.3

Hospital leadership is identified and is collectively responsible for defining the hospital's mission and creating the programs and policies needed to fulfill the mission.

### Intent of GLD.3

Hospital leadership comes from many sources. The governing entity names the chief executive(s). The chief executive(s) may name others to hospital leadership. Hospital leadership 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 leadership is recognized and brought into the process of defining the hospital's values and mission. Based on that mission, hospital leadership works 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 leadership works collaboratively to carry out the mission and policies.

### Measurable Elements of GLD.3

- ❑ 1. The chief executive(s) and hospital leadership are identified by title and name, and their collective accountabilities are described in written documents.
- ❑ 2. Hospital leadership is responsible for defining the hospital's values and mission.
- ❑ 3. Hospital leadership is responsible for creating the policies and procedures necessary to carry out the mission.
- ❑ 4. Hospital leadership ensures that policies and procedures are followed.

## Standard GLD.3.1

Hospital leadership identifies and plans for the type of clinical services required to meet the needs of the patients served by the hospital. Ⓟ

### Intent of GLD.3.1

Patient care services are planned and designed to respond to the needs of the patient population. The care and services to be provided are documented and are consistent with the hospital's mission. Hospital leadership determines with the leaders of the various clinical departments and services in the hospital the diagnostic,

therapeutic, rehabilitative, and other services that are essential to the patient population. Hospital leadership also plans 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 leadership plans and participates with the community, local hospitals, and others in meeting community health care needs. The services planned reflect the strategic direction of the hospital and the perspective of the patients cared for by the hospital. (*Also see* ACC.2)

Planning patient care services also involves hospital leadership defining its communities and patient populations, identifying community needs for services, and planning ongoing communication with those key community stakeholder groups. (*Also see* PCC.1 and MOI.1) 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
- information on the quality of services, which is provided to the public and to referral sources. (*Also see* QPS.6)

### Measurable Elements of GLD.3.1

❑ 1. Hospital leadership determines and plans with department/service leaders the type of care and services to be provided by the hospital that are consistent with the hospital's mission and needs of the patients served by the hospital.

❑ 2. Hospital leadership communicates with key stakeholders in its community to facilitate access to care and access to information about its patient care services.

❑ 3. Hospital leadership provides data and communicates information related to safety and quality of its services to stakeholders, which include nursing staff, nonclinical and management staff, patients, families, and external interested parties.

❑ 4. Hospital leadership describes and documents the care and services to be provided.

## Standard GLD.3.2

Hospital leadership ensures effective communication throughout the hospital. Ⓟ

### Intent of GLD.3.2

Effective communication within a hospital is the responsibility of hospital leadership. Thus, hospital leadership understands 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, **for example**. Hospital leadership not only sets the parameters of effective communication but leaders also serve as role models with the effective communication of the hospital's mission, strategies, plans, and other relevant information. Hospital leadership pays attention to the accuracy and timeliness of information shared and communicated throughout the hospital.

To coordinate and to integrate patient care, hospital leadership develops 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. (*Also see* MOI.1)

### Measurable Elements of GLD.3.2

- ❑ 1. Hospital leadership ensures that processes are in place for communicating relevant information throughout the hospital in a timely manner.
- ❑ 2. Hospital leadership ensures effective communication among clinical and nonclinical departments, services, and individual staff members.
- ❑ 3. Hospital leadership communicates the hospital's vision, mission, goals, policies, and plans to staff.

## Standard GLD.3.3

Hospital leadership ensures that there are uniform programs for the recruitment, retention, development, and continuing education of all staff.

### Intent of GLD.3.3

A hospital's ability to care for patients is directly related to its ability to attract and to retain qualified, competent staff. Hospital leadership recognizes that staff retention, rather than recruitment, provides greater long-term benefit. Retention is increased when hospital leadership supports staff advancement through continuing education. Thus, hospital leadership plans and implements a uniform program and processes related to recruitment, retention, development, and continuing education for each category of staff. (*Also see* SQE.2 and SQE.8) The hospital's recruitment program considers published guidelines, such as those from the World Health Organization, International Council of Nurses, and World Medical Association.

### Measurable Elements of GLD.3.3

- ❑ 1. The hospital develops and implements a process for staff recruitment.
- ❑ 2. The hospital develops and implements a process for staff retention.
- ❑ 3. The hospital develops and implements a process for staff personal development and continuing education.
- ❑ 4. The planning is collaborative and includes all departments and services in the hospital.

## *Hospital Leadership for Quality and Patient Safety*

## Standard GLD.4

Hospital leadership plans, develops, and implements a quality improvement and patient safety program.

## Standard GLD.4.1

Hospital leadership communicates quality improvement and patient safety information to the governing entity and hospital staff on a regular basis.

### Intent of GLD.4 and GLD.4.1

If a hospital is to successfully initiate and to maintain improvement and reduce risks to patients and staff, leadership and planning are essential. Leadership and planning begins with the governing entity of the hospital, along with those who manage and lead the clinical and managerial activities of the hospital on a daily basis. Collectively, these persons represent the leaders of the departments and services of the hospital. Hospital leadership is responsible for establishing and providing ongoing support for an organizational commitment

to quality. Hospital leadership develops the quality and patient safety program for governance approval by the governing entity, and through its vision and support, shapes the quality culture of the hospital. (*Also see* QPS.1)

Hospital leadership selects the approach to be used by the hospital to measure, assess, and improve quality and patient safety. Also, hospital leadership determines how the program will be directed and managed on a daily basis, such as a quality department, and ensures that the program has adequate resources to be effective.

Hospital leadership also implements a structure and process for the overall monitoring and coordination of the program throughout the hospital. (*Also see* FMS.4) 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, or some 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. (*Also see* QPS.2 and PCI.14)

Hospital leadership is also responsible for seeing that at least quarterly quality reports are prepared for the governing entity review and discussion and for seeing that the actions of the governing entity related to the quality program reports are carried out. (*Also see* QPS.8) In addition, at least quarterly, the quality report to the governing entity includes

- the number and type of sentinel events and associated root causes; (*Also see* QPS.7)
- whether the patients and families were informed of the event;
- actions taken to improve safety in response to events; and
- if the improvements were sustained.

Regular communication of information about the quality improvement and patient safety program to staff is essential. 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, progress in meeting the International Patient Safety Goals, the results of the analysis of sentinel and other adverse events, or recent research or benchmark programs, among others. (*Also see* QPS.1)

## Measurable Elements of GLD.4

❑ 1. Hospital leadership participates in developing and implementing a hospitalwide quality improvement and patient safety program.

❑ 2. Hospital leadership selects and implements a hospitalwide process to measure, assess data, plan change, and sustain improvements in quality and patient safety, and provides for staff education on this quality improvement process.

❑ 3. Hospital leadership determines how the program will be directed and managed on a daily basis and ensures that the program has adequate technology and other resources to be effective.

❑ 4. Hospital leadership implements a structure and process for the overall monitoring and coordination of the quality improvement and patient safety program.

## Measurable Elements of GLD.4.1

❑ 1. Hospital leadership reports on the quality and patient safety program at least quarterly to the governing entity.

❑ 2. Hospital leadership reports to the governing entity include, at least quarterly, the number and type of sentinel events and root causes, whether the patients and families were informed of the sentinel event, actions taken to improve safety in response to sentinel events, and if the improvements were sustained.

❑ 3. Hospital leadership regularly communicates information on the quality improvement and patient safety program to staff, including progress on meeting the International Patient Safety Goals.

# Standard GLD.5

The chief executive and hospital leadership 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.5

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 the chief executive and hospital leadership is to set hospitalwide measurement and improvement priorities. These are measurement and improvement efforts that impact or reflect activities in multiple departments and services. The chief executive and hospital leadership 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.1 or monitoring the process for reporting critical results of diagnostic tests as noted in IPSG.2.1. Priorities may focus on the achievement of strategic objectives; **for example**, to become the leading regional referral center for cancer patients. Similarly, the chief executive and hospital leadership may give priority to projects that increase efficiency, reduce readmission rates, eliminate patient flow problems in the emergency department, or create a monitoring process for the quality of services provided by contractors. The chief executive and hospital leadership 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. The chief executive and hospital leadership ensure that, when present, clinical research and medical education programs are represented among the priorities.

The chief executive and hospital leadership also assess the impact of 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**. (*Also see* QPS.5) 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. The chief executive and hospital leadership support the creation of simple tools to quantify resource use of the old process and for assessing a new process. Understanding both the impact of an improvement on patient outcome 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, the chief executive and hospital leadership can better understand how to allocate available quality and patient safety resources. (*Also see* QPS.2; QPS.4.1; PCI.5; PCI.5.1; GLD.11; and FMS.3)

## Measurable Elements of GLD.5

- ❑ 1. The chief executive and hospital leadership use available data to set collective priorities for hospitalwide measurement and improvement activities and consider potential system improvements.
- ❑ 2. The chief executive and hospital leadership ensure that, when present, clinical research and health professional education programs are represented in the priorities.
- ❑ 3. The chief executive and hospital leadership set priorities for compliance with the International Patient Safety Goals.
- ❑ 4. The chief executive and hospital leadership assess the impact of hospitalwide and departmental/service improvements on efficiency and resource use.

## Hospital Leadership for Contracts

# Standard GLD.6

Hospital leadership is accountable for the review, selection, and monitoring of clinical and nonclinical contracts and inspects compliance with contracted services as needed. Ⓟ

### Intent of GLD.6

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. Such services may range from radiology and diagnostic imaging services to financial accounting services and services provided for housekeeping, food, or linens. Hospital leadership describes, in writing, the nature and scope of services provided through contractual agreements.

When contracts relate to health practitioner staffing—**for example**, a contract for critical care nurses—the contracts stipulate that the professional staff provided meet the hospital's requirement for similar staff. (*Also see* SQE.7; SQE.14; and SQE.15) In all cases, hospital leadership is 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. (*Also see* AOP.6.6; ASC.1; ASC.2; QPS.6; and MOI.11)

### Measurable Elements of GLD.6

- ❑ 1. Hospital leadership is accountable for contracts to meet patient and management needs.
- ❑ 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 share accountability for the review, selection, and monitoring of clinical and nonclinical contracts.
- ❑ 4. Hospital leadership inspects compliance with contracted services as needed.
- ❑ 5. When contracts are renegotiated or terminated, the hospital maintains the continuity of patient services.

# Standard GLD.6.1

Hospital leadership ensures that contracts and other arrangements are included as part of the hospital's quality improvement and patient safety program.

### Intent of GLD.6.1

The quality and safety of patient care require evaluation of all services provided by the hospital or provided through contracted services. Thus, the hospital needs to receive, to analyze, and to act on quality information 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. (*Also see* AOP.5.10; AOP.5.10.1; AOP.6.6; and MOI.11)

### Measurable Elements of GLD.6.1

- ❑ 1. All contracts stipulate the quality 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.
- ❑ 2. Quality data reported under contracts are integrated into the hospital's quality monitoring program.
- ❑ 3. The relevant clinical and managerial leaders participate with the quality improvement program in the analysis of quality and safety information from outside contracts.

## Standard GLD.6.2

Hospital leadership ensures that licensed health care professionals and independent health care practitioners 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.6.2

Clinical leaders may recommend contracts with or arrange services from physicians, dentists, and other independent practitioners, as well as other licensed health care professionals outside the hospital (**for example**, diagnostic services such as pathology or electrocardiogram interpretations, contracted nursing staff, pharmacists, or other licensed professionals) or arrange for them to come into the hospital to provide services (**for example**, contracting for an interventional cardiologist to come in once a week to provide diagnostic angiography). The services provided by independent health care practitioners may also include telemedicine or teleradiology. In some cases, these individuals may be located outside the region or country of the hospital.

At times, independent practitioners may be accompanied by staff reporting to them and who are not part of the hospital. Any support staff accompanying independent practitioners and providing care and services in the hospital are compliant with requirements for primary source verification. (*Also see* SQE.13 and SQE.15)

If the services provided determine the care choice or course of care for the patient, the practitioner must proceed through the credentialing and privileging processes of the hospital. (*Also see* SQE.9 through SQE.12)

### Measurable Elements of GLD.6.2

- ❑ 1. Hospital leadership determines those services that will be provided by independent practitioners outside the hospital.
- ❑ 2. All diagnostic, consultative, and treatment services provided by independent practitioners outside the hospital, such as telemedicine, teleradiology, and interpretations of other diagnostics, such as electrocardiogram (ECG), electroencephalogram (EEG), pathology, and the like, are credentialed and privileged by the hospital to provide such services.
- ❑ 3. Independent 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.9 through SQE.12.
- ❑ 4. Any support staff accompanying independent practitioners and providing care and services in the hospital are compliant with requirements for primary source verification.
- ❑ 5. The quality of services by independent practitioners outside the hospital is monitored as a component of the hospital's quality improvement program.
- ❑ 6. When the hospital utilizes staff contracts for licensed health care professional staff the hospital ensures that a credential review comparable to the hospital's review process is conducted.

# Hospital Leadership for Resource Decisions

## Standard GLD.7

Hospital leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.

### Intent of GLD.7

Hospital leadership improves decision making when they have data upon which to base those 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, alarm issues, and others, 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 need to be brought forward to inform the decision. (*Also see* SQE.6) Hospital leadership develops a process to gather data and information for key purchase or resource decisions to ensure that they include a safety and quality due-diligence component. (*Also see* GLD.7.1)

One component of data gathering related to resource decisions is to understand the required or recommended medical equipment, supplies, and medications necessary to provide a service. Recommendations on medical equipment, supplies, and medication can come from a government agency, national or international professional organizations, or other authoritative sources. (*Also see* QPS.3)

An important resource for hospitals is the investment in health information technology (IT). Health IT covers a wide variety of technologies that include methods for documenting and sharing patient information, such as with electronic medical records. In addition, health IT includes methods for storing and analyzing data, communicating information among health care practitioners to better coordinate care, and receiving information to help diagnose illnesses and provide safer patient care. Successful implementation of health IT resources requires the direction, support, and oversight of hospital leadership. (*Also see* MOI.11) When resource decisions are made by a third party—**for example**, a Ministry of Health—hospital leadership provides data and information to the third party on their experiences and preferences to better inform future resource choices.

When a hospital uses what is identified as "experimental" medical equipment and/or pharmaceutical agents in patient care procedures (that is, medical equipment or agents identified as "experimental" either nationally or internationally), there is a process to review and to approve such use. (*Also see* GLD.19) It is essential that such approval occur prior to use in patient care. A determination is made if special patient consent is necessary. (*Also see* PCC.4.2; COP.8; and SQE.11)

### Measurable Elements of GLD.7

- ❑ 1. Hospital leadership uses data and information on the quality and safety implications of medical equipment choices.
- ❑ 2. Hospital leadership uses data and information on the quality and safety implications of staffing choices.
- ❑ 3. Hospital leadership uses the recommendations of professional organizations and other authoritative sources in making resource decisions.
- ❑ 4. Hospital leadership provides direction, support, and oversight of information technology resources.
- ❑ 5. Hospital leadership provides direction, support, and oversight of the emergency and disaster management program(s).
- ❑ 6. Hospital leadership monitors the results of its decisions and uses the data to evaluate and improve the quality of its resource purchasing and allocation decisions.

# Standard GLD.7.1

Hospital leadership seeks and uses data and information on the safety of the supply chain to protect patients and staff from unstable, contaminated, defective, and counterfeit supplies.

## Intent of GLD.7.1

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. The variety and quantity of supplies that hospitals use are vast, thus the hospital may manage many supply chains. Due to staff and resource limitations, not every supply chain can be tracked and evaluated at the same time. Therefore, hospitals identify the medications, medical supplies, and medical devices that are at most risk of losing stability, becoming contaminated, becoming defective, or being replaced with a counterfeit or imitation product.

For those supplies at most risk, the hospital identifies the steps in the supply chains. Although this information may not be complete and may be difficult to piece together, the hospital, at minimum, decides where the significant risks reside. **For example**, a flowchart can be used to help map out each step, or point, in the supply chain for a supply. Points in the flowchart would likely include the manufacturer, warehouse facilities, the vendor, shipping company, and so on. The hospital can indicate points in the flowchart that it has identified as a significant risk. **For example**, a hospital has identified insulin as a medication at most risk for the organization and develops a flowchart that shows each step in the supply chain. The hospital identifies points such as the insulin manufacturer, vendor, warehousing, and shipping, and determines that important elements such as the manufacturer's regulatory compliance, temperature control and monitoring in the warehouses, and limiting travel distance between points in the chain are taken into account. However, while reviewing for potential risks in the supply chain, the hospital learns that the vendor has recently contracted with a shipping company whose services have been unsatisfactory, including delayed deliveries to the hospital and inconsistent documentation for temperature monitoring during travel. After assessing the situation, the hospital may identify this as a significant risk in that supply chain. Hospital leadership makes decisions about changes to supply chains and sets priorities for purchasing decisions based on their understanding of the risk points in supply chains. (*Also see* GLD.6 and GLD.7)

Supply chain management 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. (*Also see* ASC.7.4) When applicable, the hospital notifies the manufacturer and/or distributor when unstable, contaminated, defective, or counterfeit supplies are identified through retrospective tracing.

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 take measures to prevent potential patient harm. Although such 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.7.1

- ❑ 1. Hospital leadership outlines the steps in the supply chains for supplies defined as at most risk.
- ❑ 2. Hospital leadership identifies any significant risk points in the steps of the supply chains.
- ❑ 3. Hospital leadership makes resource decisions based on their understanding of the risk points in the supply chains.
- ❑ 4. The hospital has a process for performing retrospective tracing of supplies found to be unstable, contaminated, defective, or counterfeit.
- ❑ 5. The hospital notifies the manufacturer and/or distributor when unstable, contaminated, defective, or counterfeit supplies are identified.

## *Clinical Staff Organization and Accountabilities*

## Standard GLD.8

Medical, nursing, and other leaders of departments and clinical services plan and implement a professional staff structure to support their responsibilities and authority. Ⓟ

### Intent of GLD.8

Medical, nursing, and other leaders of departments and clinical services have special responsibilities to patients and to the hospital. These department/service leaders

- support good communication between professionals;
- jointly plan and develop policies; clinical guidelines; and related protocols, pathways, and other documents that guide the delivery of clinical services; (*Also see* GLD.11.2)
- provide for the ethical practice of their professions; (*Also see* GLD.12.1) and
- oversee the quality of patient care.

The department/service leaders of the medical and nursing staff create a suitable professional staff structure(s) to carry out these responsibilities. The structure(s) and the associated processes or committees used to carry out these responsibilities can be through a single professional staff composed of physicians, nurses, and other health care practitioners or separate medical and nursing staff structures, **for example**. The structure chosen can be highly organized with committees, bylaws, and rules and regulations or can be informally organized. In general, the structure(s) chosen

- includes all the relevant clinical staff;
- is consistent with the hospital's ownership, mission, and structure;
- is appropriate for the hospital's complexity and size of the professional staff; and
- is effective in carrying out the responsibilities listed above.

### Measurable Elements of GLD.8

- ❑ 1. There is a professional staff structure(s) used by medical, nursing, and other department/service leaders to carry out their responsibilities and authority.
- ❑ 2. The structure(s) is appropriate to the hospital's size and complexity.
- ❑ 3. The organizational structure(s) and processes support a culture of safety and professional communication.
- ❑ 4. The organizational structure(s) and processes support clinical planning and policy development.
- ❑ 5. The organizational structure(s) and processes support oversight of the quality of clinical services.

## Direction of Hospital Departments and Services

# Standard GLD.9

One or more qualified individuals provide direction for each department or service in the hospital. Ⓟ

### Intent of GLD.9

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 a qualified individual. In larger departments or services, there may be multiple leaders. In such a case, the responsibilities of each role are defined in writing. (*Also see* AOP.5.1; AOP.5.2; AOP.6.2; COP.3.3; COP.8; COP.8.1; ASC.2; MMU.1; QPS.1; PCI.1; GLD.1.1; FMS.2; and MOI.11)

Each department/service leader communicates his or her human resources and other resource requirements to hospital leadership. This helps ensure that adequate staff, space, medical equipment, technology, and other resources are available to meet patients' needs at all times. 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. (*Also see* SQE.6 and SQE.6.1)

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. (*Also see* SQE.7) **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.

### Measurable Elements of GLD.9

- ❑ 1. Each department or service in the hospital is directed by an individual with the training, education, and experience comparable to the services provided.
- ❑ 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.
- ❑ 3. Department/service leaders recommend criteria for selecting the department's or service's professional staff and choose or recommend individuals who meet those criteria.
- ❑ 4. Department/service leaders provide orientation and training for all staff on the duties and responsibilities for the department or service to which they are assigned.

# Standard GLD.10

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. Ⓟ

### Intent of GLD.10

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. (*Also see* ACC.2.3)

Clinical services provided to patients are coordinated and integrated within each department or service. **For example**, there is integration of medical and nursing services. 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.

### Measurable Elements of GLD.10

- ❑ 1. Department/service leaders have selected and use a uniform format and content for planning documents.
- ❑ 2. The departmental or service documents describe the current and planned services provided by each department or service.
- ❑ 3. The departmental or service documents guide the provision of identified services.
- ❑ 4. The departmental or service documents address the staff knowledge and skills needed to assess and to meet patient needs.
- ❑ 5. There is coordination and/or integration of services within and with other departments and services.

## Standard GLD.11

Department/service leaders improve quality and patient safety by participating in hospitalwide improvement priorities and in monitoring and improving patient care specific to the department/service.

### Intent of GLD.11

Department/service leaders engage their staff in improvement activities that reflect the hospitalwide priorities (*also see* GLD.5) and address the 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 also 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 also may monitor and improve the accuracy of patient bills.

Department/service leaders consider the Joint Commission International Library of Measures and/or other well-defined, evidence-based measures as applicable to the services provided by the department or service. (*Also see* APR.7)

Thus, the leaders of the department or service implement the selection and monitoring of measures specific to the department or service that include the following:

- Those hospitalwide measurement and improvement priorities set by hospital leadership 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 of 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 improvement and patient safety program. (*Also see* QPS.1; QPS.2; and QPS.9)

**Note:** 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. (*Also see* AOP.6.5 and PCI.14)

### Measurable Elements of GLD.11

- ❑ 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.
- ❑ 2. Department/service leaders implement quality measures to reduce variation and improve processes within the department or service, including implementation of measures found in the Joint Commission International Library of Measures or other resources for well-defined, evidence-based clinical measures.
- ❑ 3. Department/service leaders select measures based on the need for improvement, and when improvement has been sustained, select a new measure.
- ❑ 4. Department and service quality measurement and improvement activities are integrated into and supported by the quality management and coordination structure of the organization.



## Standard GLD.11.1

Measures selected by the department/service leaders that are applicable to evaluating the performance of physicians, nurses, and other professional staff participating in the clinical care processes are used in the staff's performance evaluation.

### Intent of GLD.11.1

Leaders are responsible for ensuring the quality of care and services provided by their department/service. Measurement activities provide the opportunity for the evaluation of these 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. Quality measurement activities can be important to ensuring that the department/service leader has objective information to support these activities. Over time, quality measurement includes all of the services provided by the department or service and includes the clinical privileges of all the physicians. The "Clinical Results" section of the intent of SQE.11 provides additional information on the ongoing professional practice evaluation process. In some cases, the measures will be linked to the clinical practice guidelines implemented in the department or service. (*Also see* GLD.11.2) When applicable, measures may be taken from the Joint Commission International Library of Measures to permit the use of standardized measures within the department or service. Similarly, 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. Standard SQE.3 describes the evaluation process for these individuals, and the measurement activities described in this standard will support an objective evaluation process. 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. (*Also see* QPS.2 and SQE.10)

### Measurable Elements of GLD.11.1

- ❑ 1. When applicable, assessment of participation in quality activities and the results of measurement activities are included in the ongoing professional practice evaluation of the department's or service's physicians.
- ❑ 2. When applicable, assessment of participation in quality activities and the results of measurement activities are included in the performance evaluation of nursing staff.
- ❑ 3. When applicable, assessment of participation in quality activities and the results of measurement activities are included in the performance evaluation of other health practitioners.

## Standard GLD.11.2

Department/service leaders select and implement clinical practice guidelines, and related clinical pathways and/or clinical protocols, to guide clinical care. Ⓟ

### Intent of GLD.11.2

The goals of hospitals include

- 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; and
- 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 are useful tools in this effort to understand and to apply the best science to a particular diagnosis or condition. (*Also see* IPSG.5; IPSG.5.1; COP.3.4; COP.8.6; MMU.1.1; PCI.5; and PCI.5.1) The hospital uses only those clinical practice guidelines that have been reviewed and endorsed by relevant authoritative sources; **for example**, a national professional association or council, or an international organization that catalogues approved guidelines. If the clinical practice guideline was developed by the hospital, it would be submitted to an authoritative source for endorsement.

Frequently, the effective implementation of a clinical practice guideline 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 and any related clinical care pathways and clinical protocols relevant to the hospital's patient population and mission are

a) selected from among those applicable to the services and patients of the hospital (mandatory national guidelines are included in this process, if present);
b) evaluated for their relevance to identified patient populations;
c) adapted when needed to the technology, drugs, and other resources of the hospital or to accepted national professional norms;
d) assessed for their scientific evidence and endorsement by an authoritative source;
e) formally approved or adopted by the hospital;
f) implemented and measured for consistent use and effectiveness;
g) supported by staff trained to apply the guidelines or pathways; and
h) 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 collectively expected to accomplish the following on an annual basis:

- Department/service leaders collectively determine at least five hospitalwide priority areas on which to focus—**for example**, a patient diagnosis such as stroke, or a procedure such as transplantation, or a population such as geriatric, or a disease such as diabetes, among others—for which guidelines would impact the quality and safety of patient care and reduce unwanted variation in outcomes. (*Also see* APR.7 and GLD.11.1)
- Complete the process described in a) through h) for the guideline related to the identified priority focus areas.

This collective selection process does not prohibit an individual department or service from selecting additional guidelines, and any associated protocols or pathways, more specific to the services provided in that department or service.

### Measurable Elements of GLD.11.2

❑ 1. On an annual basis, department/service leaders collectively determine at least five hospitalwide priority areas on which to focus the use of clinical practice guidelines.

❑ 2. Department/service leaders follow the process described in a) through h) of the intent in selecting and implementing clinical practice guidelines.

❑ 3. Department/service leaders implement clinical guidelines and any associated clinical pathways or clinical protocols for each identified priority area as relevant to the department/service.

❑ 4. Department/service leaders demonstrate how the use of clinical practice guidelines, clinical pathways, and/or clinical protocols has reduced variation in processes and outcomes

## *Organizational and Clinical Ethics*

## Standard GLD.12

Hospital leadership establishes 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. Ⓟ

## Standard GLD.12.1

The hospital's framework for ethical management addresses operational and business issues, including marketing, admissions, transfer, discharge, and disclosure of ownership and any business and professional conflicts that may not be in patients' best interests. Ⓟ

## Standard GLD.12.2

The hospital's framework for ethical management addresses ethical issues and decision making in clinical care. Ⓟ

### Intent of GLD.12 Through GLD.12.2

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 leadership has a professional and legal responsibility to create and promote an environment and culture that operate within an ethical framework. The ethical framework must apply to both the hospital's business and clinical activities alike. Hospital leadership must demonstrate ethical behaviors and

develop guidelines for organizational performance and conduct. Hospital leadership's actions and the hospital's guidelines for ethical behavior must be congruent with the hospital's vision, mission, and value statements; staff policies; annual reports; and other documents.

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 and disagreements between patients and their health care practitioners regarding care decisions. Such support is readily available and includes ethics resources and training for health care practitioners and other 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

- 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;
- encourage transparency in reporting organizational and clinical performance measures;
- 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 and timely resolution to ethical conflicts that arise;
- ensure nondiscrimination in employment practices and provision of patient care in the context of the cultural and regulatory norms of the country; and
- reduce disparities in health care access and clinical outcomes. (*Also see* PCC.1.1; COP.1; QPS.7; QPS.7.1; and GLD.8)

## Measurable Elements of GLD.12

❑ 1. Hospital leadership establishes a framework for the hospital's ethical management that promotes a culture of ethical practices and decision making to ensure the protection of patients and their rights.

❑ 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 leadership examines national and international ethical norms for incorporation when developing the hospital's framework for ethical conduct.

## Measurable Elements of GLD.12.1

❑ 1. The hospital discloses its ownership and any conflicts of interest.

❑ 2. The hospital honestly portrays its services to patients.

❑ 3. The hospital accurately bills for services and ensures that financial incentives and payment arrangements do not compromise patient care.

### Measurable Elements of GLD.12.2

- ❑ 1. The hospital's framework for ethical management establishes a mechanism by which health care practitioners and other staff may raise ethical concerns without fear of retribution.
- ❑ 2. The organizational structure(s) and processes support oversight of professional ethical issues.
- ❑ 3. Support for identifying and addressing ethical concerns is readily available and includes ethics resources and training for health care practitioners and other staff.
- ❑ 4. The hospital provides an effective and timely resolution to ethical conflicts that arise.

## Standard GLD.13

Hospital leadership creates and supports a culture of safety program throughout the hospital. Ⓟ

## Standard GLD.13.1

Hospital leadership implements, monitors, and takes action to improve the program for a culture of safety throughout the hospital.

### Intent of GLD.13 and GLD.13.1

A *culture of safety* has been defined as "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 (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."

Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the hospital. Hospital leadership demonstrates its commitment to a culture of safety and leaders set expectations for those who work in the hospital. Behaviors that are not consistent with a safe culture or that intimidate others and affect morale or staff turnover can be harmful to patient care. Key features of a program for a culture of safety include

- acknowledgment of the high-risk nature of a hospital's activities and the determination to achieve consistently safe operations;
- an environment in which individuals are able to report errors or near misses without fear of reprimand or punishment; (*Also see* QPS.7 and QPS.7.1)
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems; and
- organizational commitment of resources, such as staff time, education, a safe method for reporting issues, and the like, to address safety concerns. (*Also see* APR.9)

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 reckless behavior and do require accountability. **Examples** of reckless behavior include failure to follow hand-hygiene guidelines, not performing the time-out before surgery, or not marking the surgical site. 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 reckless behavior. Accountability distinguishes between human error (such as a mix-up), at-risk behavior (**for example**, taking shortcuts), and reckless behavior (such as ignoring required safety steps).

Hospital leadership evaluates the culture on a regular basis using a variety of methods, such as formal surveys, focus groups, staff interviews, and data analysis. Hospital leadership encourages teamwork and creates

structures, processes, and programs that allow this positive culture to flourish. Hospital leadership must address undesirable behaviors of individuals working at all levels of the hospital, including management, clinical and nonclinical staff, licensed independent practitioners, and governing entity members.

### Measurable Elements of GLD.13

- ❑ 1. Hospital leadership establishes and supports an organizational culture that promotes accountability and transparency.
- ❑ 2. Hospital leadership develops and documents a code of conduct and identifies and corrects behaviors that are unacceptable.
- ❑ 3. Hospital leadership provides education and information (such as literature and advisories) relevant to the hospital's culture of safety to all individuals who work in the hospital.
- ❑ 4. Hospital leadership defines how issues related to a culture of safety within the hospital are identified and managed.
- ❑ 5. Hospital leadership provides resources to promote and support the culture of safety within the hospital.

### Measurable Elements of GLD.13.1

- ❑ 1. Hospital leadership provides a simple, accessible, and confidential system for reporting issues relevant to a culture of safety in the hospital.
- ❑ 2. Hospital leadership ensures that all reports related to the hospital's culture of safety are investigated in a timely manner.
- ❑ 3. The hospital identifies systems issues that lead health care practitioners to engage in unsafe behaviors.
- ❑ 4. Hospital leadership uses measures to evaluate and monitor the safety culture within the hospital and implements improvements identified from measurement and evaluation.
- ❑ 5. Hospital leadership implements a process to prevent retribution against individuals who report issues related to the culture of safety.

## *Health Professional Education*

**Note:** For hospitals that meet the eligibility criteria for academic medical center (AMC) hospital accreditation, GLD.14 applies to education provided to nursing students and/or other nonmedical, health professional students. For hospitals that are not academic medical centers, GLD.14 applies to education provided to medical trainees, nursing students, and/or other health professional students.

# Standard GLD.14

Health professional education, when provided within the hospital, is guided by the educational parameters defined by the sponsoring academic program and the hospital's leadership.

### Intent of GLD.14

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 center hospitals for the purpose of these standards.

When the hospital participates in these types of training programs, the hospital

- provides a mechanism(s) for oversight of the program(s);
- obtains and accepts the parameters of the sponsoring academic program;
- has a complete record of all students and trainees within the hospital;
- has documentation of the enrollment status, licensure or certifications achieved, and academic classification of the students and trainees;
- understands and provides the required level of supervision for each type and level of student and trainee; and
- integrates students and trainees into the hospital's orientation, quality, patient safety, infection prevention and control, and other programs. (*Also see* GLD.1.1)

### Measurable Elements of GLD.14

- ❑ 1. The hospital provides a mechanism(s) for oversight of the training program(s).
- ❑ 2. The hospital obtains and accepts the parameters of the sponsoring academic program.
- ❑ 3. The hospital has a complete record of all students and trainees within the hospital.
- ❑ 4. The hospital has documentation of the enrollment status, licensure or certifications achieved, and academic classification of the students and trainees.
- ❑ 5. The hospital understands and provides the required level of supervision for each type and level of student and trainee.
- ❑ 6. The hospital integrates students and trainees into its orientation, quality, patient safety, infection prevention and control, and other programs.



## *Human Subjects Research*

**Note:** Standards GLD.15 through GLD.19 apply to hospitals that conduct human subjects research but do not meet the eligibility criteria for academic medical center hospital accreditation.

## Standard GLD.15

Human subjects research, when provided within the hospital, is guided by laws, regulations, and hospital leadership. Ⓟ

### Intent of GLD.15

Human subjects research on a large scale or small scale is a complex and significant endeavor for a hospital. Hospital leadership recognizes the required level of commitment and personal involvement required to advance scientific inquiry in the context of protecting the patients for whom they have made a commitment to diagnose and treat. Hospital leadership's commitment to human subjects research is not separate from its commitment to patient care—commitment is integrated at all levels. Thus, ethical considerations, good communication, responsible leaders, regulatory compliance, and financial and nonfinancial resources are components of this commitment. One such resource is indemnity insurance to adequately compensate patients for adverse events due to the research protocol. Hospital leadership recognizes the obligation to protect patients irrespective of the sponsor of the research. (*Also see* GLD.1.1)

When the hospital's research requires admission to specialized wards, such admission is through established criteria or an established protocol. 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.

### Measurable Elements of GLD.15

- ❑ 1. Hospital leadership identifies the official(s) responsible for maintaining the development of and compliance with all human subjects research policies and procedures.
- ❑ 2. Hospital leadership assumes responsibility for patient protection irrespective of the sponsor of the research.
- ❑ 3. Hospital leadership recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research.
- ❑ 4. Hospital leadership ensures that there is a source of indemnity insurance to adequately compensate patients participating in clinical research who experience an adverse event.
- ❑ 5. The hospital establishes entry and/or transfer criteria for an admission to a specialized ward due to research and/or another specialized program to meet patient needs.

## Standard GLD.16

Patients and families are informed about how to gain access to clinical research, clinical investigations, or clinical trials involving human subjects. Ⓟ

### Intent of GLD.16

A hospital that conducts clinical research, clinical investigations, or clinical trials involving human subjects provides information to patients and families about how to gain access to those activities when relevant to the patients' treatment needs. When patients are asked to participate, they need information on which to base their decisions. That information includes

- expected benefits;
- potential discomforts and risks;
- alternatives that might also help them; and
- procedures that must be followed.

Patients are informed that they can refuse to participate or withdraw participation and that their refusal or withdrawal will not compromise their access to the hospital's services. The hospital has policies and procedures for providing patients and families with this information.

### Measurable Elements of GLD.16

- ❑ 1. As appropriate, 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.
- ❑ 2. Patients and families asked to participate are informed about expected benefits.
- ❑ 3. Patients and families asked to participate are informed about potential discomforts and risks.
- ❑ 4. Patients and families asked to participate are informed about alternatives that might also help them.
- ❑ 5. Patients and families asked to participate are informed about the procedures that must be followed.
- ❑ 6. Patients and families are assured that their refusal to participate or withdraw from participation will not compromise their access to the hospital's services.

## Standard GLD.17

Patients and families are informed about how patients who choose to participate in clinical research, clinical investigations, or clinical trials are protected.

### Intent of GLD.17

A hospital that conducts clinical research, clinical investigations, or clinical trials involving human subjects knows that its first responsibility is to the patient's health and well-being. To assist with decisions regarding participation in clinical research, clinical investigations, or clinical trials, the hospital informs patients and families about

- the research and the patient's role in the research;
- the potential risks and benefits to the patient;
- the patient's rights related to withdrawal from participation in the research;
- the patient's rights to confidentiality and security of information; (*Also see* MOI.2) and
- obtaining patient consent for participation in the research. (*Also see* PCC.4.1 and GLD.18)

### Measurable Elements of GLD.17

❑ 1. Patients and families are informed about the research and the potential benefits and risks to patients who decide to participate.

❑ 2. Patients and families are informed about their rights related to withdrawing from participation.

❑ 3. Patients and families are informed about their rights to confidentiality and security of information.

❑ 4. Patients and families are informed about the hospital's process for obtaining consent.

## Standard GLD.18

Informed consent is obtained before a patient participates in clinical research, clinical investigations, or clinical trials. Ⓟ

### Intent of GLD.18

When patients and families decide to participate in clinical research, clinical investigations, or clinical trials, informed consent is obtained. The information provided at the time the decision to participate is made serves as the basis for the informed consent. (*Also see* PCC.4.1 and GLD.17) The individual(s) providing the information and obtaining the consent is noted on the informed consent document and stored in the files for the research protocol.

### Measurable Elements of GLD.18

❑ 1. Informed consent is obtained when a patient decides to participate in clinical research, clinical investigations, or clinical trials.

❑ 2. The identity of the individual(s) providing the information and obtaining the consent is noted on the informed consent document and stored in the files for the research protocol.

❑ 3. Consent is documented and dated on the informed consent document by signature or record of verbal consent.

# Standard GLD.19

The hospital has a committee or another way to oversee all research in the hospital involving human subjects. Ⓟ

## Intent of GLD.19

When the hospital conducts clinical research, investigations, or trials that involve 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. (*Also see* MOI.2)

## Measurable Elements of GLD.19

- ❑ 1. The hospital has a committee or other mechanism such as a hospital-specific or shared Institutional Review Board (IRB) to oversee all research within the hospital.
- ❑ 2. The hospital develops a clear statement of purpose for the oversight activities.
- ❑ 3. Oversight activities include a review process.
- ❑ 4. Oversight activities include a process to weigh relative risks and benefits to subjects.
- ❑ 5. Oversight activities include processes to provide confidentiality and security of research information.

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# 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

- reduce and control hazards and risks;
- prevent accidents and injuries; and
- maintain safe conditions.

Effective management includes multidisciplinary 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, facility-wide 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—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.
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 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 programs
- Emergency management programs
- Fire safety programs

Laws, regulations, and inspections by local authorities determine in large part 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

# 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.1** The hospital complies with relevant laws, regulations, building and fire safety codes, and facility inspection requirements.

**FMS.2** A qualified individual oversees the facility management and safety structure to reduce and control risks in the care environment.

## Risk Assessment and Monitoring

**FMS.3** The hospital develops and documents a comprehensive 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.

**FMS.4** Data are collected and analyzed from each of the facility management and safety programs to reduce risks in the environment, track progress on goals and improvements, and support planning for replacing and upgrading facilities, systems, and equipment.

## Safety

**FMS.5** The hospital develops and implements a program to provide a safe physical facility through inspection and planning to reduce risks. Ⓟ

## Security

**FMS.6** The hospital develops and implements a program to provide a secure environment for patients, families, staff, and visitors. Ⓟ

## Hazardous Materials and Waste

**FMS.7** The hospital develops and implements a program for the management of hazardous materials and waste. Ⓟ

**FMS.7.1** The hospital's program for the management of hazardous materials and waste includes the inventory, handling, storage, and use of hazardous materials. Ⓟ

**FMS.7.2** The hospital's program for the management of hazardous materials and waste includes the types, handling, storage, and disposal of hazardous waste. Ⓟ

## Fire Safety

**FMS.8** The hospital establishes and implements a program for fire safety that includes an ongoing assessment of risks and compliance with national and local codes, laws, and regulations for fire safety. Ⓟ

**FMS.8.1** The fire safety program includes the early detection, suppression, and containment of fire and smoke. Ⓟ

**FMS.8.2** The fire safety program includes measures to ensure safe exit from the facility when fire and non-fire emergencies occur. Ⓟ

**FMS.8.3** All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, tested, and maintained. Ⓟ

**FMS.8.4** The hospital involves staff in regular exercises to evaluate the fire safety program. Ⓟ

**FMS.8.5** The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility. Ⓟ

## Medical Equipment

**FMS.9** The hospital develops and implements a program for the management of medical equipment throughout the organization.

**FMS.9.1** The medical equipment program includes inspection, testing, preventive maintenance, and documenting the results. Ⓟ

**FMS.9.2** The hospital has a process for monitoring and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures. Ⓟ

## Utility Systems

**FMS.10** The hospital develops and implements a program for the management of utility systems throughout the organization.

**FMS.10.1** 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. Ⓟ

**FMS.10.2** 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 established and tested. Ⓟ

**FMS.10.3** Designated individuals or authorities monitor water quality regularly.

**FMS.10.3.1** Quality of water used in hemodialysis is tested for chemical, bacterial, and endotoxin contaminants, and processes for hemodialysis services follow professional standards for infection prevention and control. Ⓟ

## Emergency and Disaster Management

**FMS.11** The hospital develops, maintains, and tests an emergency management program to respond to internal and external emergencies and disasters that have the potential of occurring within the hospital and community. Ⓟ

## Construction and Renovation

**FMS.12** When planning for construction, renovation, and demolition projects, or maintenance activities that affect patient care, the organization conducts a preconstruction risk assessment. Ⓟ

### Education

**FMS.13** Staff and others are trained and knowledgeable about the hospital's facility management and safety programs and their roles in ensuring a safe and effective facility.

# Standards, Intents, and Measurable Elements

## *Leadership and Planning*

## Standard FMS.1

The hospital complies with relevant laws, regulations, building and fire safety codes, and facility inspection requirements.

### Intent of FMS.1

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. Such requirements may differ depending on the facility's age and location and other factors. **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 leadership to communicate with the property owner to ensure that the building complies with relevant laws, regulations, codes, and other requirements. In addition, hospital leadership communicates and collaborates 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, fire safety (**for example**, fire alarms, fire suppression systems), emergency exits, maintenance of utilities (**for example**, ventilation, water quality), and other building issues. It is important for hospital leadership to have access to documents managed by the property owner, such as maintenance records and inspection reports relevant to the hospital's facilities.

Hospital leadership and the hospital's facility management and safety structure are responsible for

- 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; and
- planning and budgeting for the necessary replacement or upgrading of facilities, systems, and equipment to meet applicable requirements or as identified by monitoring data or to meet applicable requirements and providing evidence of progress toward implementing the improvements. (*Also see* GLD.1.1 and GLD.2)

When the hospital has been cited for not meeting requirements, hospital leadership takes 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 by completing the "Laws and Regulations Worksheet" and "External Auditing Body Recommendation Worksheet" in the *Joint Commission International Hospital Survey Process Guide* or provides the same information in a different form or document.

### Measurable Elements of FMS.1

- ❑ 1. Hospital leadership and the facility management and safety structure understand and implement the national and local laws, regulations, building and fire safety codes, and other requirements applicable to the hospital's facilities.
- ❑ 2. Hospital leadership and the facility management and safety structure document corrective actions taken to meet the conditions of external facility reports or citations from inspections by national and local authorities.
- ❑ 3. Hospital leadership plans and budgets for replacing or upgrading facilities, systems, and equipment needed to meet applicable requirements and for the continued operation of a safe, secure, and effective facility.
- ❑ 4. Hospital leadership approves and allocates budgeted resources or implements alternative strategies to reduce risks until the resources can be allocated.
- ❑ 5. When the hospital is located inside a multiuse building, hospital leadership obtains 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.2

A qualified individual oversees the facility management and safety structure to reduce and control risks in the care environment.

### Intent of FMS.2

Hospitals work to provide safe, functional, and supportive facilities for patients, families, staff, and visitors. To reach this goal, the physical facility, equipment, medical equipment, and people must be effectively managed. In particular, management must strive to

- reduce and control hazards and risks;
- prevent accidents and injuries; and
- maintain safe conditions.

Effective management includes multidisciplinary planning, education, and monitoring as follows:

- Hospital leadership plans the space, medical equipment, technology, and resources needed to safely and effectively support the clinical and nonclinical 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.

Hospital leadership identifies an individual qualified by training and experience to oversee the facility management and safety structure, which includes coordinating and managing risk assessment and risk reduction activities in the physical environment. (*Also see* GLD.9) 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 leadership, 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. The individual who oversees the facility management and safety structure is responsible for ensuring the following:

a) Recommendations for space, medical equipment, technology, and other resources to support the facility management and safety structure are provided to hospital leadership.
b) Facility management and safety programs are planned and developed for the following: safety, security, hazardous materials and waste, fire safety, medical equipment, utility systems, emergency and disaster management and construction and renovation.
c) The facility management and safety programs are current and fully implemented.
d) Staff and others are trained on the program.
e) The programs are evaluated and monitored.
f) 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; changes to the hospital's facilities, systems, or equipment; and so on).

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. Whatever the mechanism chosen by the hospital to support the individual responsible for the facility management and safety structure, a multidisciplinary team should be considered, and include representatives from the various facility management and safety programs as well as 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, and banks.

### Measurable Elements of FMS.2

- ❑ 1. Oversight and direction of the facility management and safety structure is assigned to an individual qualified by experience and training, and evidence of the experience and training is documented.
- ❑ 2. The qualified individual is responsible for elements a) through f) of the intent.
- ❑ 3. The qualified individual is responsible for coordinating and managing risk assessment and risk reduction activities for the facility management and safety structure.
- ❑ 4. When independent business entities are present within the organization, the entities comply with the facility management and safety programs, as applicable.

## *Risk Assessment and Monitoring*

## Standard FMS.3

The hospital develops and documents a comprehensive 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.3

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 comprehensive, facility-wide risk assessment, at least annually, that integrates all eight facility management and safety programs to maximize safety to patients, patient's family, staff, and visitors. The eight programs are as follows:

a) Safety
b) Security
c) Hazardous materials and waste
d) Fire safety
e) Medical equipment
f) Utility systems
g) Emergency and disaster management
h) Construction and renovation

The hospital prioritizes the integrated risks. 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. (*Also see* GLD.5)

**Note:** Refer to the standards in this chapter for requirements related to risk assessment activities for each program.

### Measurable Elements of FMS.3

- ❑ 1. The risk assessments from all eight facility management and safety programs listed as a) through h) in the intent are integrated to develop and document a comprehensive, facility-wide risk assessment, at least annually.
- ❑ 2. The hospital prioritizes the risks, identifies goals and improvements, and implements improvements to reduce and eliminate risks.
- ❑ 3. The hospital evaluates the effectiveness of the improvements, and based on the results, the hospital updates the applicable facility management and safety programs.

## Standard FMS.4

Data are collected and analyzed from each of the facility management and safety programs to reduce risks in the environment, track progress on goals and improvements, and support planning for replacing and upgrading facilities, systems, and equipment.

### Intent of FMS.4

Monitoring each of the facility management and safety programs through data collection and analysis provides information that helps the hospital reduce risks, track progress on goals, make decisions on system improvements, and plan for upgrading or replacing medical equipment, technology, and utility systems. The monitoring data for the facility management and safety programs are documented and integrated into the hospital's quality and patient safety program. The individual who oversees the facility management and safety structure submits reports of the monitoring data and goals to hospital leadership at least quarterly. This individual submits the risk assessment and planned and implemented improvements to hospital leadership at least annually.

Hospital leadership provides an annual report to the governing entity on the effectiveness of the facility management and safety programs. (*Also see* GLD.4 and GLD.4.1) The annual report includes

- the results of the comprehensive risk assessment, including priorities;
- goals, monitoring data, improvements, and any challenges from the past year; and
- goals, planned improvements, and anticipated challenges for the coming year.

### Measurable Elements of FMS.4

❑ 1. Monitoring data are collected and analyzed for each of the facility management and safety programs and used to reduce risks in the environment and support planning for replacing or upgrading facilities, systems, and equipment.

❑ 2. Monitoring data for the facility management and safety programs are documented and integrated into the hospital's quality and patient safety program.

❑ 3. The individual who oversees the facility management and safety structure provides monitoring data reports that address the effectiveness of each program and progress on goals to hospital leadership on a quarterly basis, and leadership takes action.

❑ 4. The individual who oversees the facility management and safety structure provides the comprehensive, facility-wide risk assessment and planned and implemented improvements to hospital leadership at least annually.

❑ 5. Hospital leadership provides an annual report to the governing entity on the effectiveness of the facility management and safety programs, and the governing entity takes action.

## *Safety*

## Standard FMS.5

The hospital develops and implements a program to provide a safe physical facility through inspection and planning to reduce risks. Ⓟ

### Intent of FMS.5

*Safety* refers to ensuring that the building, property, medical and information technology, equipment, and systems do not pose a physical 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. (*Also see* PCC.1.5; AOP.5.3; AOP.6.2; COP.3.5; COP.4; COP.4.1; and PCI.2) 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 risk assessment, at least annually, to identify areas in which safety risks and potential for harm exist. 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, help 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.5

- ❑ 1. The hospital develops and implements a written program to provide a safe physical facility.
- ❑ 2. The hospital has a documented, current, accurate inspection of its physical facilities.
- ❑ 3. The results from the facility inspection are reviewed and addressed in a safety risk assessment that is conducted and documented annually, and safety risks are identified and prioritized from the risk assessment.
- ❑ 4. The hospital identifies goals, implements improvements, and monitors data to ensure that safety risks are reduced or eliminated.

## *Security*

## Standard FMS.6

The hospital develops and implements a program to provide a secure environment for patients, families, staff, and visitors. Ⓟ

### Intent of FMS.6

*Security* refers to protecting the organization's property and the patients, families, visitors, and staff from harm or loss. (*Also see* PCC.1.4 and COP.3.5) **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. 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 and laws and regulations.

Restricted areas such as the pharmacy, newborn nursery, and operating theatres must be secure and monitored. (*Also see* MMU.3.1) 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.6

- ❑ 1. The hospital develops and implements a written program to provide a secure environment.
- ❑ 2. A security risk assessment is conducted and documented annually throughout the facility, and security risks are identified and prioritized from the risk assessment.
- ❑ 3. The security program identifies all security risk areas and restricted areas and ensures they are monitored and kept secure.
- ❑ 4. The security program ensures that all staff, students, trainees, contract workers, volunteers, vendors, and individuals associated with independent business entities are identified.
- ❑ 5. The hospital identifies goals and implements improvements in the security program, and monitors data to ensure that security risks are reduced or eliminated.

# Hazardous Materials and Waste

## Standard FMS.7

The hospital develops and implements a program for the management of hazardous materials and waste. Ⓟ

## Standard FMS.7.1

The hospital's program for the management of hazardous materials and waste includes the inventory, handling, storage, and use of hazardous materials. Ⓟ

## Standard FMS.7.2

The hospital's program for the management of hazardous materials and waste includes the types, handling, storage, and disposal of hazardous waste. Ⓟ

### Intent of FMS.7 Through FMS.7.2

The hospital develops and implements a written program for the management of hazardous materials and waste that includes identifying and safely controlling these materials and waste throughout the facility. (*Also see* AOP.5.3; AOP.5.6; MMU.3; and PCI.8) As part of the hazardous materials and waste program, the hospital conducts and documents a risk assessment, at least annually, to identify areas in which risks exist. The risk assessment also considers a review of processes and an evaluation of new and planned services that may increase risk related to hazardous materials and waste.

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 (**for example**, approximate or average) and the location(s) in the organization. This documentation should also address 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, hand hygiene, and others)
- Cytotoxic drugs
- Radioactive material
- Medical gases

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 addresses hazardous materials and hazardous waste and include processes for

- the inventory of hazardous materials and waste that includes the type, the location(s), and the quantities (**for example**, approximate or average in each location);
- updating the inventory of hazardous materials at least annually;
- safe handling, storage, and use of hazardous materials;
- proper and clear labeling of hazardous materials that is consistent with information from the safety data sheets (SDS);
- establishing and identifying categories of hazardous waste;
- safe handling and storage of hazardous waste;
- tracking quantity of and proper disposal of hazardous waste in accordance with local laws and regulations;
- proper protective equipment and procedures for spills and exposures;
- reporting and investigation of spills, exposures, and other incidents; and
- documentation, including any 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 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 stations installed must ensure proper maintenance, including a weekly flush and annual preventive maintenance.

## Measurable Elements of FMS.7

- ❑ 1. The hospital develops and implements a written program for the management of hazardous materials and waste.
- ❑ 2. A hazardous materials and waste risk assessment is conducted and documented annually throughout the facility, and risks related to hazardous materials and waste are identified and prioritized from the risk assessment.
- ❑ 3. The hospital identifies goals, implements improvements, and monitors data to ensure that risks related to hazardous materials and waste are reduced or eliminated.

### Measurable Elements of FMS.7.1

- ❑ 1. The hazardous materials and waste program identifies the type, quantities, and locations of hazardous materials and has a complete inventory, which is updated at least annually, to reflect changes in the hazardous materials used and stored in the organization.
- ❑ 2. The hazardous materials and waste program establishes and implements procedures for safe handling, storage, and use of hazardous materials.
- ❑ 3. The hazardous materials and waste program establishes and implements the proper protective equipment required during handling and use of hazardous materials.
- ❑ 4. The hazardous materials and waste program establishes and implements proper and clear labeling of hazardous materials that is consistent with information from the safety data sheets (SDS).
- ❑ 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.

### Measurable Elements of FMS.7.2

- ❑ 1. The hazardous materials and waste program establishes the types of hazardous waste generated by the hospital and how they are identified.
- ❑ 2. The hazardous materials and waste program establishes and implements procedures and the proper protective equipment required for safe handling and storage of hazardous waste.
- ❑ 3. When required by local laws and regulations, the hazardous materials and waste program documents the quantities of hazardous waste generated by the hospital.

## *Fire Safety*

## Standard FMS.8

The hospital establishes and implements a program for fire safety that includes an ongoing assessment of risks and compliance with national and local codes, laws, and regulations for fire safety. Ⓟ

### Intent of FMS.8

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. (*Also see* PCC.1.5) The fire safety program also addresses non-fire emergencies; **for example**, a toxic gas leak, which can pose a threat to occupants and require evacuation.

An ongoing assessment of compliance with the country's codes, laws, and regulations related to fire safety is important for identifying and minimizing risks. The hospital performs and documents an ongoing fire safety risk assessment that includes the following:

a) Fire separations
b) Smoke separations/compartments
c) Hazardous areas (and spaces above the ceilings in those areas) such as soiled linen rooms, trash collection rooms, and oxygen storage rooms
d) Fire exits
e) Kitchen grease-producing cooking devices

f) Laundry and trash chutes
g) Emergency power systems and equipment
h) Medical gas and vacuum system components
i) Storage and handling of potentially flammable materials (**for example**, flammable liquids, combustible gases, and oxidizing medical gases such as oxygen and nitrous oxide)
j) Procedures and precautions to prevent and manage surgical fires
k) Fire hazards related to construction, renovation, or demolition projects

Risks are identified from the ongoing assessment. **For example**, risks may include equipment, systems, or other features for fire safety that are damaged, obstructed, nonfunctional, or need to be removed. Risks may also be identified from construction projects, hazardous storage conditions, equipment and system breakdowns, or necessary maintenance that impacts fire safety systems, among other reasons.

When risks are identified, they are immediately addressed and corrected (**for example**, through repair, removal, replacement, or other means). When the risks cannot be addressed immediately, the hospital has a process for identifying when interim measures should be implemented. 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 is documented.

**Note:** A list of additional interim measures can be found in the Appendix at the end of the "Facility Management and Safety" (FMS) chapter.

## Measurable Elements of FMS.8

❑ 1. The hospital develops and implements a written program for fire safety to protect all occupants of the hospital's facilities from fire, smoke, and non-fire emergencies.

❑ 2. The hospital performs and documents an ongoing fire safety risk assessment related to at least a) through k) in the intent, and fire safety risks are identified and prioritized from the risk assessment.

❑ 3. 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.

❑ 4. The hospital identifies goals, implements improvements, and monitors data to ensure that fire safety risks are reduced or eliminated.

## Standard FMS.8.1

The fire safety program includes the early detection, suppression, and containment of fire and smoke. Ⓟ

## Standard FMS.8.2

The fire safety program includes measures to ensure safe exit from the facility when fire and non-fire emergencies occur. Ⓟ

### Intent of FMS.8.1 and FMS.8.2

Every hospital needs to plan how it will keep its occupants safe in case of fire, smoke, and non-fire emergencies. Health care facility structure and design can help prevent, detect, and suppress fires and provide safe exit from the facility. The hospital's program for fire safety addresses

- early warning, early detection, and notification systems, such as smoke detectors, fire alarms, and fire patrols;
- suppression mechanisms, 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; and
- safe and unobstructed access to exits in the event of a fire or non-fire 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, smoke, or non-fire emergencies. These features are effective no matter what the age, size, or construction of the facility.

### Measurable Elements of FMS.8.1

❑ 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. 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.

### Measurable Elements of FMS.8.2

❑ 1. The fire safety program includes the safe exit from the facility through free and unobstructed access to exits.

❑ 2. The fire safety program includes clearly visible exit signage that is understandable to the hospital's occupants.

❑ 3. The fire safety program includes lighting for emergency exit corridors and stairs.

## Standard FMS.8.3

All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, tested, and maintained. Ⓟ

### Intent of FMS.8.3

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, tests, 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.

**Note:** A list of interim measures can be found in the Appendix at the end of the "Facility Management and Safety" (FMS) chapter.

### Measurable Elements of FMS.8.3

❑ 1. All fire safety equipment and systems, including those for smoke and fire detection and suppression, are inspected, tested, 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.8.4

The hospital involves staff in regular exercises to evaluate the fire safety program. Ⓟ

### Intent of FMS.8.4

The hospital's fire safety program identifies

- the plan for reporting and responding to a fire emergency;
- the plan for safely evacuating the facility in the event of fire, smoke, or non-fire emergencies;
- the process for testing all portions of the fire safety program during each 12-month period;

- the responsibilities of different staff members during a fire emergency;
- the necessary education of staff to effectively protect and evacuate patients when an emergency occurs; and
- the participation of staff members in at least one fire safety exercise per year. (*Also see* FMS.13)

Exercises to evaluate the fire safety program can be accomplished in multiple ways. **For example**, to ensure that staff know 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. (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 involve patients.

Another **example** of an exercise to evaluate the fire safety program includes assigning a "fire marshal" to each unit and having him or her 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? How do you report a fire? How do you protect the patients during a fire? If you need to evacuate patients, 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.8.4

- ❑ 1. Staff from all shifts, including the night shift and weekends, annually participate in an exercise to evaluate the fire safety program.
- ❑ 2. Staff are knowledgeable of the fire safety program and can describe 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.8.5

The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility. Ⓟ

### Intent of FMS.8.5

The fire safety program addresses limiting smoking and

- 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; and
- 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.8.5

- ❑ 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.
- ❑ 4. Smoking is prohibited in all areas under construction or renovation.

## *Medical Equipment*

## Standard FMS.9

The hospital develops and implements a program for the management of medical equipment throughout the organization.

## Standard FMS.9.1

The medical equipment program includes inspection, testing, preventive maintenance, and documenting the results. Ⓟ

### Intent of FMS.9 and FMS.9.1

The hospital develops and implements a written program for the management of medical equipment throughout the hospital. 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. To ensure that medical equipment is available for use and functioning properly, the hospital performs and documents

- an inventory of medical equipment;
- regular inspections of medical equipment;
- testing of medical equipment according to its use and manufacturers' requirements; and
- performance of preventive maintenance.

Qualified individuals provide these services. Medical equipment is inspected and tested when new and then on an ongoing basis, according to the equipment age, use, and manufacturers' instructions. Inspections, testing results, and any maintenance are documented. This helps ensure the continuity of the maintenance process and helps when doing capital planning for replacements, upgrades, and other changes. (*Also see* AOP.5.5; AOP.6.4; COP.3.3; COP.4; and COP.4.1)

### Measurable Elements of FMS.9

- ❑ 1. The hospital develops and implements a written program for the management of medical equipment throughout the hospital.
- ❑ 2. A medical equipment risk assessment is conducted and documented annually throughout the hospital, and medical equipment risks are identified and prioritized from the risk assessment.
- ❑ 3. The hospital identifies goals, implements improvements, and monitors data to ensure that medical equipment risks are reduced or eliminated.

### Measurable Elements of FMS.9.1

- ❑ 1. The medical equipment program addresses hospital-owned and nonhospital-owned medical equipment in the organization, such as equipment that is leased, rented, brought in by physicians and other health care practitioners, brought in by patients, and so on.
- ❑ 2. The medical equipment program includes an inventory of all medical equipment.
- ❑ 3. Medical equipment is inspected and tested when new and according to age, use, and manufacturers' recommendations thereafter.
- ❑ 4. The medical equipment program includes preventive maintenance and calibration as applicable.

## Standard FMS.9.2

The hospital has a process for monitoring and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures. Ⓟ

### Intent of FMS.9.2

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 reporting of medical equipment incidents. The hospital conducts a root cause analysis in response to any sentinel events. 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. (*Also see* ASC.7.4)

### Measurable Elements of FMS.9.2

- ❑ 1. The hospital has a process for monitoring and acting on medical equipment and implantable device hazard notices, recalls, reportable incidents, problems, and failures.
- ❑ 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.
- ❑ 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.10

The hospital develops and implements a program for the management of utility systems throughout the organization.

## Standard FMS.10.1

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. Ⓟ

### Intent of FMS.10 and FMS.10.1

*Utilities* can be defined as the systems and equipment that support essential services that provide for safe health care. Such systems include electrical distribution; power; plumbing; boiler/steam; heating, ventilation, 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. (*Also see* PCI.10) As part of the utility systems program, the hospital conducts and documents a risk assessment, at least annually, to identify areas in which risks exist related to the utility systems. The risk assessment also considers new and planned services that may pose risks to the utility systems.

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, tested, maintained, and, when necessary, improved, to reduce and eliminate risks.

### Measurable Elements of FMS.10

- ❑ 1. The hospital develops and implements a written program for the management of utility systems throughout the hospital.
- ❑ 2. The hospital conducts and documents the utility systems risk assessment annually throughout the hospital and prioritizes the utility systems risks that are identified from the risk assessment.
- ❑ 3. The hospital identifies goals, implements improvements, and monitors data to ensure that the utility systems risks are reduced or eliminated.

### Measurable Elements of FMS.10.1

- ❑ 1. The hospital inventories its utility systems components and maps the current distribution of them.
- ❑ 2. The hospital identifies, in writing, the activities and intervals for inspecting, testing, 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.
- ❑ 3. The hospital updates or replaces utility systems and components when the need for improvement is identified through inspection, testing, and maintenance.
- ❑ 4. The hospital labels utility system controls to facilitate partial or complete emergency shutdowns.

## Standard FMS.10.2

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 established and tested. Ⓟ

### Intent of FMS.10.2

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. (*Also see* PCI.10)

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. (*Also see* FMS.11)

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, become interrupted, or become contaminated. To prepare for such emergencies, the hospital

- 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, and so on);
- 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 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); and
- ensures that the testing 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.10.2

- ❑ 1. The hospital identifies the areas and services at greatest risk when essential utilities (including power, water, and medical gas) become unavailable.
- ❑ 2. The hospital ensures backup availability/continuity of essential utilities (including power, water, and medical gas) 24 hours a day, 7 days a week.
- ❑ 3. The hospital assesses for and reduces the risks of interruption, contamination, and failure of essential utilities (including power, water, and medical gas).
- ❑ 4. The hospital tests 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.
- ❑ 5. The hospital tests 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.
- ❑ 6. When emergency sources of power require a fuel source, the hospital establishes and has available the necessary amount of on-site fuel stored.

## Standard FMS.10.3

Designated individuals or authorities monitor water quality regularly.

## Standard FMS.10.3.1

Quality of water used in hemodialysis is tested for chemical, bacterial, and endotoxin contaminants, and processes for hemodialysis services follow professional standards for infection prevention and control. Ⓟ

### Intent of FMS.10.3 and FMS.10.3.1

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.

Quality of potable (drinking) water is tested at least quarterly and testing of non-potable water is performed at least every six (6) months. Testing of potable and/or non-potable water is conducted more frequently if required by local laws and regulations, if indicated by the conditions of the sources for water, and/or if there was 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.

Water quality is essential for the safe and effective delivery of hemodialysis, as patients may be more vulnerable to infection risk and adverse outcomes. It is necessary that the processes and procedures used in hemodialysis follow industry standards and professional guidelines for water quality and infection prevention and control measures. This includes testing water used in hemodialysis monthly for bacterial growth and endotoxins and testing annually for chemical contaminants.

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.

When conducting water testing of hemodialysis machines, samples are taken from 10% of the hospital's machines on a monthly basis. This will result in all machines being tested at least once during each 12-month period, including machines that are not in use. 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.10.3

- ❑ 1. Quality of potable water is tested at least quarterly 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.
- ❑ 2. Quality of non-potable water is tested 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. Actions are taken and documented when water quality is found to be unsafe.
- ❑ 5. Dental unit waterlines are treated and tested according to manufacturer's guidelines, and treatments and testing are documented.

## Measurable Elements of FMS.10.3.1

- ❑ 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 monthly for bacterial growth and endotoxins and tested 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 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.

# Emergency and Disaster Management

## Standard FMS.11

The hospital develops, maintains, and tests 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.11

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, or others) 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.

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, 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. (*Also see* PCI.12.2 and MOI.13) 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 the 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 hospital's emergency and disaster management program provides processes for

a) determining the type, likelihood, and consequences of hazards, threats, and events;
b) 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;

c) planning for alternative sources of power and water in emergencies and disasters; (*Also see* FMS.10.2)
d) determining the hospital's role in such events;
e) determining communication strategies for events;
f) managing resources during events, including alternative sources;
g) managing clinical activities during an event, including alternative care sites;
h) identifying and assigning staff roles and responsibilities during an event (including contract staff, vendors, and others identified by the hospital); (*Also see* FMS.13) and
i) managing emergencies and disasters when personal responsibilities of staff conflict with the hospital's responsibility for providing patient care. (*Also see* MOI.13)

The emergency and disaster management program is tested by

- an annual test of the full program internally or as part of a community-wide test; or
- testing of critical elements c) through i) of the program during the year.

**Note:** Letter c) is part of requirements for testing alternative sources of utilities in FMS.10.2.

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.11

❑ 1. The hospital develops, evaluates, and maintains a written emergency and disaster management program that identifies its response to likely emergencies and disasters, including items a) through i) in the intent.

❑ 2. The hospital has identified the 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.

❑ 3. The hospital identifies the probable impact that each type of disaster will have on all aspects of care and services.

❑ 4. The entire program, or at least critical elements c) through i) of the program, is tested annually.

❑ 5. At the conclusion of every test, debriefing of the test is conducted.

❑ 6. Follow-up actions identified from testing and debriefing are developed and implemented.

## *Construction and Renovation*

## Standard FMS.12

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.12

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.

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. 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. Required areas of the preconstruction risk assessment include

a) air quality;
b) infection prevention and control; (*Also see* PCI.11)
c) utilities;
d) noise;
e) vibration;
f) hazardous materials and waste;
g) fire safety;
h) security;
i) emergency procedures, including alternate pathways/exits and access to emergency services; and
j) other hazards that affect care, treatment, and services.

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.12

- ❑ 1. When planning for construction, renovation, or demolition projects, or maintenance activities that affect patient care, the hospital conducts a preconstruction risk assessment (PCRA) for at least a) through j) in the intent.
- ❑ 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.

## *Education*

## Standard FMS.13

Staff and others are trained and knowledgeable about the hospital's facility management and safety programs and their roles in ensuring a safe and effective facility.

### Intent of FMS.13

Staff are the hospital's primary source of contact with patients, families, and visitors. Thus, they need to be educated and trained to carry out their roles in identifying and reducing risks, protecting others and themselves, and creating a safe and secure facility. (*Also see* FMS.8.4 and FMS.11)

Each hospital must decide the type and level of training for staff and then implement and document a program for the training. The training program can include group instruction, online educational modules, printed educational materials, a component of new staff orientation, and/or some other mechanism that meets the hospital's needs. Training is provided to all staff on all shifts on an annual basis and addresses all facility

management and safety programs. Training includes instruction on the processes for reporting potential risks and reporting incidents and injuries. The training program involves testing staff knowledge. Staff are trained and tested on emergency procedures, including fire safety procedures. As applicable to the staff member's role and responsibilities, training and testing address hazardous materials and response to hazards, such as the spill of a hazardous chemical, and the use of medical equipment that may pose a risk to patients and staff. Knowledge can be tested through a variety of means, such as individual or group demonstrations, the staging of mock events such as an epidemic in the community, the use of written or computer tests, or other means suitable to the knowledge being tested. The hospital documents who was tested and the results of the testing.

## Measurable Elements of FMS.13

- ❑ 1. All staff receive annual training and testing on each facility management and safety program to ensure they can safely and effectively carry out their responsibilities, and testing results are documented.
- ❑ 2. Training on the facility management and safety programs includes vendors, contract workers, volunteers, students, trainees, and others, as applicable to the individuals' roles and responsibilities, and as determined by the hospital.
- ❑ 3. Staff can describe and/or demonstrate their roles in response to a fire.
- ❑ 4. Staff can describe and/or demonstrate actions to eliminate, minimize, or report safety, security, and other risks.
- ❑ 5. Staff can describe and/or demonstrate precautions and procedures for handling and managing medical gases and hazardous materials and waste, as applicable to the staff member's role and responsibilities.
- ❑ 6. Staff can describe and/or demonstrate procedures for and their roles in internal and community emergencies and disasters.

# Appendix

## 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, or a breakdown or repair. When fire safety risks cannot be immediately addressed and corrected, the hospital identifies and 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.

*See* FMS.8 and FMS.8.3 for requirements related to interim measures.

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 more than 4 out of 24 hours, or a sprinkler system is out of service 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, maintenance activities, and so on).
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 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. Other interim measures, as determined by the hospital and appropriate to the fire safety risk.

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# Staff Qualifications and Education (SQE)

## Overview

A health care organization needs an appropriate variety of skilled, qualified people to fulfill its mission and to meet patient needs. The organization's leaders work together to identify the number and types of staff needed based on the recommendations from department and service leaders.

Recruiting, evaluating, and appointing 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 and nursing 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 protect patients.

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.

In order 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 dynamic, 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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

**SQE.1** Leaders of hospital departments and services define the desired education, skills, knowledge, and other requirements of all staff members.

**SQE.1.1** Each staff member's responsibilities are defined in a current job description. Ⓟ

**SQE.2** Leaders of hospital departments and services develop and implement processes for recruiting, evaluating, and appointing staff as well as other related procedures identified by the hospital.

**SQE.3** The hospital uses a defined process to ensure that clinical staff knowledge and skills are consistent with patient needs.

**SQE.4** The hospital uses a defined process to ensure that nonclinical staff knowledge and skills are consistent with hospital needs and the requirements of the position.

**SQE.5** There is documented personnel information for each staff member. Ⓟ

**SQE.6** A staffing strategy for the hospital, developed by the leaders of hospital departments and services, identifies the number, types, and desired qualifications of staff. Ⓟ

**SQE.6.1** The staffing strategy is reviewed on an ongoing basis and updated as necessary.

**SQE.7** All clinical and nonclinical staff members are oriented to the hospital, the department or unit to which they are assigned, and to their specific job responsibilities at appointment to the staff.

**SQE.8** Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge.

**SQE.8.1** Staff members who provide patient care are trained and demonstrate competence in the resuscitative techniques specific to the level of training identified.

**SQE.8.1.1** Other staff identified by the hospital are trained and can demonstrate appropriate competence in resuscitative techniques.

## Staff Health and Safety

**SQE.8.2** The hospital provides a staff health and safety program that addresses staff physical and mental health and safe working conditions. Ⓟ

**SQE.8.3** 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. Ⓟ

## Determining Medical Staff Membership

**SQE.9** The hospital has a uniform process for gathering the credentials of those medical staff members permitted to provide patient care without supervision. Ⓟ

**SQE.9.1** Medical staff members' education, licensure/registration, and other credentials required by law or regulation and the hospital are verified and kept current. Ⓟ

**SQE.9.2** There is a uniform, transparent decision process for the initial appointment of medical staff members. Ⓟ

## The Assignment of Medical Staff Clinical Privileges

**SQE.10** The hospital has a standardized, objective, evidence-based procedure to authorize medical staff members to admit and to treat patients and/or to provide other clinical services consistent with their qualifications. Ⓟ

## Ongoing Professional Practice Evaluation of Medical Staff Members

**SQE.11** The hospital uses an ongoing standardized process to evaluate the quality and safety of the patient care provided by each medical staff member. Ⓟ

## Medical Staff Reappointment and Renewal of Clinical Privileges

**SQE.12** At least every three years, the hospital determines, from the ongoing professional practice evaluation of each medical staff member, if medical staff membership and clinical privileges are to continue with or without modification. Ⓟ

### Nursing Staff

**SQE.13** The hospital has a uniform process to gather, to verify, and to evaluate the nursing staff's credentials (license, education, training, and experience). Ⓟ

**SQE.14** The hospital has a standardized process to identify job responsibilities and to make clinical work assignments based on the nursing staff member's credentials and any regulatory requirements.

**SQE.14.1** The hospital has a standardized process for nursing staff participation in the hospital's quality improvement activities, including evaluating individual performance when indicated.

### Other Health Care Practitioners

**SQE.15** The hospital has a uniform process to gather, to verify, and to evaluate other health care practitioners' credentials (license, education, training, and experience). Ⓟ

**SQE.16** The hospital has a uniform process to identify job responsibilities and to make clinical work assignments based on other health care practitioners' credentials and any regulatory requirements.

**SQE.16.1** The hospital has a uniform process for other health care practitioners' participation in the hospital's quality improvement activities.

# Standards, Intents, and Measurable Elements

## *Planning*

## Standard SQE.1

Leaders of hospital departments and services define the desired education, skills, knowledge, and other requirements of all staff members.

### Intent of SQE.1

The department/service leaders define staffing requirements to meet the needs of patients. (*Also see* QPS.1) They define the desired education, skills, knowledge, and any other requirements for individual positions or for classes of similar positions; **for example**, intensive care nurses. To project staffing needs, department/service leaders use factors such as the following:

- The hospital's mission
- The mix of patients served by the hospital and the complexity and severity of their needs
- The diagnostic and clinical services provided by the hospital
- The volume of inpatients and outpatients
- The medical equipment used in patient care

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.1

❑ 1. The hospital's mission, volume, and mix of patients, services, and medical equipment are used in planning.

❑ 2. The desired education, skills, and knowledge are defined for staff.

❑ 3. Applicable laws and regulations are incorporated into the planning.

# Standard SQE.1.1

Each staff member's responsibilities are defined in a current job description. Ⓟ

## Intent of SQE.1.1

Individual staff members who are not licensed to practice independently have their responsibilities defined in current job descriptions. The job descriptions are the basis for their assignments, orientation to their work, and evaluation of how well they fulfill job responsibilities. (*Also see* SQE.5 and SQE.14)

Job descriptions are also needed for health care practitioners when

a) the individual serves in primarily a managerial role, such as a department manager, or in dual clinical and managerial roles, with the managerial responsibilities identified in a job description; (*Also see* SQE.10)
b) the individual has some clinical responsibilities for which he or she has not been authorized to practice independently, such as an independent practitioner learning a new role or new skills;
c) the individual is in an educational program and under supervision, and the academic program identifies, for each stage or level of training, what can be done independently and what must be under supervision. (*Also see* MPE.7) The program description can serve as the job description in such cases; and
d) the individual is permitted to temporarily provide services in the hospital; **for example**, a nurse from a temporary staffing agency.

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 nurse, pediatric nurse, or operating theatre nurse, among others). For those permitted by law and the hospital to practice independently, there is a process to identify and to authorize the individual to practice based on education, training, and experience. (*Also see* SQE.9) The requirements of this standard apply to all types of "staff" who require job descriptions (**for example**, full-time, part-time, employed, voluntary, or temporary).

## Measurable Elements of SQE.1.1

❑ 1. Each staff member not permitted to practice independently has a job description.

❑ 2. Those individuals identified in a) through d) in the intent, when present in the hospital, have job descriptions appropriate to their activities and responsibilities or have been privileged if noted as an alternative.

❑ 3. Job descriptions are current according to hospital policy.

# Standard SQE.2

Leaders of hospital departments and services develop and implement processes for recruiting, evaluating, and appointing staff as well as other related procedures identified by the hospital.

## Intent of SQE.2

The hospital provides an efficient, coordinated, or centralized process for

- recruiting individuals for available positions; (*Also see* GLD.3.3)
- evaluating the training, skills, and knowledge of candidates; (*Also see* SQE.10; SQE.14; and SQE.16) and
- appointing individuals to the hospital's staff. (*Also see* SQE.9.2)

If the process is not 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 services to patients, as well as nonclinical support functions, and to fulfill any teaching, research, or other departmental responsibilities. Department and service leaders also help make decisions about individuals to be appointed to the staff. Thus, the standards in this chapter complement the Governance, Leadership, and Direction (GLD) standards that describe a department/service leader's responsibilities.

### Measurable Elements of SQE.2

- ❑ 1. The hospital establishes and implements a process to recruit staff.
- ❑ 2. The hospital establishes and implements a process to evaluate the qualifications of new staff.
- ❑ 3. The hospital establishes and implements a process to appoint individuals to the staff.
- ❑ 4. The hospital establishes and implements a process that is uniform across the hospital for similar types of staff.

## Standard SQE.3

The hospital uses a defined process to ensure that clinical staff knowledge and skills are consistent with patient needs.

### Intent of SQE.3

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 process also ensures that the staff member's skills are initially and over time consistent with the needs of patients. (*Also see* ACC.6; COP.3.2; COP.3.5; COP.4; COP.4.1; COP.7; COP.8; COP.8.2; ASC.3.1; MMU.6; PCI.1; SQE.14; and SQE.15)

For the hospital's health care practitioners who are independent practitioners (that is, they do not practice under job descriptions), the process is identified in SQE.9 through SQE.12.

For clinical staff under job descriptions, the process includes the following:

- An initial evaluation to ensure that he or she can actually assume those responsibilities 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 high-risk services or providing care to high-risk patients are evaluated at the time they begin providing care, before the probationary or orientation period is completed. This evaluation of necessary skills, and knowledge and desired work behaviors, is carried out by the department or service to which the staff member is assigned. (*Also see* SQE.9.2)
- The evaluation of necessary skills, knowledge, and desired work behaviors also includes an assessment of the staff member's ability to operate medical equipment and clinical alarms and oversee medication 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 then defines the process for and the frequency of the ongoing evaluation of staff abilities. (*Also see* SQE.5 and SQE.11)

Ongoing evaluation ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. Although such evaluation is best carried out in an ongoing manner, there is at least one documented evaluation of each clinical staff member working under a job description each year.

### Measurable Elements of SQE.3

❑ 1. The hospital uses a defined process to match clinical staff knowledge, skills, and competency with patient needs.

❑ 2. New clinical staff members are evaluated before or at the time they begin their work responsibilities.

❑ 3. The department or service to which the individual is assigned conducts the evaluation.

❑ 4. The hospital defines the frequency of ongoing clinical staff evaluation.

❑ 5. There is at least one documented evaluation of each clinical staff member working under a job description each year or more frequently as defined by the hospital.

## Standard SQE.4

The hospital uses a defined process to ensure that nonclinical staff knowledge and skills are consistent with hospital needs and the requirements of the position.

### Intent of SQE.4

The hospital seeks staff who can competently fill the requirement of nonclinical positions. The supervisor of the nonclinical staff member provides an orientation to the position and ensures that the worker 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. (*Also see* AOP.5.2; AOP.6.1; SQE.3; and SQE.4)

### Measurable Elements of SQE.4

❑ 1. The hospital uses a defined process to match nonclinical staff knowledge and skills with the requirements of the position.

❑ 2. New nonclinical staff are evaluated before or at the time they begin their work responsibilities.

❑ 3. The department or service to which the individual is assigned conducts the evaluation.

❑ 4. The hospital defines the frequency of ongoing nonclinical staff evaluation.

❑ 5. There is at least one documented evaluation of nonclinical staff members each year or more frequently as defined by the hospital.

## Standard SQE.5

There is documented personnel information for each staff member. Ⓟ

### Intent of SQE.5

An accurate personnel file provides documentation of staff knowledge, skill, competency, and training required for carrying out job responsibilities. (*Also see* SQE.9; SQE.13; and SQE.15) In addition, the record shows evidence of staff performance and whether they are meeting job expectations. Personnel files may contain sensitive information and thus must be kept confidential. (*Also see* MOI.2)

Each staff member in the hospital, including those permitted by law and the hospital to work independently, has a record(s) with information about his or her qualifications; required health information, such as immunizations and evidence of immunity; evidence of participation in orientation as well as ongoing in-service and continuing education; results of evaluations, including individual performance of job responsibilities and competencies; and work history. The records are standardized and kept current according to hospital policy. (*Also see* SQE.4; SQE.7; SQE.8; SQE.8.1; SQE.8.1.1; SQE.8.2; and SQE.9.2)

### Measurable Elements of SQE.5

- ❑ 1. Personnel files for each staff member are standardized and current and maintained and kept confidential according to hospital policy.
- ❑ 2. Personnel files contain the qualifications and the work history of the staff member.
- ❑ 3. Personnel files contain the job description of the staff member when applicable.
- ❑ 4. Personnel files contain a record of orientation to the hospital and the staff member's specific role and in-service education attended by the staff member.
- ❑ 5. Personnel files contain the results of performance reviews.
- ❑ 6. Personnel files contain required health information.

## Standard SQE.6

A staffing strategy for the hospital, developed by the leaders of hospital departments and services, identifies the number, types, and desired qualifications of staff. Ⓟ

## Standard SQE.6.1

The staffing strategy is reviewed on an ongoing basis and updated as necessary.

### Intent of SQE.6 and SQE.6.1

Appropriate and adequate staffing is critical to patient care as well as to all teaching and research activities in which the hospital may be engaged. 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 strategy is written and identifies the number and types of required staff and the skills, knowledge, and other requirements needed in each department and service. (*Also see* SQE.14) The strategy addresses

- the reassignment of staff from one department or service to another in response to changing patient needs or staff shortages;
- the consideration of staff requests for reassignment based on cultural values or religious beliefs; and
- compliance with local laws and regulations.

Planned and actual staffing is monitored on an ongoing basis, and the strategy is updated as necessary. There is a coordinated process for the department/service leaders to update the overall strategy. (*Also see* GLD.7 and GLD.9)

### Measurable Elements of SQE.6

- ❑ 1. The hospital's department/service leaders develop a written strategy for staffing the hospital in a manner that complies with local laws and regulations.
- ❑ 2. The number, types, and desired qualifications of staff are identified in the strategy using a recognized staffing method.
- ❑ 3. The strategy addresses the assignment and reassignment of staff.

### Measurable Elements of SQE.6.1

- ❑ 1. The effectiveness of the staffing strategy is monitored on an ongoing basis.
- ❑ 2. The strategy is revised and updated when necessary.
- ❑ 3. The strategy is coordinated through a process that involves the department/service leaders.

## Standard SQE.7

All clinical and nonclinical staff members are oriented to the hospital, to the department or unit to which they are assigned, and to their specific job responsibilities at appointment to the staff.

### Intent of SQE.7

The decision to appoint an individual to the staff of a hospital sets several processes in motion. To perform well, a new staff member, no matter what his or her employment status, needs to understand the entire hospital and how his or her specific clinical or nonclinical responsibilities contribute to the hospital's mission. This is accomplished through a general orientation to the hospital and his or her role in the hospital and a specific orientation to the job responsibilities of his or her position. (*Also see* AOP.5.3; AOP.6.2; and PCI.15) This orientation is recorded in the staff member's personnel file. (*Also see* SQE.5) The orientation includes the reporting of medical errors, infection prevention and control practices, the hospital's policies on telephone medication orders, and so on. Contract workers, volunteers, and students and trainees are also oriented to the hospital and their specific assignments or responsibilities, such as patient safety and infection prevention and control. (*Also see* GLD.6; GLD.9; and GLD.14)

### Measurable Elements of SQE.7

- ❑ 1. New clinical and nonclinical staff members are oriented to the hospital, to the department or unit to which they are assigned, and to their job responsibilities and any specific assignments.
- ❑ 2. Contract workers are oriented to the hospital, to the department or unit to which they are assigned, and to their job responsibilities and any specific assignments.
- ❑ 3. Staff who accompany independent practitioners and provide care and services are oriented to the hospital.
- ❑ 4. Students, trainees, and volunteers are oriented to the hospital and assigned responsibilities.

## Standard SQE.8

Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge.

### Intent of SQE.8

The hospital collects data from several sources to understand its staff's ongoing education needs. The results of quality and safety measurement activities are one source of information to identify staff education needs. Also,

monitoring data from the facility management program, the introduction of new medical equipment, skill and knowledge areas identified through the review of job performance, new clinical procedures, and future plans to provide new services represent such sources of data. The hospital has a process to gather and to integrate data from sources to plan the staff education program. (*Also see* SQE.5) Also, the hospital determines which staff, such as health care practitioners, are required to obtain continuing education to maintain their credentials and how the education of these staff will be monitored and documented. (*Also see* GLD.3.3)

To maintain acceptable staff performance, to teach new skills, and to provide training on new medical equipment and procedures, the hospital provides or arranges for facilities, educators, and time for ongoing in-service and other education. (*Also see* AOP.5.3; AOP.6.3; PCI.15; and SQE.5) This education is 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 educational achievements are documented in his or her personnel record.

Hospital leadership supports the commitment to ongoing staff in-service education by making available space, equipment, and time for education and training programs. The availability of current scientific information supports the education and training. The education and training can take place in a centralized location or in several smaller learning and skill development locations throughout the facility. The education can be offered once to all or repeated for staff on a shift-by-shift basis to minimize the impact on patient care activities.

### Measurable Elements of SQE.8

- ❑ 1. The hospital uses various sources of data and information, including the results of quality and safety measurement activities, to identify staff education needs.
- ❑ 2. Education programs are planned based on these data and information.
- ❑ 3. Hospital staff are provided ongoing in-service education and training.
- ❑ 4. The education is relevant to each staff member's ability to meet patient needs and/or continuing education requirements.
- ❑ 5. The hospital provides adequate time and facilities for all staff to participate in relevant education and training opportunities.

## Standard SQE.8.1

Staff members who provide patient care are trained and demonstrate competence in the resuscitative techniques specific to the level of training identified.

## Standard SQE.8.1.1

Other staff identified by the hospital are trained and can demonstrate appropriate competence in resuscitative techniques.

### Intent of SQE.8.1 and SQE.8.1.1

All staff who provide patient care, including physicians, and other 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 staff who provide patient care. (*Also see* COP.3.3) **For example**, the hospital may determine that all 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. (*Also see* ASC.3) The hospital may also determine that other staff who do not provide patient care, such as transporters or registration clerks, may require training in basic life support.

The appropriate level of training for those identified is repeated based on the requirements and/or time frames identified by a recognized training program, or every two years if a recognized training program is not used. There is evidence to show if each staff member attending the training actually achieved the desired competency level. (*Also see* SQE.5)

### Measurable Elements of SQE.8.1

- ❑ 1. Staff members who provide patient care, including physicians, 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 staff who provide patient care.
- ❑ 3. There is evidence to show if a staff member passed the training.
- ❑ 4. The desired level of training for each individual 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.

### Measurable Elements of SQE.8.1.1

- ❑ 1. If applicable, the hospital identifies other staff who do not provide patient care to be trained in basic life support (BLS).
- ❑ 2. When other staff who do not provide patient care are trained in basic life support, there is evidence to show if a staff member passed the training.
- ❑ 3. When other staff are trained, training for each individual 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.8.2

The hospital provides a staff health and safety program that addresses staff physical and mental health and safe working conditions. Ⓟ

### Intent of SQE.8.2

A hospital's staff health and safety program is important to maintain staff physical and mental health, satisfaction, productivity, and safe conditions for work. (*Also see* SQE.5)

How a hospital orients and trains staff, provides a safe workplace, maintains equipment and medical equipment, prevents or controls health care–associated infections, and many other factors determine the health and well-being of staff. A staff health and safety program can be located within the hospital or be integrated into external programs. The program provides for the following:

a) Initial employment health screening
b) Measures to control harmful occupational exposures, such as exposure to toxic drugs and harmful noise levels (*Also see* AOP.5.3; COP.4; and COP.4.1)
c) Education, training, and interventions on safe patient handling

d) Education, training, and interventions on managing workplace violence (*Also see* QPS.7 and QPS.7.1)
e) Education, training, and interventions for staff who may be second victims of adverse or sentinel events
f) Treatment for common work-related conditions, such as back injuries, or more urgent injuries

Whatever the staffing and structure of the program, staff understand how to report, be treated for, and receive counseling and follow-up for common work-related injuries such as those that may result from needlesticks, exposure to infectious diseases, encounters with workplace violence, handling of patients, hazardous conditions in the facility, and other health and safety matters. The design of the program includes staff input and draws upon the hospital's clinical resources as well as those in the community.

Nursing and other staff who assist with moving 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. Patient movement and handling tasks are being done in many different types of clinical settings. Thus, there is not any one specific solution that is appropriate for all areas in which patient movement and handling occurs. **Examples** of safe handling interventions may include the use of gait belts, lateral transfer aids, training on body mechanics, implementation of a transfer team, and the like.

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. (*Also see* QPS.7)

The caregiving environment often presents emotional challenges that can be mentally and physically stressful. Health care practitioners provide empathy and emotional support to patients and families, are often involved in ethical decision making, are frequently exposed to death and dying, and deliver care, treatment, and services in a physically demanding, high-stress environment. Repeated exposure to these emotional and physical challenges 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 are essential to creating a positive culture for the benefit of patients as well as staff. In addition, health care practitioners are often the second victims of errors and sentinel events. When patients and their family members are compromised by clinical errors, the remorse and anxiety felt by caregivers and their feelings of moral distress are frequently not acknowledged or addressed. Hospitals need to acknowledge that the emotional health and performance of health care practitioners involved in adverse and sentinel events can have an impact on the quality and safety of patient care. Best-practice research related to compassion fatigue and staff 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 promote staff health and well-being.

## Measurable Elements of SQE.8.2

- ❑ 1. The hospital provides 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 includes at least a) through f) in the intent.
- ❑ 3. The hospital identifies areas/situations for potential workplace violence and implements interventions to reduce the risk.
- ❑ 4. The hospital provides evaluation, counseling, and follow-up treatment for staff who are injured as a result of workplace violence.
- ❑ 5. The hospital provides education, evaluation, counseling, and follow-up for staff who are second victims of adverse or sentinel events.
- ❑ 6. The hospital promotes staff well-being by creating a culture of wellness that supports physical well-being and emotional health.

## Standard SQE.8.3

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.8.3

Due to their contact with patients and patients' infectious material, many health care practitioners are at risk for exposure to and possible transmission of vaccine-preventable diseases. Identifying epidemiologically important infections, determining staff at high risk for these infections, and implementing screening and prevention programs (such as immunizations, vaccinations, and prophylaxis) can significantly reduce the incidence of infectious disease transmission. (*Also see* AOP.5.3.1; PCI.2; PCI.8; and PCI.8.1) Asymptomatic infections are common, and individuals can be infectious prior to having any symptoms, including from influenza. In addition, studies show that health care practitioners 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 health care practitioners, particularly in the case of influenza. Hospitals must consider taking steps toward reducing the risks associated with the transmission of infectious diseases by unvaccinated health care practitioners. Health care practitioners have an ethical and professional obligation to protect themselves, their coworkers, and patients/families. Vaccination is a duty for all health care practitioners.

Strategies for reducing patients' risk of exposure to infectious diseases may include efforts to promote flu vaccination, encouraging staff to get the flu vaccine, and requiring unvaccinated staff to wear masks during flu season. 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.8.3

- ❑ 1. The hospital identifies epidemiologically significant infections, as well as staff who are at high risk for exposure to and transmission of infections.
- ❑ 2. The hospital develops and implements a staff vaccination and immunization program.
- ❑ 3. The hospital evaluates the risks associated with unvaccinated staff and identifies strategies for reducing the patient's risk of exposure to infectious diseases from unvaccinated staff.
- ❑ 4. The infection prevention and control program guides the evaluation, counseling, and follow-up of staff exposed to infectious diseases.

## *Determining Medical Staff Membership*

## Standard SQE.9

The hospital has a uniform process for gathering the credentials of those medical staff members permitted to provide patient care without supervision. Ⓟ

## Standard SQE.9.1

Medical staff members' education, licensure/registration, and other credentials required by law or regulation and the hospital are verified and kept current. Ⓟ

# Standard SQE.9.2

There is a uniform, transparent decision process for the initial appointment of medical staff members. Ⓟ

## Intent of SQE.9 Through SQE.9.2

Explanations of terms and expectations found in these standards are as follows:

### Credentials

*Credentials* are documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, such as a diploma from a medical school, specialty training (residency) completion letter or certificate, completion of the requirements of a medical professional organization, a license to practice, or recognition of registration with a medical or dental council. 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.

Credentials can also be documents from individuals and entities that address some aspect of the applicant's professional history or competency, such as letters of recommendation, a history of all previous hospital medical staff appointments, records of previous clinical care, health history, picture, or police background check, **for example**. These documents may be required by hospital policy as part of the credential-gathering process but are not verified from the source that issued the document unless required by hospital policy. This requirement for verification of the credential 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.

### Medical Staff

*Medical staff* are 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, and others allowed to provide patient care services temporarily. A hospital must define those other practitioners, 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). (*Also see* SQE.1.1) Note that in some cultures traditional medicine practitioners, such as 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. (*Also see* GLD.6.2)

### 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 by an inquiry to a secure online database of, **for example**, those individuals licensed in the hospital's city or country. The process can also be accomplished by documenting a telephone conversation with the issuing source, or by 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, and 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, and others) 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.9.1, MEs 1 and 2. *Full compliance* means the hospital's Official Survey Findings Report indicates that all measurable elements are fully met, or any not met or partially met measurable element 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.

It is important to understand the process for issuing some credentials. **For example**, 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 and payment of fees? Also, 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. If the hospital does not have direct knowledge of the process used by the agency to verify education, or the hospital has never had an opportunity to verify that the agency carries out the process as described, then the hospital needs to perform its own verification. (*Also see* SQE.13 and SQE.15)

**Exception for SQE.9.1, 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 practitioners 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 have to have their credentials gathered and reviewed, and their privileges granted. There is no "phasing in" of this process.

### Appointment

*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 independent practitioners for emergency needs or a temporary period. For such individuals, the appointment and identification of privileges are not made until at minimum licensure has been verified.

### Reappointment

*Reappointment* is the process of reviewing the medical staff member's file to verify

- continued licensure;
- that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies;
- that the file contains sufficient documentation for seeking new or expanded privileges or duties in the hospital; and
- that the medical staff member is physically and mentally able to provide patient care and treatment without supervision.

The information for this review is from both internal and external sources. When a clinical department/service (**for example**, a subspecialty service) does not have a leader, there is a hospital policy that identifies who will do the review of the professionals in that department/service. The credential file of a medical staff member should be a dynamic source of information and under constant review. (*Also see* SQE.5) **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 files are complete and accurate, the files are reviewed at least every three years, and a note in the file indicates any actions taken or that no action is necessary and the appointment to the medical staff continues.

Medical staff membership may not be granted if the hospital does not have the 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. (*Also see* SQE.3)

## Measurable Elements of SQE.9

- ❑ 1. The hospital has an ongoing, uniform process to manage the credentials of medical staff members.
- ❑ 2. Medical staff members permitted by laws, regulations, and the hospital to provide patient care without supervision are identified.
- ❑ 3. Education, licensure/registration, and other credentials required by law or regulation are copied by the hospital and maintained for each medical staff member in his or her personnel file or in a separate credential file.
- ❑ 4. All credentials required by hospital policy are copied by the hospital and maintained for each medical staff member in his or her personnel file or in a separate credential file.

### Measurable Elements of SQE.9.1

- ❑ 1. Education, licensure/registration, and other credentials required by law or regulation 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 policy or regulations and that the process meets the expectations described in the intent.

### Measurable Elements of SQE.9.2

- ❑ 1. Medical staff appointments are made according to hospital policy and are consistent with the hospital's patient population, mission, and services provided to meet patient needs.
- ❑ 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 file of the individual.

## *The Assignment of Medical Staff Clinical Privileges*

## Standard SQE.10

The hospital has a standardized, objective, evidence-based procedure to authorize medical staff members to admit and to treat patients and/or to provide other clinical services consistent with their qualifications. Ⓟ

### Intent of SQE.10

The determination of a medical staff member's current clinical competence and making a decision about what clinical services the medical staff member will be permitted to perform, often called privileging, is the most critical determination a hospital will make to protect the safety of patients and to advance the quality of its clinical services.

Considerations for clinical privilege delineation at initial appointment include the following:

- Decisions regarding a practitioner's clinical competence, and thus what clinical privileges he or she is to be granted, are based primarily on information and documentation received from outside the hospital. The source may include specialty education programs, letters of recommendation from previous medical staff appointments and/or close colleagues, and any quality data that may be released to the hospital. In general, these 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. Although these outside sources may not give clear, objective evidence of current clinical competence, at least the areas of presumed competence are identified. (*Also see* SQE.2) Ongoing professional practice evaluation (*also see* SQE.11) will validate the areas of presumed competence.
- There is no one best way to delineate those 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. Thus, the privileges will be different for general surgeons, pediatricians, dentists, or radiologists, **for example**; however, within each of these groups the process for privilege delineation will be standardized. For family practitioners, primary care practitioners, and others who provide a variety of general medicine, obstetrics, pediatrics, and other services, the privilege delineation identifies which "specialty" services can be provided.
- The decision as to how clinical privileges are delineated in a specialty area is linked with other processes, including
  - selection by the department/service leaders of what processes are to be monitored through data collection; (*Also see* GLD.11.1)
  - use of those data in the ongoing professional practice evaluation process of the medical staff in the department/service; (*Also see* SQE.11) and
  - use of the monitoring data in the process of reappointment and the renewal of privileges. (*Also see* SQE.12)
- In addition to the privileges granted in relation to the individual's education and training, the hospital identifies areas of high risk, such as the administration of chemotherapeutic agents, other classes of drugs, or high-risk procedures for which the medical staff member is explicitly granted such privileges or denied such privileges. 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 in the case of 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. (*Also see* ASC.7.4)
- Also, 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.

**Note:** When a medical staff member also has administrative responsibilities, such as chair or chief of a clinical department, administrator of the hospital, or other such position, the responsibilities for this role are identified in a job description. (*Also see* SQE.1.1) Hospital policy identifies the primary source verification of the credentials presented in support of this administrative role.

The privilege delineation process

a) is standardized, objective, and evidence-based;
b) is documented in hospital policies;
c) is active and ongoing as the credentials of medical staff members change;
d) is followed for all classes of medical staff membership; and
e) can be demonstrated as to how the procedure is used effectively.

The clinical privileges of all medical staff members are made available by printed copy, electronic copy, or other means to those individuals or locations (**for example**, operating room, emergency department) in the hospital in which the medical staff member will provide services. The medical staff member is provided a copy of his or her clinical privileges. Updated information is communicated when the clinical privileges of a medical staff member change. (*Also see* GLD.6.2)

### Measurable Elements of SQE.10

- ❑ 1. The privilege delineation process used by the hospital meets criteria a) through e) found in the intent.
- ❑ 2. The clinical privileges of all medical staff members are made available by printed copy, electronic copy, or other means to those individuals or locations (**for example**, operating room, emergency department) in the hospital in which the medical staff member will provide services.
- ❑ 3. Each medical staff member provides only those services that have been specifically granted by the hospital.

## *Ongoing Professional Practice Evaluation of Medical Staff Members*

# Standard SQE.11

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.11

Explanations of terms and expectations found in these standards are as follows:

#### Ongoing Professional Practice Evaluation

*Ongoing professional practice evaluation* is the process of ongoing data collection for the purpose of assessing a practitioner's clinical competence and professional behavior. The information gathered during this process is factored into decisions to maintain, revise, or revoke existing privilege(s) prior to or at the end of the three-year renewal decision. The department/service leader is responsible for the integration of the data and information on medical staff and taking appropriate actions. Immediate actions may be to counsel the staff member, place him or her under supervision, limit privileges, or other measures intended to limit risks to patients and improve quality of care and patient safety. Longer-term actions include synthesizing the data and information into a recommendation for continued medical staff membership and clinical privileges. Other actions may be to 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 of medical staff members provides critical information to the process of maintaining medical staff membership and to the process of granting clinical privileges. (*Also see* SQE.10) Although three-year cycles are required for renewing medical staff membership and clinical privileges, the process is intended to be ongoing and dynamic. 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

- 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; and
- 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 safe culture 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 feedback through surveys and other mechanisms can shape desired behaviors and can support medical staff role models.

An evaluation of behaviors can include

- evaluation of whether a medical staff member understands and supports the hospital's code of behavior and the identification of acceptable and unacceptable behaviors;
- an absence of reported behaviors by the medical staff member that are identified as unacceptable; and
- gathering, analysis, and use of information and data from staff surveys and other sources regarding the culture of safety in the hospital.

The ongoing professional practice evaluation process should indicate, as part of the review process, the relevant achievements and challenges of the medical staff member in efforts to be a full participant in a safe and just culture. (*Also see* SQE.10)

### Professional Growth

Medical staff members grow and mature as the organizations in which they practice evolve, introducing new patient groups, technologies, and clinical science. Each medical staff member, to varying degrees, will reflect growth and improvement in the following 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. (Potential measures include frequency of preventive services and reports/complaints from patients and families.) (*Also see* PCC.3.1)
- 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. (Potential measures include application of clinical practice guidelines, including the adaptation and revision of guidelines; participation in professional conferences; and publications.) (*Also see* GLD.11.2)
- 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 include 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 include 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 include 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 include 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 include 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.) (*Also see* GLD.7)

The ongoing professional practice evaluation process should recognize, as part of the review process, 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 his or her specialty

***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. To be useful in the ongoing evaluation of an individual medical staff member, such hospitalwide data

- need to be collected in such a manner that individual practitioners can readily be identified;
- must relate to the clinical practice of the individual medical staff member; and
- can be benchmarked internally and, as available, externally to understand individual practitioner patterns.

**Examples** of such potential sources of data include length of stay, frequency of diagnostic testing, blood usage, and usage of certain drugs, among others.

***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. As with hospitalwide data, to be useful in the ongoing evaluation of an individual department/service member, the data

- need to be collected in a manner such that individual practitioners can readily be identified;
- must relate to the clinical practice of the individual medical staff member; and
- can be benchmarked within the department/service and/or externally to understand individual practitioner patterns.

**Examples** of such potential department/service data include frequency of clinical procedures performed, complications, outcomes, and use of resources such as consultants, among others.

Also, it is important to note that it is not anticipated that any department/service will have the capacity or need to monitor all the listed privileges of every practitioner. It is more feasible to collect data on key services or some aspect of 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 record of the medical staff member are very specific to the department/service, to the relevant profession, and to the privileges of the practitioner. The ongoing professional practice evaluation of medical staff members is supported by a variety of data sources, including electronic and paper records, observations, and peer interactions.

An important final step is to ask the question: "How is this practitioner doing compared to other colleagues within his or her department and in comparison to professional colleagues in other hospitals, regions, or countries?" The internal comparison is primarily to reduce variation in practice and outcomes within the department and learn from the best practices within the department. The external comparison is to ensure that the hospital achieves best practices within the respective profession. Each department will have knowledge of

those professional databases, clinical practice guidelines, and scientific literature sources that describe those desirable benchmark practices. **For example**, oncology registries can be helpful, or data from practitioners using the same science (clinical practice guidelines). Similarly, a national or international surgical society may collect outcome or complication data.

In summary, the medical staff member ongoing professional practice evaluation process

- is standardized by type of medical staff member and/or department or clinical services unit;
- uses the monitoring data and information for internal comparisons to reduce variation in behaviors, professional growth, and clinical results;
- uses the monitoring data and information for external comparisons with available, objective, evidence-based best practice or benchmark sources of clinical result data and information;
- is conducted by the individual's department or service head, senior medical manager, or a medical staff review body;
- includes the monitoring and evaluation of senior medical staff and department heads by an appropriate professional; and
- provides information that will be documented in the medical staff member's file, including the results of reviews, actions taken, and the impact of those actions on privileges (if any). (*Also see* SQE.12)

Finally, although the process of monitoring and evaluation of medical staff members is intended to be ongoing, and data and information may be accumulated on an ongoing basis, hospital policy requires a review at least once during a 12-month period. The review is conducted by the individual's department or service head, a senior medical manager, or a medical staff review body. Findings, conclusions, and any actions taken or recommended are recorded in the medical staff member's file. When the findings affect the appointment or privileges of the medical staff member, there is a process to act on the findings. Such immediate "for cause" actions are documented in the practitioner's file and are reflected in the list of clinical privileges. Notification is sent to those sites in which the practitioner provides services. (*Also see* SQE.3)

## Measurable Elements of SQE.11

❑ 1. All medical staff members are included in an ongoing professional practice evaluation process as defined by hospital policy and standardized evaluation at the department/service level.

❑ 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.

❑ 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 file and other relevant files.

❑ 4. 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 practitioner's file and are reflected in the list of clinical privileges. Notification is sent to those sites in which the practitioner provides services.

# Medical Staff Reappointment and Renewal of Clinical Privileges

## Standard SQE.12

At least every three years, the hospital determines, from the ongoing professional practice evaluation of each medical staff member, if medical staff membership and clinical privileges are to continue with or without modification. Ⓟ

### Intent of SQE.12

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 file to verify

- continued licensure;
- that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies;
- that the file contains sufficient documentation for seeking new or expanded privileges or duties in the hospital; and
- that the medical staff member is physically and mentally able to provide patient care and treatment without supervision.

The information for this review is gathered from the internal, ongoing professional practice evaluation of the medical staff member, 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 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 credential file of a medical staff member should be a dynamic source of information and under constant review. **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 files are complete and accurate, the files are reviewed at least every three years, and a note in the file 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 results of the ongoing professional practice review process; (*Also see* SQE.11)
  - limitations placed on the individual's privileges by an outside professional, governmental, or regulatory agency;
  - the hospital's findings from an evaluation of a sentinel or other event;
  - the health of the practitioner; or
  - the request of the practitioner.

### Measurable Elements of SQE.12

- ❑ 1. Based on the ongoing professional practice evaluation of the medical staff member, the hospital determines, at least every three years, if medical staff membership and clinical privileges are to continue with or without modification.
- ❑ 2. There is evidence in the file of each medical staff member that all credentials that require periodic renewal, payment of a registration fee, or other action by the medical staff member are current.
- ❑ 3. Credentials obtained subsequent to initial appointment are evident in the file of the medical staff member and have been verified from the primary source prior to use in modifying or adding to clinical privileges.
- ❑ 4. The renewal decision is documented in the medical staff member's credential file and includes the identification of the reviewer and any special conditions identified during the review.

## *Nursing Staff*

## Standard SQE.13

The hospital has a uniform process to gather, to verify, and to evaluate the nursing staff's credentials (license, education, training, and experience). Ⓟ

### Intent of SQE.13

The hospital needs to ensure that it has a qualified nursing staff that appropriately matches its mission, resources, and patient needs. The nursing staff are responsible for providing direct patient care. In addition, nursing care contributes to the overall patient outcomes. 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

- understanding the applicable laws and regulations that apply to nurses and nursing practice;
- gathering all available credentials on each nurse, including at least
  - evidence of education/training;
  - evidence of current licensure;
  - evidence of current competence through information from other sources in which the nurse was employed; and
  - letters of recommendation and/or other information the organization may require, such as health history, pictures, among others; and
- 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 needs to make every effort to verify essential information, even when the education took place in another country and a significant time ago. Secure websites, documented phone confirmation from the source, written confirmation, and third parties, such as a designated, official governmental or nongovernmental agency, can be used. The situations described for medical staff in the intent of SQE.9 are considered acceptable substitutes for an organization performing primary source verification of nurse credentials.

Standards compliance requires that primary source verification is carried out for all nurses. ***Exception:*** For a JCI initial 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, such as in the operating theatre, emergency department, or intensive care unit.

**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.

The hospital has a process that ensures that the credentials of each contract nurse have also been gathered, verified, and reviewed to ensure current medical competence prior to assignment. (*Also see* GLD.6)
The hospital gathers and maintains a file of each nurse's credentials. The files contain current licenses when regulations require periodic renewal. There is documentation of training related to any additional competencies. (*Also see* SQE.5)

### Measurable Elements of SQE.13

- ❑ 1. The hospital has a standardized procedure to gather and document the education, certifications, and experience of each nursing staff member.
- ❑ 2. Education, training, and certifications are verified from the original source according to parameters found in the intent of SQE.9 and are documented.
- ❑ 3. Licensure is verified from the original source according to the parameters found in the intent of SQE.9 and is documented.
- ❑ 4. There is a record maintained of the credentials of every nursing staff member.
- ❑ 5. The hospital has a process to ensure that the credentials of contract 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.14

The hospital has a standardized process to identify job responsibilities and to make clinical work assignments based on the nursing staff member's credentials and any regulatory requirements.

## Standard SQE.14.1

The hospital has a standardized process for nursing staff participation in the hospital's quality improvement activities, including evaluating individual performance when indicated.

### Intent of SQE.14 and SQE.14.1

Review of the qualifications of the nursing staff member provides the basis for assigning job responsibilities and clinical work assignments. Work assignments may be described in more detail in a job description (*also see* SQE.1.1) or described in other ways or documents that support how nurse staffing assignments are made (*also see* SQE.6), 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. (*Also see* MMU.5.1; SQE.2; and SQE.3)

The nursing staff's essential clinical role requires them to actively participate in the hospital's clinical quality improvement program. 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 file or in a separate credential file.

### Measurable Elements of SQE.14

- ❑ 1. Licensure, education/training, and experience of a nursing staff member are used to make clinical work assignments.
- ❑ 2. The process considers relevant laws and regulations.
- ❑ 3. The process supports nurse staffing plans.

### Measurable Elements of SQE.14.1

- ❑ 1. Nursing staff participate in the hospital's quality improvement activities.
- ❑ 2. The performance of individual nursing staff members is reviewed when indicated by the findings of quality improvement activities.
- ❑ 3. Appropriate information from the review process is documented in the nurse's personnel file or in a separate credential file.

## *Other Health Care Practitioners*

## Standard SQE.15

The hospital has a uniform process to gather, to verify, and to evaluate other health care practitioners' credentials (license, education, training, and experience). Ⓟ

### Intent of SQE.15

Hospitals employ or may permit a variety of other health care practitioners to provide care and services to their patients or to participate in patient care processes. **For example**, these professionals include nurse practitioners, nurse midwives, surgical assistants, emergency medical care specialists, pharmacists, and 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.

For those other health care practitioners permitted to work or to practice in the hospital, the hospital is responsible for gathering and verifying their credentials. The hospital must ensure that other health care practitioners 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 health care practitioners are qualified to provide safe and effective care and treatment to patients by

- understanding the applicable laws and regulations that apply to such practitioners;
- gathering all available credentials on each individual, including at least evidence of education and training and evidence of current licensure or certification when required; and
- verification of the essential information, such as current registry, licensure, or certification.

The hospital needs to make every effort to verify essential information relevant to the individual's intended responsibilities, even when the education took place in another country and a significant time ago. Secure websites, documented phone confirmation from the source, written confirmation, and third parties, such as a designated, official governmental or nongovernmental agency, can be used.

The situations described for medical staff in the intent of SQE.9 are acceptable substitutes for a hospital performing primary source verification for the credentials of other health care practitioners staff. (*Also see* GLD.6.2)

Standards compliance requires that primary source verification is carried out for all other health care practitioners.

***Exception:*** For a JCI initial accreditation survey, hospitals are required to have completed primary source verification for new applicants within the twelve (12) months leading up to the initial survey. Hospitals are required to complete primary source verification for all other currently employed health care practitioners before the triennial accreditation survey.

**Note:** This exception refers only to the verification of credentials.

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. 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. (*Also see* SQE.5)

### Measurable Elements of SQE.15

- ❑ 1. The hospital has a standardized process to gather and document the education, certifications, and experience of each health care practitioner.
- ❑ 2. Education, training, and certifications are verified from the original source according to the parameters found in the intent of SQE.9 and are documented.
- ❑ 3. Licensure is verified from the original source according to the parameters found in the intent of SQE.9 and is documented.
- ❑ 4. There is a record maintained on other health care practitioners that contains copies of any required license, certification, or registration.
- ❑ 5. The hospital has a process to ensure that other 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.16

The hospital has a uniform process to identify job responsibilities and to make clinical work assignments based on other health care practitioners' credentials and any regulatory requirements.

## Standard SQE.16.1

The hospital has a uniform process for other health care practitioners' participation in the hospital's quality improvement activities.

### Intent of SQE.16 and SQE.16.1

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. (*Also see* SQE.1.1 and SQE.2) In addition, the hospital defines the level of supervision (consistent with existing laws and regulations), if any, for these professionals. Other health care practitioners are included in the hospital's quality management and improvement program.

## Measurable Elements of SQE.16

- ❑ 1. Licensure, education, training, and experience of other health care practitioners are used to make clinical work assignments.
- ❑ 2. The process considers relevant laws and regulations.
- ❑ 3. The process supports the staffing process for other health care practitioners.

## Measurable Elements of SQE 16.1

- ❑ 1. Other health care practitioners participate in the hospital's quality improvement activities.
- ❑ 2. The performance of other health care practitioners is reviewed when indicated by the findings of quality improvement activities.
- ❑ 3. Appropriate information from the review process is documented in the health care practitioner's file.

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# Management of Information (MOI)



## Overview

Providing patient care is a complex endeavor that is highly dependent on the communication of information. 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 organization's leaders. Every organization seeks to obtain, to manage, and to use information to improve patient outcomes as well as individual and overall organization performance.

Over time, organizations become more effective in

- identifying information and information technology needs;
- designing/deploying information management systems;
- defining and capturing data and information;
- analyzing data and transforming it into information;
- transmitting and reporting data and information;
- protecting confidentiality, security, and integrity of data and information; and
- 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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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 Management

**MOI.1** The hospital plans and designs information management processes to meet the information needs of those who provide clinical services, the hospital's leaders, and those outside the hospital who require data and information from the organization.

**MOI.2** The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes to manage and control access.

**MOI.2.1** The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes that protect against loss, theft, damage, and destruction.

**MOI.3** The hospital determines the retention time of patient medical records, data, and other information. Ⓟ

**MOI.4** The hospital uses standardized diagnosis and procedure codes and ensures the uniform use of approved symbols and abbreviations across the hospital.

**MOI.5** The data and information needs of those in and outside the hospital are met on a timely basis in a format that meets user expectations and with the desired frequency.

**MOI.6** 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.



## Management and Implementation of Documents

**MOI.7** Documents, including policies, procedures, and programs, are managed in a consistent and uniform manner. Ⓟ

**MOI.7.1** The policies, procedures, plans, and other documents that guide consistent and uniform clinical and nonclinical processes and practices are fully implemented. Ⓟ

## Patient Medical Record

**MOI.8** 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.8.1** The medical record contains sufficient information to identify the patient, to support the diagnosis, to justify the treatment, and to document the course and results of treatment.

**MOI.9** Every patient medical record entry identifies its author and when the entry was made in the medical record.

**MOI.10** As part of its monitoring and performance improvement activities, the hospital regularly assesses patient medical record content.

## Information Technology in Health Care

**MOI.11** Hospital leadership identifies a qualified individual to oversee the hospital's health information technology systems and processes.

**MOI.12** When mobile devices are used for texting, e-mailing, or other communications of patient data and information, the hospital implements processes to ensure quality of patient care and maintains security and confidentiality of patient information. Ⓟ

**MOI.13** The hospital develops, maintains, and tests a program for response to planned and unplanned downtime of data systems. Ⓟ

# Standards, Intents, and Measurable Elements

## *Information Management*

## Standard MOI.1

The hospital plans and designs information management processes to meet the information needs of those who provide clinical services, the hospital's leaders, and those outside the hospital who require data and information from the organization.

### Intent of MOI.1

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 incorporates input from a variety of sources who need or require data and information, including the following:

- The health care practitioners and other staff who provide clinical services
- The hospital's leadership and department/service leaders (*Also see* GLD.3.2)
- Individuals, services, and agencies outside the hospital who need or require data or information about the hospital's operation and care processes (*Also see* GLD.3.1)

The planning also includes the hospital's mission, services provided, resources, access to affordable technology, and support for effective communication among caregivers. The priority information needs of these sources influence the hospital's information management strategies and ability to implement those strategies. The strategies 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 of 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. (*Also see* QPS.4 and PCI.3)

### Measurable Elements of MOI.1

❑ 1. The hospital plans and implements processes to meet the information needs of those who provide clinical services

❑ 2. The hospital plans and implements processes to meet the information needs of the hospital's leadership and department/service leaders.

❑ 3. The hospital plans and implements processes to meet the information needs and requirements of individuals, services, and agencies outside the hospital.

❑ 4. The processes implemented are appropriate to the hospital's size, complexity of services, availability of trained staff, technical resources, and other resources.

## Standard MOI.2

The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes to manage and control access.

## Standard MOI.2.1

The hospital maintains the confidentiality, security, privacy, and integrity of data and information through processes that protect against loss, theft, damage, and destruction.

## Intent of MOI.2 and MOI.2.1

The hospital maintains the confidentiality, security, and integrity of data and information and is particularly careful about preserving confidential patient data and information. The balance between data sharing and data confidentiality is addressed. (*Also see* PCC.1.3; MMU.4.1; QPS.4; GLD.17; GLD.19; SQE.5; and MOI.8)

Whether a hospital uses paper and/or electronic information systems, the hospital implements measures to secure and protect data and information at all times. Data and information include patient medical records, data from medical equipment and devices, research data, quality data, billing data, human resources data, and other sources, as applicable to the organization. Security measures include processes to manage and control access. **For example**, to maintain confidentiality and security of patient medical records, the hospital determines who is authorized to access medical records and the authorized individual's level of access to the records.

When electronic information systems are used, the hospital implements processes for assigning privileges to authorized users in accordance with their level of access. Depending on level of access, an authorized user may be able to enter, modify, and delete information, or may have read-only access or restricted access to some systems or modules. Levels of access for an electronic medical record system 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.

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. (*Also see* MOI.9) An effective process defines

- 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); and
- the process followed when confidentiality, security, or data integrity are violated or compromised.

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 a process to proactively monitor access logs. Regular security audits can identify system vulnerabilities in addition to confidentiality and security policy violations. **For example**, as part of the process, the hospital can identify system users who have altered, edited, or deleted information and can track changes made to the electronic medical record. The results from this audit process can be used to validate that user permissions are appropriately set. Conducting security audits can also be effective in identifying vulnerabilities in security, such as user access and permissions that need to be updated or removed due to staff changes or turnover.

When documentation assistants, or scribes, assist health care practitioners with documentation, the hospital has processes to ensure protection of patient data and information. The hospital identifies the required qualifications, training, and competencies for scribes, as well as their job responsibilities, including the scope of documentation activities that a scribe can perform. As with anyone who has access to patient medical records, scribes must be authorized to access and make entries in the medical record, and their level of access is identified. When electronic medical records are used, any additional security measures for logging into the system are defined and implemented. **For example**, the hospital has processes to ensure that individuals log into and access the system using a unique credential assigned to only them and that credentials are not shared.

In addition to processes for managing and controlling access, the hospital ensures that paper and electronic medical records, data, and other information are protected from loss, theft, tampering, damage, and unintended destruction. It is important for the hospital to assess for vulnerabilities in the organization that pose potential risks to the security of data and information. The hospital conducts and documents an ongoing information security risk assessment, at least annually. The risk assessment considers a review of processes and new and planned services that may pose risks to data and information, wherever it is accessed or stored. 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.

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 (*Also see* MOI.13)
- Storing physical medical records in locations where heat, water, and fire will not likely occur
- Storing active medical records in areas where only authorized health care practitioners have access
- Ensuring that server rooms and rooms for physical medical records are secured and accessible to only authorized individuals
- Ensuring that server rooms and rooms for physical medical records are kept at proper temperature and humidity levels to protect records/servers



### Measurable Elements of MOI.2

❑ 1. The hospital develops and implements processes consistent with laws and regulations to ensure the confidentiality, security, and integrity of data and information.

❑ 2. The hospital identifies 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.

❑ 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 takes actions when confidentiality, security, or data integrity are violated or compromised.

### Measurable Elements of MOI.2.1

❑ 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, and destruction.

❑ 3. The hospital implements data security best practices to protect and secure data and information.

❑ 4. The hospital identifies goals, implements improvements to address data security risks, and monitors improvement data to ensure that risks are reduced or eliminated.

## Standard MOI.3

The hospital determines the retention time of patient medical records, data, and other information. Ⓟ

### Intent of MOI.3

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. (*Also see* MOI.2 and MOI.8) 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 the hospital policies and procedures for maintaining the confidentiality and security of such information. When the retention period is complete, patient medical records, data, and other information are destroyed in a manner that does not compromise confidentiality and security.

### Measurable Elements of MOI.3

- ❑ 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.4

The hospital uses standardized diagnosis and procedure codes and ensures the uniform use of approved symbols and abbreviations across the hospital.

### Intent of MOI.4

Standardization of codes and uniform use of symbols and abbreviations prevents miscommunication and potential errors in patient care. In addition, the uniform use of standardized diagnosis and procedure codes supports data aggregation and analysis.

Abbreviations can be problematic and at times even dangerous, particularly in the context of prescribing medications. For this reason, some hospitals do not allow the use of abbreviations in their organizations at all. When abbreviations are allowed in the hospital, processes are implemented to prevent or reduce risks to patient safety. Abbreviations are not used on informed consent documents, patient rights documents, discharge instructions, and discharge summaries. (*Also see* ACC.4.2 and ACC.5.1) Patients and families may not be familiar with or understand the hospital's approved abbreviations and may not be comfortable asking for clarification. In addition, if a discharge summary of the patient's care and treatment contains abbreviations and is sent with a patient being transferred to another organization, there is a risk to patient safety if the receiving organization uses some of the same abbreviations but with different meanings, or simply does not know the meanings of the abbreviations in the discharge summary.

Abbreviations are typically used on reports of laboratory and diagnostic imaging test results. When a patient receives laboratory and diagnostic imaging test results with abbreviations, it is expected that these test results are also shared with the patient's physician so that they can be reviewed with the patient. However, if the name of a test is used in the context of education or follow-up instructions (**for example**, discharge instructions that include information about monitoring serial blood tests, such as International Normalized Ratio [INR] or hemoglobin A1c), the abbreviations are not used, and the terms are spelled out and explained for the patient.

When a hospital uses abbreviations, the hospital develops and implements a process for the uniform use of approved abbreviations, such as through the use of a 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 case (**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.

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.

The principles of the standardized use of codes and uniform use of approved symbols and abbreviations apply to electronic medical record systems and electronic communications, such as e-mail and texting, that are used for communicating about patient care. (*Also see* MOI.10)



### Measurable Elements of MOI.4

- ❑ 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, the hospital implements the uniform use of approved abbreviations, and each abbreviation has only one meaning.
- ❑ 4. If the hospital allows abbreviations, the hospital develops and/or adopts a do-not-use list of abbreviations.
- ❑ 5. Abbreviations are not used on informed consent and patient rights documents, discharge instructions, and discharge summaries.
- ❑ 6. The hospital monitors the uniform use of codes, symbols, and abbreviations throughout the organization and takes actions to improve processes when needed.

## Standard MOI.5

The data and information needs of those in and outside the hospital are met on a timely basis in a format that meets user expectations and with the desired frequency.

### Intent of MOI.5

The dissemination of data and information to meet the needs of those in and outside the hospital is an important aspect of information management. Internally, health care practitioners, hospital leadership, 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 in order 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 organizations (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 organization. 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. (*Also see* ACC.3 and COP.3)

**Examples** of dissemination strategies to meet user expectations include

- providing the specific data and information requested/required;
- providing reports with the frequency needed by the individual or organization;
- providing data and information in a format that facilitates its use;
- linking sources of data and information; and
- providing interpretation or clarification of data.

### Measurable Elements of MOI.5

❑ 1. Data and information dissemination meets the needs of individuals and organizations within and outside the hospital, including patients, health care practitioners, hospital leadership, health care services and organizations, and regulatory agencies.

❑ 2. When data and information are required by individuals or organizations for the care of a patient, the hospital has processes to ensure that it is received in a timely manner that supports continuity of care and patient safety.

❑ 3. Individuals and organizations within and outside the hospital receive data and information in a format that facilitates its intended use.

❑ 4. 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.



## Standard MOI.6

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.6

Individuals in the hospital who generate, collect, enter, review, analyze, and use data and information are educated and trained to effectively participate in using and managing information. This education and training enables these individuals to

- use information systems, such as an electronic medical record system, to carry out their job responsibilities effectively and provide care efficiently and safely;
- understand and comply with policies and procedures to ensure security and confidentiality of data and information; (*Also see* PCC.1.3)
- understand and implement tactics and strategies for the management of data, information, and documentation during planned and unplanned downtime; (*Also see* MOI.13)
- use data and information to help in decision making; (*Also see* MMU.5.1 and QPS.3)
- educate and support patients and families regarding participation in care processes; (*Also see* PCC.2) and
- use measures to assess and improve care and work processes.

Individuals are educated and trained according to their responsibilities, job descriptions, and data and information needs. Hospitals with electronic medical 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. Various methods can be used for ongoing training; **for example**, "tips and tricks," quick reference guides, short educational modules, and newsletters can be posted or e-mailed to staff to provide helpful guidance on how to use the system. Ongoing training should be relevant to the staff

member's needs and use of the system. Staff are assessed to ensure that they have the competency and skill necessary to effectively and efficiently use the system to carry out their job responsibilities.

The information management process makes it possible to combine information from various sources and generate reports to support decision making. In particular, the combination of clinical and managerial information helps department/service leaders to plan collaboratively. The information management process supports department/service leaders with integrated longitudinal data and comparative data.

### Measurable Elements of MOI.6

- ❑ 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 medical 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. Clinical and managerial data and information are integrated as needed to support decision making.

## *Management and Implementation of Documents*

# Standard MOI.7

Documents, including policies, procedures, and programs, are managed in a consistent and uniform manner. Ⓟ

### Intent of MOI.7

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. This guidance document includes the following key components:

a) Review and approval of all documents by an authorized person before issue
b) The process and frequency of review and continued approval of documents
c) The controls for ensuring that only current, relevant versions of documents are available
d) How changes in a document can be identified
e) The maintenance of document identity and legibility
f) A process for managing documents that originated outside the hospital
g) Retention of obsolete documents for at least the time required by laws and regulations, while ensuring that they will not be mistakenly used (*Also see* MOI.3)
h) Identification and tracking of 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)

These processes for developing and maintaining policies, procedures, and programs are implemented.

### Measurable Elements of MOI.7

- ❑ 1. There is a written guidance document that defines the requirements for developing and maintaining policies, procedures, and programs, including at least items a) through h) in the intent.
- ❑ 2. There are standardized formats for all similar documents; **for example**, all policies.
- ❑ 3. The requirements of the guidance document are implemented and evident in the policies, procedures, and programs found throughout the hospital.

## Standard MOI.7.1

The policies, procedures, plans, and other documents that guide consistent and uniform clinical and nonclinical processes and practices are fully implemented. Ⓟ

### Intent of MOI.7.1

Throughout the accreditation standards found in this manual, policies, procedures, plans, and other written documents are required (noted with the icon Ⓟ as above). These documents are required, as they reduce process variation and reduce the risk inherent in processes. This is particularly important in clinical 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 their responsibilities or may be part of groupwide or hospitalwide special training sessions. Most importantly, 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.7.1

- ❑ 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.



## *Patient Medical Record*

## Standard MOI.8

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. Ⓟ

## Standard MOI.8.1

The medical record contains sufficient information to identify the patient, to support the diagnosis, to justify the treatment, and to document the course and results of treatment.

### Intent of MOI.8 and MOI.8.1

Every patient assessed or treated in a hospital as an inpatient, outpatient, or emergency care patient has a medical record. The patient medical record is assigned with identifiers unique to the patient, or some other mechanism is used to link the patient with his or her medical record (**for example**, a combination of medical record number and patient's name or a combination of patient's name and date of birth). Unique identifiers used for patient medical records are uniform throughout the hospital. A single record with unique identifiers enables the hospital to easily locate patient medical records and to document the care of patients over time. (*Also see* IPSG.1)

The integrity of the patient medical record is critical to the quality and safety of patient care and continuity of care, as it is the principal tool for communication between health care practitioners. The medical record

facilitates medical decision making, clinical follow-up, transitions of care, and medication ordering and dosing. (*Also see* MOI.13)

The use of copy-and-paste, auto-fill, auto-correct, and other functions in documentation by health care practitioners is becoming common practice as more hospitals adopt electronic medical record systems. Copy-and-paste is the practice of selecting text or data from an original or previous source to reuse in a different location. **For example**, a health care practitioner may copy his or her own notes to reuse, copy a note from another practitioner, or copy from a prior admission. Copy-and-paste and similar functions can have several advantages, including enhancing the efficiency of documentation. However, there are potential risks, such as duplicating information that is inaccurate or outdated.

The use of templates provided in electronic medical records may cause additional inaccuracies in documentation. **For example**, 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, auto-fill, auto-correct, and templates in the electronic medical record, as well as monitoring their use. Monitoring may involve partnering with the electronic medical record vendor to develop a way to track information that has been copied-and-pasted (**for example**, displaying this information in a different font or underlined) or using a manual process to review for copied-and-pasted information. Hospitals also provide training and education on the proper use of copy-and-paste, auto-fill, auto-correct, and templates to all staff who document in the medical record.

Processes to ensure accuracy of the patient medical record address both written and electronic information. When inaccuracies are present in the medical record, there are implications for patient safety and quality of care and services. **For example**, inconsistencies in timing and dating of entries, such as two different arrival times documented in separate locations of the medical record for a patient in the emergency department, may affect the care the patient receives, billing activity, and/or the hospital's quality indicators, among other issues. In addition, discrepancies in the medical record can cause confusion about which information is correct and should be followed—**for example**, a patient's discharge summary stating, "advised patient to make another appointment," and from the same visit, the patient's discharge instructions noting, "no follow-up required." To prevent inconsistencies and discrepancies in the patient medical record, the hospital establishes and implements processes and guidelines to facilitate accurate and complete documentation. **For example**, to facilitate accurate recording of time, clocks are synchronized throughout the hospital, including wall clocks, computer clocks, clocks on medical equipment and devices that are connected to the computer network, and so on.

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 on an inpatient, outpatient, or emergency basis. The medical record needs to present sufficient information to support the diagnosis; to justify the patient's care, treatment, and services; to document the course and results of the patient's care, treatment, and services; and to facilitate the continuity of care. (*Also see* ACC.5.1; AOP.1.2; AOP.1.2.1; COP.2; COP.2.1; ASC.5; ASC.6; ASC.7.2; and MMU.4.2)

### Measurable Elements of MOI.8

- ❑ 1. A medical record with at least two identifiers unique to the patient is initiated for every patient assessed or treated by the hospital.
- ❑ 2. The specific content, format, and location of entries for patient medical records is standardized and determined by the hospital.
- ❑ 3. The hospital establishes and implements guidelines on the proper use of copy-and-paste, auto-fill, auto-correct, and templates and provides education and training on the guidelines to all staff who document in the electronic medical record.
- ❑ 4. The hospital has a process to monitor compliance with the guidelines on the proper use of copy-and-paste, auto-fill, auto-correct, and templates and implements corrective action as needed.
- ❑ 5. The hospital establishes and implements processes and guidelines to facilitate accurate and complete documentation in patient medical records.

### Measurable Elements of MOI.8.1

- ❑ 1. Patient medical records contain adequate information to identify the patient.
- ❑ 2. Patient medical records contain adequate information to support the diagnosis and promote continuity of care.
- ❑ 3. Patient medical records contain adequate information to justify and document the course and results of the patient's care, treatment and services.



## Standard MOI.9

Every patient medical record entry identifies its author and when the entry was made in the medical record.

### Intent of MOI.9

The hospital's processes ensure that each entry in the patient medical record identifies the author of the entry and the date of entry. The time of the entry is also noted, such as for timed treatments and medication orders. (*Also see* IPSG.2 through IPSG.2.2; IPSG.4; IPSG.4.1; COP.2; MMU.4.1; and MMU.4.2) The hospital also establishes and implements a process for how entries in the patient medical record are corrected or overwritten.

When documentation assistants, or scribes, assist physicians or other health care practitioners with documentation in the patient medical record, the scribes are expected to sign, time, and date their entries. In addition, the hospital has a process to ensure that the physician or health care practitioner reviews and authenticates the entries of the scribe who is assisting them. (*Also see* MOI.2)

### Measurable Elements of MOI.9

- ❑ 1. The author of each entry in the patient medical record can be identified.
- ❑ 2. The date of each entry in the patient medical record can be identified.
- ❑ 3. The time of each entry in the patient medical record can be identified.
- ❑ 4. There is a process that addresses how entries in the patient medical record are corrected or overwritten.
- ❑ 5. When scribes are used to assist with documentation in the patient medical record, they sign, date, and time their entries, and there is a process for the physician/health care practitioner to review and authenticate the scribe's entries.

## Standard MOI.10

As part of its monitoring and performance improvement activities, the hospital regularly assesses patient medical record content.

### Intent of MOI.10

Each hospital determines the content and format of the patient medical record and has a process to assess medical record content and the completeness of medical records. That process is a 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 who are 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. (*Also see* MMU.4.2 and MOI.4) The hospital's medical record review process includes medical records of patients currently receiving care as well as medical records of discharged patients. In addition, medical records from outpatient, inpatient, and other services provided to patients are included in the review. A representative sample means medical records from all services and not a specific sample size; however, it should make sense for the organization. **For example**, random sampling and selecting approximately 5% of medical records may achieve a representative sample.

### Measurable Elements of MOI.10

- ❑ 1. A representative sample of medical records that includes active and discharged medical records and inpatient and outpatient medical records, 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 make entries in patient medical records or to manage 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.

## *Information Technology in Health Care*

## Standard MOI.11

Hospital leadership identifies a qualified individual to oversee the hospital's health information technology systems and processes.

### Intent of MOI.11

Health information technology can significantly improve patient safety by automating and streamlining work, providing a seamless transition of patient health information, and offering safety mechanisms that potentially reduce the risk of errors. **For example**, medications errors can be greatly reduced through the implementation of a computerized prescribing mechanism and the use of bar codes for medication administration. However, when not evaluated and tested prior to implementation, health information technology can pose increased risks to patients.

An important resource for hospitals is the investment in health information technology. Health information technology includes electronic systems for documenting and sharing patient information, such as electronic

medical records. Health information technology also includes methods for storing, managing, and securing data and information; communicating information among health care practitioners to better coordinate care; and interfacing with other systems to facilitate patient care and treatment.

Successful implementation of new and evolving health information technology systems requires support, resources, and direction from hospital leadership. Leadership identifies a qualified individual to oversee health information technology systems in the organization. The individual is qualified by education, training, and/or experience relevant to the role and responsibilities. Depending on the size and scope of the hospital's information technology systems, there may be several individuals who support this individual and help manage aspects of the program. (*Also see* GLD.9)

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:

a) Recommending space, equipment, technology, and other resources to hospital leadership to support information technology systems in the hospital
b) Coordinating and conducting risk assessment activities to assess information security risks, prioritize risks, and identify improvements
c) Ensuring that staff and others are educated and trained on information security and applicable policies and procedures
d) Identifying metrics to assess how systems, such as the electronic medical record system, are functioning and affecting staff and patients



Health information technology represents a major investment of resources for a hospital. For this reason, technology is carefully matched to the hospital's current and future needs and its resources. (*Also see* GLD.7) However, new technology may not integrate well with a hospital's existing technology and processes. New technology systems may not address all service areas (**for example**, the operating theatre or emergency department), or may not allow interfaces with existing systems. Consequently, analysis of workflow processes prior to selection and implementation of new technology will help the hospital assess how existing processes and technology could be optimized, changed, and enabled by new technology.

Information technology does not operate independently. Health information technology interacts with processes within the hospital, other organizations outside of the hospital, and internal and external health care practitioners, as well as patients and families. This level of complex integration requires coordinated participation from key stakeholders. Under the leadership of the individual who oversees health information technology in the hospital, stakeholders, such as clinical and nonclinical staff and department/service leaders, are involved in workflow analysis, the selection process for new technologies/systems, and testing, implementation, and evaluation of the technology.

All or part of integrating new and existing health information technology may be done through contracted services. The same level of workflow analysis, assessment, testing, and evaluation is required for contracted services and involves appropriate stakeholders. Oversight for the contract is provided by the individual who oversees health information technology. (*Also see* GLD.6 and GLD.6.1) When information technology systems are implemented, it is important for the hospital to identify metrics and have a process to evaluate the usability and effectiveness of the technology. Evaluation includes, but is not limited to, whether or not the technology is being used as designed and implemented; how well the technology integrates with existing technology; what effects the technology has on improving patient safety, reducing errors, and enhancing the hospital's performance; and how the technology may be affecting staff (**for example**, increasing efficiency, increasing stress/burnout, and so on).

### Measurable Elements of MOI.11

- ❑ 1. Hospital leadership provides direction, support, and resources for health information technology in the hospital.
- ❑ 2. Hospital leadership identifies a qualified individual to oversee health information technology systems in the hospital with responsibility for at least a) through d) in the intent.
- ❑ 3. Stakeholders, such as clinical and nonclinical staff and department/service leaders, 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, staff outcomes, and patient safety, and improvements are identified and implemented based on results.

## Standard MOI.12

When mobile devices are used for texting, e-mailing, or other communications of patient data and information, the hospital implements processes to ensure quality of patient care and maintains security and confidentiality of patient information. Ⓟ

### Intent of MOI.12

As technology has evolved, many health care practitioners have begun to use mobile devices to communicate patient data and information through text messages and e-mails, such as critical results, referrals, and notes about patient care. Health care practitioners may exchange communications with other practitioners, in and outside the hospital, or may receive text messages or e-mails from patients. Hospitals may provide mobile devices to their health care practitioners or may allow practitioners to use their personal devices. When mobile devices are used, the hospital needs to ensure that patient data and information are kept secure and confidential. (*Also see* COP.2) **For example**, the hospital implements access controls with authentication of users, a secure password policy, ability to remotely disable or remove patient data and information from the mobile devices if they are lost or stolen, and other forms of security controls. When the mobile 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.

Newer text messaging platforms may offer the functionality to address previous concerns related to texting and confidentiality, security of information, accuracy, timeliness, documentation, and patient safety. When the hospital allows confidential and private patient information to be transmitted through text messaging (**for example**, patient identification, diagnoses, history, test results, and other confidential information), the hospital ensures that a secure messaging platform is implemented and includes the following:

a) Secure, encrypted sign-on process(es) for authentication of users (sign-on processes that are password protected and unique to each user)
b) Processes for ensuring that only authorized individuals are in the platform's directory of users who can receive messages
c) Delivery and read receipts for messages
d) Date and time stamp for messages
e) Processes for protecting and securing patient information against unauthorized access and use (**for example**, automatic logout after a period of inactivity, ability for the hospital to remotely deactivate mobile devices or wipe data from devices if lost or stolen, and so on)

In addition, the hospital establishes processes for ensuring that text messages with patient information are documented in the medical record when the content relates to the care of the patient. (*Also see* MOI.8 and

MOI.8.1) **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.

E-mail has increasingly become part of normal communication in health care. There are many advantages to e-mail communication; however, there may be issues associated with security, confidentiality, and timeliness, such as when mobile devices are used or when patients initiate contact through e-mail with the physician. The physician or hospital may have a secure e-mail system, but patients often do not. In addition, time-sensitive issues sent via e-mail, such as urgent health matters, may not be viewed by the physician in a timely manner, thereby delaying immediate actions that may be needed. One way of ensuring confidentiality and preventing delays in urgent actions is to limit e-mail use to areas in which the risk for breach of confidentiality or delay in response is lower (**for example**, appointment scheduling and reporting of home records such as blood pressure or weight gain from patients with renal failure or congestive heart failure). As with text messages, the hospital establishes a process to ensure that e-mail messages with data and information relating to a patient's care are documented in the patient's medical record.



Another means for patients to communicate with their health care practitioners is through a patient portal. Patient portals provide a range of services that can be performed online or through an app on a mobile device, such as completing registration forms, requesting prescription refills, accessing test results, scheduling nonurgent appointments, sending/receiving messages with the physician, downloading educational materials, and 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; secure, 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. (*Also see* MOI.2)

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.

## Measurable Elements of MOI.12

- ❑ 1. When the hospital allows patient data and information to be transmitted through text messaging, the hospital ensures that the process is through a secure messaging platform and complies with a) through e) in the intent.
- ❑ 2. When mobile devices are used for communicating patient data and information, the hospital implements guidelines and processes to protect and secure patient information.
- ❑ 3. The hospital establishes processes to ensure that text messages and e-mails on mobile devices that have data and information relating to a patient's care are documented in the patient's medical record.
- ❑ 4. When the hospital implements a patient portal or communicates with patients via text messages or e-mails, the hospital first 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-mail, 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 MOI.13

The hospital develops, maintains, and tests a program for response to planned and unplanned downtime of data systems. Ⓟ

## Intent of MOI.13

Whether or not a hospital has implemented an electronic medical record (EMR), 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 systems are an important part of providing safe, high-quality patient care.

Data system interruptions and failures are unavoidable events. These interruptions, often referred to as downtime, are either planned or unplanned. 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. Hospitals may be in danger of permanently losing data if systems are not in place to copy and archive data.

Downtime, whether planned or unplanned, can affect an entire system or may affect only a single application. Hospitals must prepare all departments and services with training specific to tactics and interventions for managing downtime in their particular area. (*Also see* FMS.11) **For example**, how downtime is managed in the emergency department may be different from the process for managing downtime in a diagnostic imaging area or pharmacy.

Communication is an essential element of continuity strategies 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—no changes expected
  - Enhancement to system

When unplanned downtime occurs, staff need to be notified immediately upon discovery of the event. The manner in which information is communicated to staff will depend 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 in order 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.

The quality and safety of patient care depend on the hospital's ability to maintain patient care services during periods of downtime, both planned and unplanned. The hospital must develop strategies and measures for continuing patient care during data system interruptions. One approach to managing downtime may include 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 may be to maintain a downtime computer that allows read-only access to patient data.

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. Organizations 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, and so on), 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 organization should have a documented process for the management of any paper documentation used during downtime. (*Also see* MOI.8 and MOI.8.1)

Downtime recovery tactics include disaster recovery and failover systems for backing up, recovering, and maintaining data systems. Disaster recovery systems are typically located at remote locations to recover data that may have become corrupted or unintentionally deleted. These systems are backed up periodically, usually every night. Failover systems minimize disruptions in patient care and loss of data. Failover systems are usually on the premises and switch over within a few seconds or minutes of the primary system becoming unavailable due to planned or unplanned downtime. Many tools are available for backing up data. In hospitals that use a cloud-based system for data backup, the vendor of the cloud-based system is required to have adequate backup systems in place to minimize disruptions to care, prevent loss of data, and maintain data integrity. (*Also see* MOI.2) 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.

Most hospitals test their data recovery plans at least once a year. However, 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 particularly important to run a test after an upgrade to make sure the upgrade works properly with the rest of the systems. The hospital plans for interruptions by training staff on alternative procedures, testing the hospital's emergency management program conducting regularly scheduled data backups, and testing data restoration procedures. Regardless of whether an organization uses a paper-based system or an electronic system, a plan to address the process for information continuity, including knowledge-based information, should be in place. 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.



## Measurable Elements of MOI.13

- ❑ 1. The hospital develops and maintains, and tests at least annually, a program for response to planned and unplanned downtime of data systems.
- ❑ 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 identifies and 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.

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# Section IV: Academic Medical Center Hospital Standards

The Medical Professional Education (MPE) and Human Subjects Research Programs (HRP) standards for Academic Medical Center Hospitals 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 center hospitals. 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 7th edition manual, will result in an organization being deemed accredited under the Joint Commission International Standards for Academic Medical Center Hospitals.

Organizations with questions about their eligibility for Academic Medical Center Hospital accreditation should contact JCI Accreditation's Central Office at jciaccreditation@jcrinc.com.

# 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 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. The hospital's governing entity and leadership are responsible to ensure that there is appropriate supervision of patient care 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 leadership.

Trainees and students

- are oriented to the organization and relevant departments;
- understand and participate in quality improvement activities; and
- actively engage in the hospital's culture of safety.

The hospital's governing entity and leadership

- 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; and
- require improvement processes in the teaching programs related to patient care when opportunities for improvement emerge.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.

**MPE.1** The hospital's governing body and leadership of the hospital approve and monitor the participation of the hospital in providing medical education.

**MPE.2** The hospital's clinical staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

**MPE.3** Clinical teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

**MPE.4** The hospital understands and provides the required frequency and intensity of medical supervision for each type and level of medical student and trainee. Ⓟ

**MPE.5** Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

**MPE.6** 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.7** 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 through the hospital's established credentialing, privileging, job specification, or other relevant processes.

# Standards, Intents, and Measurable Elements

## Standard MPE.1

The hospital's governing body and leadership of the hospital approve and monitor the participation of the hospital in providing medical education.

### Intent of MPE.1

Integrating education of medical students and trainees into a hospital's operations requires a significant commitment of time, energy, and resources. Trainees include interns, residents, house officers, and fellows. Decisions on the integration of education and operations are best made at the highest decision-making level of the hospital. (*Also see* GLD.14) When the decision to provide medical education involves a network or consortia of organizations, the governing entity is fully informed as to all the relationships and accountabilities. As the governing entity level also is responsible for decisions related to the hospital's mission, strategic plans, resource allocation, and quality program, it is necessary to make this an integrated decision. (*Also see* GLD.1 through GLD.7.1) **For example**, is the commitment to educate medical students and trainees consistent with the hospital's mission, and how will this commitment be portrayed to the public and the hospital's patients?

The governing entity and leadership of the hospital are also responsible for obtaining, reviewing, and agreeing to the education program parameters of the sponsoring academic program.

A set of metrics, relevant to the education programs within the hospital, is selected and reported to the governing entity and hospital leadership on an annual basis for a review of the scope and activities of the program, achievement of program goals, any relevant regulatory compliance issues, and the satisfaction of patients and staff with the program.

### Measurable Elements of MPE.1

- ❑ 1. The decision to provide medical education is made by the governing entity and leadership of the hospital, is consistent with the hospital's mission, and is documented.
- ❑ 2. The hospital's governing entity and leadership obtain, review, and accept the parameters of the participating medical school, and this action is documented.
- ❑ 3. The hospital's governing entity and leadership 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 leadership review, at least annually, the medical education programs within the hospital, 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.2

The hospital's clinical staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

### Intent of MPE.2

Providing a rich and meaningful learning experience for medical students and trainees requires many factors, in addition to the governing entity and hospital leadership commitment. The clinical staff of the hospital must be adequate in number and in expertise to advance medical student and trainee education. **For example**, nursing staff numbers support the educational program, and nursing staff understand their relationship to the educational program.

The hospital's patient population is sufficient in number and needs to support the education and clinical learning experience. There must also be adequate classroom space, off-duty study and rest facilities, and print and online resources to support an effective learning environment. In addition, adequate opportunities and time for learning and interactions with clinical staff must be provided. Contemporary technology needs to be available so that evidence-based health care practices can be taught.

### Measurable Elements of MPE.2

- ❑ 1. There is evidence that the clinical 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 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 evidence that the hospital's facilities, technology, and other resources support the education of medical students and trainees.

## Standard MPE.3

Clinical teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

### Intent of MPE.3

Those clinical staff who have responsibility for medical student and trainee education and supervision are clearly identified so that the medical students and trainees and other hospital staff understand educational accountabilities and authority. **For example**, when any hospital staff member has a comment, concern, or other matter related to the educational program or medical students and trainees, he or she will understand who is accountable for receiving and acting on that information.

The relationship of the clinical teaching staff of the hospital to the sponsoring academic institution(s) needs to be clear. **For example**, when academic titles are conferred on clinical 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. The hospital has a complete listing of clinical teaching staff with their medical and academic titles. Any requirements for the renewal or redesignation of academic titles are monitored for compliance. (*Also see* SQE.9 through SQE.11)

### Measurable Elements of MPE.3

- ❑ 1. Clinical teaching staff are identified to hospital staff, and there is a complete list of clinical teaching staff, including both professional and academic titles.
- ❑ 2. Staff are educated about these individuals, their accountabilities, and their authority.
- ❑ 3. The hospital has a process in place to monitor academic titles and requirements for renewal or redesignation and to keep such titles up to date.

## Standard MPE.4

The hospital understands and provides the required frequency and intensity of medical supervision for each type and level of medical student and trainee. Ⓟ

### Intent of MPE.4

Supervision is required to ensure safe patient care and ensure that the training program is a learning experience for the medical student and trainee. The required level of supervision is consistent with the level of training within the specialty and level of competence of the medical student and trainee. The hospital understands that medical student and trainee competence cannot be assumed and must be demonstrated early in the training program.

Each medical student and trainee understands 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 or by the patient's primary physician or by a medical school faculty member. Medical students and trainees also understand 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. Likewise, it is clear as to how the evidence of that supervision is documented, including the frequency and location of the documentation. Finally, to ensure a uniform learning experience, the hospital has identified and monitors the uniform expectations for the mentoring/supervision process.

### Measurable Elements of MPE.4

- ❑ 1. Hospital policy identifies and provides the required level of supervision within the specialty for each level of medical student and trainee.
- ❑ 2. The level to be provided is based on the demonstrated competency of the medical student and trainee.
- ❑ 3. Each medical student and trainee understands the level, frequency, and documentation of his or her supervision.
- ❑ 4. There is a uniform process for documenting the required supervision that is consistent with hospital policy, program goals, and the quality and safety of patient care.
- ❑ 5. The hospital establishes uniform expectations for all staff providing supervision to ensure that the process results in uniform medical student and trainee experiences.
- ❑ 6. Medical records are reviewed for compliance with the documentation requirements and frequency.

## Standard MPE.5

Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

### Intent of MPE.5

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 need to be established and then monitored. There is an accurate list of all medical students and trainees in the hospital. For each medical student and trainee, there is documentation of

a) enrollment status;
b) academic classification;
c) any required licensure or certification;
d) reports of medical student and trainee achievements;
e) identification of medical student and trainee competencies;
f) any known factors that will require accommodation; and
g) any known factors that may influence the level of supervision required.

The documentation of a) through g) for a medical student may be limited depending on his or her enrollment status and current level of training. When an academic program is sponsored by the hospital, it is determined how and where these activities are conducted.

### Measurable Elements of MPE.5

❑ 1. The operational structure for medical education in the hospital has been determined and is in operation as required.

❑ 2. The management structure for medical education in the hospital has been determined and is in operation as required.

❑ 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 a) through g) of the intent.

## Standard MPE.6

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.6

Training programs and their students are a critical factor in overall quality of care and patient safety. Although it would be desirable for each medical student and trainee to have basic education on quality and patient safety in his or her respective academic program, this rarely happens. Thus, the hospital must have a planned and deliberate program to introduce such concepts, support the medical students and trainees in complying with relevant policies and guidelines, and include medical students and trainees in all quality and safety monitoring programs. **For example**, medical students and trainees would be educated to comply with the International Patient Safety Goals.

Also, required clinical practice guidelines, surgical time-out procedures, medication-ordering policies, and other mechanisms to reduce variation in care processes—and thus reduce the risk in those processes—are part of all medical students' and trainees' initial orientation and ongoing training and evaluation. The orientation for the medical student and trainee includes at least

a) hospital quality and patient safety program; (*Also see* GLD.4; GLD.4.1; GLD.5; GLD.11; and GLD.11.2)
b) infection prevention and control program; (*Also see* PCI.5)
c) medication safety program; (*Also see* MMU.1)
d) the International Patient Safety Goals;

e) all other required hospital orientation, including at the department and unit level; (*Also see* SQE.7) and
f) any ongoing required education.

Those persons providing medical student and trainee supervision ensure that all medical students and trainees are knowledgeable about these quality and safety programs and are included in the evaluation process.

### Measurable Elements of MPE.6

- ❑ 1. All medical students and trainees are provided an orientation that includes at least a) through f) of the intent.
- ❑ 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.7

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 through the hospital's established credentialing, privileging, job specification, or other relevant processes.

### Intent of MPE.7

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. In these circumstances, 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. His or her work is evaluated as required by the SQE standards. (*Also see* SQE.1.1; SQE.9; SQE.10; and SQE.11)

### Measurable Elements of MPE.7

- ❑ 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 process for the services being provided.
- ❑ 3. Trainees providing such services are evaluated for the services being provided.

## References

### Hospital Leadership and Program Oversight

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# Human Subjects Research Programs (HRP)



## Overview

Human subjects research is a major commitment for hospitals that is integrated with the commitment to provide safe, high-quality care. Components of the commitment to research involve ethics, communication, responsible leaders, regulatory compliance, and financial and nonfinancial resources. The HRP standards require the governing entity and leadership in organizations that conduct human subject research to protect all participating subjects in accordance with international and national principles, and for involved sponsors and staff to comply with applicable regulations and all hospital policies.

Processes are in place to oversee research involving hospital staff conducting the research and all research subjects, regardless of who or what entity sponsors the research. All hospital patients and their families are informed of ongoing studies and their right to participate if they meet study criteria. Study subjects give informed consent to participate in research protocols only after a defined process that explains potential risks and benefits (and other required elements) has been conducted by the principal investigator or authorized designee.

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.

**Note:** Some standards require the hospital to have a written policy, procedure, program, or other written document for specific processes. Those standards are indicated by a Ⓟ icon after the standard text.

## 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.

**HRP.1** Hospital leadership is accountable for the protection of human research subjects.

- **HRP.1.1** Hospital leadership complies with all regulatory and professional requirements and provides adequate resources for effective operation of the research program.

**HRP.2** Hospital leadership establishes the scope of the research program.

**HRP.3** Hospital leadership establishes requirements for sponsors of research to ensure their commitment to the conduct of ethical research. Ⓟ

- **HRP.3.1** 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.4** Hospital leadership creates or contracts for a process to provide the initial and ongoing review of all human subjects research. Ⓟ

**HRP.5** The hospital identifies and manages conflicts of interest with research conducted at the hospital. Ⓟ

**HRP.6** The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

**HRP.7** 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.

**HRP.7.1** 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



## Standard HRP.1

Hospital leadership is accountable for the protection of human research subjects.

## Standard HRP.1.1

Hospital leadership complies with all regulatory and professional requirements and provides adequate resources for effective operation of the research program.

### Intent of HRP.1 and HRP.1.1

Human subjects research is a complex and significant endeavor for a hospital. Hospital leadership recognizes the level of commitment and personal involvement required to advance scientific inquiry in the context of protecting the patients for whom they have made a commitment to diagnose and treat.

Department/service leaders' commitment to human subjects research is not separate from their commitment to patient care—commitment is integrated at all levels. Thus, ethical considerations, good communication, responsible leaders of departments and services, regulatory compliance, and financial and nonfinancial resources are components of this commitment. One such resource is adequate indemnity insurance to compensate patients for adverse events due to the research protocol. Hospital leadership recognizes the obligation to protect patients irrespective of the sponsor of the research.

Hospital leadership is knowledgeable about and complies 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 (see Endnotes at the end of this chapter). (*Also see* GLD.12.1)

### Measurable Elements of HRP.1

- ❑ 1. Hospital leadership establishes and promotes a code of ethical professional behavior.
- ❑ 2. Hospital leadership, verbally and in writing, communicates within the hospital its commitment to protect human subjects research participants and support the code of ethical professional behavior.
- ❑ 3. Hospital leadership identifies the official(s) responsible for maintaining the development of and compliance with all human subjects research policies and procedures.
- ❑ 4. Hospital leadership assumes responsibility for patient protection irrespective of the sponsor of the research.

### Measurable Elements of HRP.1.1

- ❑ 1. Hospital leadership recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research.
- ❑ 2. Hospital leadership has a process for budgeting to provide adequate resources for effective operation of the research program.
- ❑ 3. Hospital leadership provides or ensures that there is adequate indemnity insurance to compensate patients participating in clinical research who experience an adverse event.

## Standard HRP.2

Hospital leadership establishes the scope of the research program.

### Intent of HRP.2

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. To ensure that adequate control and resources support all of the research within the hospital, it is important that hospital leadership makes decisions regarding the scope of research activities, including types and locations. Leadership is also responsible for ensuring an adequate number of trained staff to serve as principal investigators and other members of research teams. There is documentation of the required qualifications. Leadership also must set parameters for when a staff member of the hospital may participate as a research subject.

### Measurable Elements of HRP.2

- ❑ 1. Hospital leadership determines the scope of the research program.
- ❑ 2. Hospital leadership identifies the facilities and resources that support the research program.
- ❑ 3. Hospital leadership identifies 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 leadership identifies those circumstances in which staff can serve as research subjects.

## Standard HRP.3

Hospital leadership establishes requirements for sponsors of research to ensure their commitment to the conduct of ethical research. Ⓟ

### Intent of HRP.3

The sponsor of a research protocol must be qualified and accountable. Thus, hospital leadership must have clear requirements for sponsors of research within the hospital. Sponsors are accountable for every aspect of the specific research, including

- monitoring the quality and safety of the research;
- ensuring that the research methods and processes are ethical; (*Also see* GLD.12)
- using trained and qualified research teams;
- protecting the data generated in terms of reliability and validity; (*Also see* MOI.2.1)
- ensuring that the results and reporting are statistically accurate, ethical, and unbiased;
- protecting the privacy and confidentiality of subject data; (*Also see* PCC.1.3 and MOI.2) and
- ensuring that patient or research incentives do not compromise the integrity of the research.

### Measurable Elements of HRP.3

- ❑ 1. The requirements include that sponsors comply with the hospital's policies and processes for monitoring and evaluating the quality, safety, and ethics of the research.
- ❑ 2. The requirements include that sponsors use research teams that are trained and qualified to conduct the research.
- ❑ 3. The requirements include that sponsors protect the privacy and confidentiality of subject data.
- ❑ 4. The requirements include that sponsors ensure that the research data are reliable and valid, and the results and reporting are statistically accurate, ethical, and unbiased.
- ❑ 5. The requirements include that sponsors do not permit patient or researcher incentives that would compromise the integrity of the research.



## Standard HRP.3.1

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.3.1

Human subjects research has many components, some of which a sponsor may choose to contract to an outside 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. The hospital and sponsor are 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.

### Measurable Elements of HRP.3.1

- ❑ 1. The hospital establishes and implements a 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.
- ❑ 4. The sponsor is responsible for monitoring the contract.

## Standard HRP.4

Hospital leadership creates or contracts for a process to provide the initial and ongoing review of all human subjects research. Ⓟ

### Intent of HRP.4

One of the most important functions 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. The composition, scope of responsibilities, and other factors may be described in laws or regulations. This group monitors all aspects of the research protocol to ensure patient protection and safe research. This function may be contracted to an outside organization such as a contract

research organization. The policies, procedures, and structure of this research review function are specified by hospital leadership, as well as which functions may or may not be transferred to a contract research organization. Also, hospital leadership is responsible for identifying the types of research that are exempt from this review function and the documentation of the activities of the review group. This documentation is an important component of leadership's responsibility to review, at least on an annual basis, how well the research review function is operating.

### Measurable Elements of HRP.4

- ❑ 1. Hospital leadership identifies and supports the structure and operational requirements of the research review function.
- ❑ 2. The research review function complies with applicable laws and regulations.
- ❑ 3. Hospital leadership specifies the requirements of entities outside of the hospital that provide all or a portion of the research review function, such as a contract research organization.
- ❑ 4. Hospital leadership ensures that research that is exempt from the research review process is identified.
- ❑ 5. Hospital leadership specifies the requirements for documentation of the activities of the research review function.
- ❑ 6. Hospital leadership provides for a review of all research review processes at least annually.

## Standard HRP.5

The hospital identifies and manages conflicts of interest with research conducted at the hospital. Ⓟ

### Intent of HRP.5

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. (*Also see* GLD.12)

### Measurable Elements of HRP.5

- ❑ 1. The hospital specifies the requirements for managing conflicts of interest, both financial and nonfinancial.
- ❑ 2. The hospital specifies the individuals, committees, and others for whom the requirements apply.
- ❑ 3. The hospital has an ongoing education and monitoring process to ensure compliance with the requirements.

## Standard HRP.6

The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

### Intent of HRP.6

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 process 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. (*Also see* QPS.7 and QPS.7.1)

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. Equally important is the handling and disposal of certain experimental research pharmaceuticals, which should be a component of the management of hazardous materials. Also, medical equipment used in experimental procedures should be monitored and maintained.

Thus, every aspect of the human subjects research program should be evaluated as to which quality and safety programs of the hospital are applicable, and then the reporting and monitoring processes ongoing within the hospital should be included in the research program. This should also be the case when some research activities are provided by a contract research organization. (*Also see* GLD.6)



### Measurable Elements of HRP.6

- ❑ 1. The research program is a component of the hospital's processes to report and act on sentinel events, adverse events of other types, and the processes to learn from near misses (or close calls).
- ❑ 2. The research program is included in the hospital's programs for hazardous materials management, medical equipment management, and medication management.
- ❑ 3. The evaluation of staff participating in the research program is incorporated into the ongoing monitoring processes of professional performance.

## Standard HRP.7

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.

## Standard HRP.7.1

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.7 and HRP.7.1

A hospital that conducts clinical research, clinical investigations, or clinical trials involving patients knows that its first responsibility is to patients' health and well-being. The hospital provides information to patients and families about how to gain access to research that is relevant to the patients' treatment needs.

To assist patients and families with decisions regarding participation in research, the hospital establishes policies and procedures for obtaining informed consent. (*Also see* PCC.4.1) Through the informed consent process, patients and families gain an understanding of the research and the patients' roles in the research, allowing them to make autonomous decisions to participate or not. The information provided during the informed consent process includes

- an explanation of the research, duration of patient participation, and procedures to be followed by patients;
- expected benefits;
- potential discomforts and risks;

- alternative treatments and procedures that might also be beneficial;
- extent to which confidentiality of records will be maintained;
- compensation or medical treatments available if injury occurs;
- a statement that participation is voluntary;
- assurance that refusal to participate or withdrawal from participation will not compromise care or access to the hospital's services; and
- whom to contact with questions about the research.

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 staff of the hospital. Staff may feel under 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. (*Also see* PCC.4.2)



## Measurable Elements of HRP.7

❑ 1. Patients asked to participate are informed about the research, duration of patient's participation, procedures to be followed, and whom to contact with questions about the research.

❑ 2. Patients asked to participate are informed about the expected benefits, potential risks, and alternative treatments and procedures that might also help them.

❑ 3. Patients asked to participate are informed about the extent to which confidentiality of records will be maintained.

❑ 4. Patients asked to participate are informed about the compensation or medical treatments available if injury occurs.

❑ 5. Patients asked to participate are assured that participation is voluntary and refusal to participate or withdrawal at any time will not compromise care or access to hospital services.

❑ 6. Through the research review function, the hospital establishes and implements how consent for participation will be obtained and documented and under which circumstances consent will be obtained again during the research.

## Measurable Elements of HRP.7.1

❑ 1. 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.

❑ 2. Through the research review function, the hospital establishes and implements safeguards to protect the safety, rights, and well-being of vulnerable patients, including children, prisoners, pregnant women, persons who are mentally disabled, persons who are economically or educationally disadvantaged, and others who may be at risk for coercion or undue influence.

❑ 3. Through the research review function, the hospital establishes and implements safeguards to protect the safety, rights, and well-being of hospital staff who may be at risk for coercion or undue influence.

## References

Council for International Organizations of Medical Sciences. *International Ethical Guidelines for Health-Related Research Involving Humans*. 2016. Accessed Jan 6, 2020. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-Ethical-Guidelines.pdf.

World Health Organization. Ethics and Health: Ethical Standards and Procedures for Research with Human Beings. Accessed Jan 6, 2020. https://www.who.int/ethics/research/en/.

# Endnotes

## International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards

Clinical studies should be carried out according to International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards. This provides a unified standard for the European Union, Japan, and the United States, as well as for Australia, Canada, the Nordic countries, and WHO. Thus, any country that adopts this guideline technically follows this same standard. The ICH is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objectives of such harmonization are a more economical use of human, animal, and material resources and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to protect public health. This mission is embodied in the Terms of Reference of ICH.

Specifically pertaining to contract research organizations (CROs) providing clinical-trials services, the ICH-GCP (E6 1.20) defines a *CRO* as "A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions." Furthermore, it states:

- (5.2.1) A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.
- (5.2.2) Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.
- (5.2.3) Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.
- (5.2.4) All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor.

# Summary of Key Accreditation Policies

This section provides a high-level summary of Joint Commission International's (JCI's) accreditation policies for hospitals. 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

### Basics of the Accreditation Process

Evaluation of compliance with the JCI Accreditation Standards for Hospitals 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.

The JCI standards are updated approximately every three years. JCI publishes its standards 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* published on the cover of the manual. JCI–accredited hospitals are expected to be in full compliance with the new standards at the time the standards become effective. 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 Time Line

Every hospital prepares for its initial or triennial JCI on-site survey differently. A sample time line 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:

- On-site survey

After Survey:

- Within 15 days after the survey—Receive accreditation decision and Official Survey Findings Report from JCI.
- Within 10 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 time line 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
- 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

The survey of all the hospital standards throughout an entire organization. This may be the initial survey or the triennial survey. Definitions of both follows.

- *Initial Survey*—The first full on-site survey of a hospital
  - *Follow-up Survey*—An on-site evaluation scheduled at least 120 days after the date the hospital received the Preliminary Survey Findings Report following an initial survey to evaluate those measurable elements (MEs) scored "not met" or "partially met" that resulted in the hospital's failure to meet the accreditation decision rules
- *Triennial Survey*—The survey of a hospital after a three-year cycle of accreditation
  - *Follow-up Survey*—An on-site evaluation scheduled at least 120 days after the date the hospital received the Preliminary Survey Findings Report following a triennial survey to evaluate those MEs scored "not met" or "partially met" that resulted in the hospital's failure to meet the accreditation decision rules

### Follow-up Survey

Follow-up surveys are on-site surveys limited in scope, content, and length and designed to gather information on specific issues, standards, or MEs. JCI conducts the following types of follow-up surveys:

- *For-Cause Survey*—JCI learns of potentially serious standards noncompliance, serious patient care or safety issues, regulatory issues or sanctions, or other serious issues within an accredited hospital or certified program that may have placed the hospital At Risk for Denial of Accreditation.
- *Extension Survey*—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:
  - A change in hospital ownership and/or name
  - The revocation or restriction of operational licenses or permits, any limitation 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
  - Alteration or changes in use of patient care buildings, construction of new or expansion of patient care buildings, or the occupation of buildings in new locations in the community, to expand the types and volume of patient care services 25% or more than was stated in the hospital's profile or was not reported as a patient care location in the E-App, or was not included in the scope of the previous accreditation survey

- Intentional expansion of the hospital'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 or deletion of one or more types of health care services, such as addition of a dialysis unit or discontinuation of trauma care
- The hospital has merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable JCI standards.

# The Survey Process

## Purpose of a Survey

An accreditation survey is designed to assess a hospital's compliance with JCI standards based on

- interviews with staff and patients and other verbal information;
- on-site 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); and
- *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 executive 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 on-site 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 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 (*Also see* APR.10). 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 acts of God, 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 an on-site 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 on-site 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 On-Site 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* 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 on-site 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*, 7th 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. It is important to note that 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 leaves 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 10 days of the end of the survey.

### Revision of the Official Survey Findings Report

The hospital has ten (10) 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 Committee 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 Committee 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's Accreditation Committee 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.

The appeals process affords the hospital an opportunity to present materials and appear before the Appeals Review Committee 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

- an accredited hospital's status (that is, whether the organization is accredited, was denied accreditation, or if accreditation was withdrawn by JCI); and
- 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 required written plan of action that the hospital develops in response to applicable "not met" and "partially met" findings that could impact patient safety and quality identified in the JCI Official Survey Findings Report. The written 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 At Risk for 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.

## When Accreditation Is at Risk

Hospitals may be At Risk for Denial of Accreditation when JCI Accreditation Central Office staff and surveyors determine that one or more of the following conditions are present in an organization or have occurred:

1. An immediate threat to patient safety, public health, or staff safety (*See* APR.12)
2. The organization does not possess a license, certificate, and/or permit, as, or when, required by applicable laws and regulations, to provide the health care services for which the organization is seeking accreditation.
3. The organization's license, certificate, and/or permit to provide health care services has been temporarily or permanently restricted or removed and/or clinical departments/services have been limited or closed by a local or national regulatory body or authority based on quality and safety conditions, incidents, or events or other legal or regulatory situations.
4. An individual who does not possess a license, registration, or certification is providing or has provided health care services.
5. The organization submitted falsified documents or misrepresented information in seeking to achieve or to retain accreditation. (*See* APR.2)
6. The organization has not met the accreditation policy for reporting requirements between surveys. (*See* APR.3)
7. The organization fails to submit an acceptable Strategic Improvement Plan (SIP) within 120 days of the organization's survey.

JCI Accreditation Central Office staff and surveyors may identify the conditions during an on-site 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 Accreditation Committee. The organization has the right to appeal this decision as previously described.

## Reporting Sentinel Events

Accredited hospitals may voluntarily report sentinel events to JCI. JCI may also become aware of a sentinel event by some other means, such as communication from a patient, a family member, an employee or a staff member of the organization, a surveyor, or through the media. Events considered sentinel events are described in Standard QPS.7.

Such events are called *sentinel* because they signal a need for immediate investigation and response. The terms *sentinel event* and *medical error* are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.

The appropriate response by a hospital to a sentinel event includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements. JCI Accreditation Central Office staff review the root cause analysis and action plan with the hospital to help ensure improvement that will reduce the risk of a similar event occurring in the future.

During the on-site survey, surveyors assess the hospital's compliance with sentinel event–related standards (such as QPS.7). If, during the survey, an unreported sentinel event is identified by the survey team, the hospital's CEO and others are informed that the event has been reported to JCI Accreditation Central Office for further review.

## Managing a Complaint or Quality Concern

JCI's Office of Quality and Safety Monitoring reviews complaints, concerns, and inquiries related to accredited hospitals. These communications may be received from a variety of sources, such as directly from patients, families, or health care practitioners, from governmental agencies in the form of reports, or through media reports. In hospitals that do not have an efficient and effective process to manage and resolve complaints, staff and patients bring those unresolved issues to JCI's attention. (*Also see* APR.11)

Following its review of a reported quality concern, JCI may take a number of actions, including

- recording the information for trending purposes and possible action in the future;
- obtaining the involved hospital's response to the concern; or
- conducting a for-cause survey.

# 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. *Also see* 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. *Also see* 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, triennial survey, and validation 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.

**validation survey** A survey that JCI may conduct in volunteer organizations as a component of JCI's internal quality improvement monitoring processes. This survey has no impact on the organization's accreditation status and is conducted at no charge to the organization.

**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. *Also see* 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.

**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. *Also see* 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** 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. *Also see* 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. *Also see* reappointment.

**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. *Also see* screening.

**assessment (performance improvement)** The systematic collection and review of patient-, process-, program-, or organization-specific data.

**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.

**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. *Also see* generic medication.

**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. *Also see* 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.

**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. *Also see* 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, gathering verbal information, making on-site observations, and educating and consulting with the program about standards compliance and performance improvement.

**certification survey** An evaluation of an organization to assess its compliance with applicable standards and to determine its certification status. The JCI certification 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 by tracer methodology
- Education 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 providers 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 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. *Also see* 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** Those who provide direct patient care (physicians, dentists, nurses, physical therapists, dietitians, among others). *Also see* 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 geographical boundaries or who share common characteristics such as health risks or disease processes. *Also see* 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. *Also see* 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.

**confidentiality** 1. The restricted 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 his or her medical records.

**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 practitioners, among organizations, and over time. *Also see* 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. *Also see* levels of care.

**contracted services** Services provided through a written agreement with another organization, agency, or individual. The agreement specifies the services or staff to be provided on behalf of the applicant organization 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.

**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. *Also see* 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. *Also see* competence.

**criteria** 1. Expected levels 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. *Also see* 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. *Also see* palliative services.

**data** Facts, clinical observations, or measurements collected during an assessment activity. Data before they are analyzed are called raw 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 2019).

**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 documents used for data collection (for example, billing or

administrative data, encounter form, enrollment form, medical record).

**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 man-made. *Also see* 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. *Also see* disaster; emergency.

**discharge** The point at which a patient's active involvement with a health care organization or program ends and the organization or program no longer maintains active responsibility for the care of the patient.

**discharge summary** A section of a patient 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.

**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. *Also see* 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.

**document, written** A printed or electronic document providing information of a formal or informal nature for a specific purpose.

**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. *Also see* emergency procedure.

**electronic medical record (EMR)** An electronic record of a patient's health-related information. *Also see* medical record; 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. And/or 2. A natural or man-made event that significantly disrupts the environment of care (for example, damage to the organization's building[s] and grounds due to severe winds, storms, 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). Some emergencies are called disasters. *Also see* 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. *Also see* 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. *Also see* 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** A means of encoding information to protect against unauthorized access.

**end-of-life/hospice services** Services aimed at meeting the medical, physical, mental, spiritual, and social needs of the dying patient.

**equipment maintenance, preventive** *See* maintenance program, preventive.

**equipment maintenance, routine** *See* maintenance program, routine.

**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.

**essential** Of utmost importance; necessary.

**essential utilities** Utility systems that must continuously operate safely and effectively in order to provide safe care and avoid harm. These include, but are not limited to, power, water, and medical gases.

**evidence-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, while 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.

**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 gather information on a specific issue(s) or limited number of standards or measurable elements, IPSGs, and/or Accreditation Participation Requirements (APRs).

**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 At Risk for 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 inpatients and outpatients; 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; 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, triennial survey, or validation 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. *Also see* 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. *Also see* brand-name medication.

**governance** Level of leadership held by the governing entity of the health care organization, which can have various configurations. *Also see* leaders and leadership.

**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).

**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. *Also see* 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 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) (HAIs)** 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** A general term used to describe many types of organizations that provide health care services. This includes ambulatory care centers, home health care organizations, hospitals, laboratories, long term care organizations, and primary care centers.

**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 person who has completed a course of study and is skilled in a field of heath care. This includes a nurse, physician, dentist, pharmacist, respiratory therapist, physical therapist, and dietitian, among others. Health care practitioners are licensed by a government agency or certified by a professional organization. *Also see* independent practitioner; licensed independent practitioner; practitioner.

**health promotion** Activities that increase an individual's control over his or her 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 medical 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 leadership** A group of individuals who typically report to the chief executive 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. *Also see* 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, and banks.

**independent practitioner** Any individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license. In many countries, licensed independent practitioners include physicians, dentists, some categories of nurses, podiatrists, optometrists, and chiropractors. *Also see* health care practitioner; licensed independent practitioner; practitioner.

**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 control the use of data and information in work activities, information resources management, information technology, and information services.

**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 he or she is 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, 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. *Also see* 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 provider 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.

**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.

**kit** All components of a test packaged together.

**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.

**leaders and leadership** In JCI standards, the term *leaders* is used to indicate that one or more individuals are accountable for the expectation(s) found in the standards. *Leadership* is used to indicate that a group of leaders is collectively accountable for the expectation(s) found in the standards. A leader is an individual who sets expectations, develops plans, and implements procedures to assess and to improve the quality of the organization's governance, management, clinical, and support functions and processes. The leaders described in the JCI standards include at least the leaders of the governing body, the chief executive officer, and other senior managers, departmental leaders, the elected and the appointed leaders of the medical staff and the clinical departments and other medical staff members in organizational administrative positions, and the nurse executive and other senior nursing leaders. *Also see* governance.

**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. *Also see* continuum of care.

**licensed independent practitioner** An individual qualified by education and training permitted by license and law (when applicable) and the organization to provide care and services, within the scope of the individual's practice, without direction or supervision. In many countries, licensed independent practitioners include physicians, dentists, some categories of nurses, podiatrists, optometrists, and chiropractors. *Also see* health care practitioner; independent practitioner; practitioner.

**licensure** A legal right to professional practice 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).

**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. *Also see* 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.

**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.

**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 practitioners. *Also see* electronic medical record (EMR); 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.

**medical student** An individual enrolled in a medical educational institution.

**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).

**medication, 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. Also called high-risk medications.

**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.

**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.

**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.

**near miss** A patient safety event that did not reach the patient. Also called a close call. *Also see* 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. *Also see* 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). *Also see* clinical 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. *Also see* structural elements (of a building).

**nosocomial infection(s)** *See* health care–associated infection(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).

**nutritional care** *See* nutritional interventions.

**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 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 health care practitioner(s).

**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 he or she 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 and professional behavior. The information gathered during this process is factored into decisions to maintain, revise, or revoke existing privilege(s) prior to or at the end of the three-year renewal decision.

**organizational chart** A graphic representation of individuals' titles and reporting relationships in an organization.

**original source (of a measure)** An organization, individual, or group of individuals who is initially responsible for developing the measure.

**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. *Also see* inpatient; patient.

**palliative services** Treatments and support services intended to alleviate pain and suffering rather than to cure illness. Palliative therapy may include medications or procedures to improve the quality of life. Palliative services include attending to the patient's psychological and spiritual needs and supporting the patient and his or her family. *Also see* 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 his or her 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. *Also see* clinical pathway.

**patient** An individual who receives care, treatment, and services. *Also see* 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 his or her own care, according to the patient's knowledge, skills, ability, and willingness to manage his or her own health.

**patient experience** How a patient is affected (physically, emotionally, and psychologically) by his or her 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, gathered, managed, accessed, and consulted by authorized health care practitioners. *Also see* electronic medical record (EMR); medical record.

**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. *Also see* 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. *Also see* 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.

**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).

**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 gathered 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.

**planned downtime** Scheduled data system interruption for the purpose of conducting maintenance, repairs, upgrades, and other changes to the system. *Also see* unplanned downtime.

**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 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. *Also see* community.

**practice guidelines** *See* evidence-based guidelines.

**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. *Also see* health care practitioner; independent practitioner; licensed independent practitioner.

**preoperative medical 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), and immunizations. *Also see* 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 through the use of 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. *Also see* 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. *Also see* credentialing; recredentialing.

**procedural sedation** A technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. *Also see* anesthesia.

**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, and the like). 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 or staff member who can serve in a specific role in the organization. Qualification is determined by the following, as applicable: education, training, experience, competence, applicable licensure, laws or regulations, registration, or certification.

**quality control** The performance of processes through which actual performance is measured and compared with goals, and the difference is acted upon.

**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 performance improvement, and total quality management.

**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 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.

**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. *Also see* 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 file to verify continued licensure; that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies; that the file 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. *Also see* appointment.

**reassessment** Ongoing data collection that begins on initial assessment, comparing the most recent data collected with the data collected at the previous assessment.

**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. *Also see* credentialing; privileging.

**recruitment** Seeking—usually new—staff 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.

**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,

research involving data/specimens, and others. 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 independent 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** *See* comprehensive systematic analysis.

**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 practitioner in a health care organization. The scope is determined by training, tradition, licensure, laws or 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. *Also see* assessment (patient).

**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.

**security** Protection from loss, destruction, tampering, or unauthorized access or use.

**sedation** *See* procedural sedation.

**sentinel event** An unanticipated occurrence involving death or serious physical or psychological injury. The intent statement for Standards QPS.7 and QPS.7.1 includes detailed information on sentinel events. *Also see* adverse event; near miss; no-harm event; patient safety event.

**severe temporary harm** Critical, potentially life-threatening harm lasting for a limited time with no permanent residual harm but that requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

**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 detector** A device that detects smoke as a primary indication of fire and activates the fire alarm system.

**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** All people who provide care, treatment, and services in the organization (for example, medical staff, nursing staff, housekeeping staff, registration clerks, engineers, and so on), 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, and so on). *Also see* clinical 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; 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 practitioner's compliance with preestablished standards. *Also see* accreditation; certification. 2. A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and 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.

**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. *Also see* 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** These (*see* tracer methodology for a description of tracers) occur during the on-site survey and focus 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. *Also see* patient tracer.

**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 the entire surgical or procedural team verifies the correct patient, procedure, or site. 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 processes and 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. *Also see* 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. *Also see* 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. *Also see* 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. *Also see* 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. *Also see* 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 services at the hospital.

**verification** The process of checking the validity and completeness of a clinical or other credential from the source that issued the credential. *Also see* primary source verification.

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