

JCI Accreditation Standards for Hospitals, 7th Edition Draft Standards for Field Review

Proposed New Standards and Requirements

Note: This document does not include all standards for the *JCI Accreditation Standards for Hospitals, 7th Edition*. The standards in this document are the proposed new standards and proposed new requirements for existing standards. New standards and new requirements are underlined.

In addition, some standards in this document do not have new requirements and are not included in the field review; however, some of these standards have been revised for the purpose of clarifying requirements and expectations. These revisions are also underlined.

International Patient Safety Goals (IPSG)

Standards, Intents, and Measurable Elements

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. ⑥

Standard IPSG.3.1

The hospital develops and implements a process for the safe use of look-alike/sound-alike medications. ⑥

Standard IPSG.3.2

The hospital develops and implements a process to manage the safe use of concentrated electrolytes. ⑥

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 Practice (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.

A recent 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, 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 the World Health Organization (WHO).¹⁵ 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,

medication errors, and sentinel events, as well as known safety issues published in professional literature. (*Also see* MMU.7.1 and QPS.7) 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.^{16,17} A 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:

- 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 look-alike/sound-alike 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.

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, and 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 the concentrated electrolytes 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) 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 and magnesium sulfate contained in emergency carts or in areas in which patients with pre-eclampsia may be treated (i.e., labor and delivery, emergency department, or intensive care unit). Wherever concentrated electrolytes are stored, they are clearly labeled with appropriate warnings (e.g., CONCENTRATED electrolyte – Dilute before administration) and segregated from other medications. Only qualified and trained individuals should have access to these vials.

Administration of electrolyte replacement therapy for hypokalemia, hyponatremia, and hypophosphatemia is best performed using standardized guidelines and/or protocols which do not involve dispensing or handling concentrated vials on the patient care units.

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 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. The hospital does not store vials of concentrated electrolytes outside of the pharmacy except in the situations identified in the intent.
- 2. Only qualified and trained individuals have access to concentrated electrolytes, and they are clearly labeled with appropriate warnings and segregated from other medications.
- 3. Standard protocols are followed for adult, pediatric, and/or neonatal electrolyte replacement therapy to treat hypokalemia, hyponatremia, and hypophosphatemia.

International Patient Safety Goals (IPSG)

Standards, Intents, and Measurable Elements

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 United States Centers for Disease Control and Prevention (US CDC), and various other national and international organizations.

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.

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 percent 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 infections (CAUTI), surgical site infection (SSI), and severe sepsis bundle.

Implementing bundles of care will have the greatest impact on patient outcomes when the hospital identifies gaps in best practice or continued poor outcomes in a particular area. Evidence-based infection prevention 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 for all applicable patients.
- 3. Evidence-based interventions used to reduce the risk of health care-associated infections are evaluated by healthcare practitioners for compliance and improvement in clinical outcomes.

Patient-Centered Care (PCC)

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 their responsibilities in relation to the community served by the hospital.

Often, the patient wishes to have family participate in their care decisions, however, they may define family differently from the traditional definition of family. The patient has 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, the patient is 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.

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 they wish to participate in their 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 their care would be provided to family or

others, and under what circumstances.

- ❑ 6. All healthcare practitioners are trained on the processes for and their role in supporting patient and family rights and participation in care.
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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, 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. 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.^{1,2}

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. Staff seek to understand the care and services they provide within the context of the patient's values and beliefs.

When a patient or family wishes to speak with someone related to 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 patients' spiritual and cultural beliefs and the patients' values are respected.
 - 3. The hospital responds to routine as well as complex requests related to religious or spiritual support.
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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.

Staff respects 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 patients have access to their health information it enables them to have the information they need to make better decisions about their healthcare. 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, healthcare 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.
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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.

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.
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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.

Measurable Elements of PCC.1.5

- 1. The hospital develops and implements a process to protect all patients from assault.
 - 2. Vulnerable populations that are at additional risks are identified.
 - 3. The hospital develops and implements a process to protect vulnerable populations from other safety issues.
 - 4. Remote or isolated areas of the facility are monitored.
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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. ⑥

Intent of PCC.2

Patients and families become engaged in their healthcare process by making decisions about care, asking questions about care, requesting a second opinion, and even refusing diagnostic procedures and treatments. 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. Education is planned to ensure that every patient and when applicable, the patient's family, are offered the education required to be able to participate in their care decisions and ensure they are able to care for themselves after discharge. By engaging with patients in the decision-making process, patients and healthcare providers can collaboratively make better decisions

regarding the patient's health that can lead to improved patient outcomes.

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. Unanticipated events may include hospital-acquired infections, pressure ulcers, or post-operative 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.

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, friend, or a surrogate decision maker.⁴

When a patient requests a second opinion, it is expected that the hospital will not prohibit, prevent, or obstruct a patient who is seeking a second opinion, but rather, the hospital 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. (P)

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. Some of the most difficult decisions related to refusing or withdrawing care are related to decisions about withholding resuscitative services or forgoing or withdrawing life-sustaining treatment. These decisions are difficult not only for patients and families, but for health care practitioners and the hospital as well. 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 has identified 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.

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.
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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 healthcare 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 identify 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.

Measurable Elements of PCC.3

- 1. Leadership determines a priority area for improving the patient experience which will positively impact patient care.
 - 2. Leadership develops and implements a process for assessing the patient experience and its impact on patient care.
 - 3. Data from the patient experience is aggregated, analyzed and transformed into information to identify strategies for improving the patient experience.
 - 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.
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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. The hospital identifies in policies and procedures those who need to be involved in the processes and how the patient and family participate.

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. ④

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 has defined 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. ③

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.

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. Patients are informed 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. ③

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. This consent process provides the information identified in PCC.5.3 and documents the identity of the individual providing the information.

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. 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 has listed 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.

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. Individuals, other than the patient, granting consent are noted in the patient's medical record.
-

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 their 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. Once 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. There is a great deal of information 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, healthcare 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 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 their 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.

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.

Care of Patients (COP)

Standards, Intents, and Measurable Elements

Standard COP.A

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.A

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.

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. 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 higher risk to patient safety:

- Input from the medical staff and clinical departments
- 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

Once the list of alarms posing a higher risk to patient safety have been identified and the locations and situations under which these alarms are used, strategies are developed, that may be specific to the alarm or location and 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.A

1. Hospital leaders develop and implement an alarm system management program for alarm signals that pose a higher 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.

Standard COP.B

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

Intent of COP.B

Suicide is considered a sentinel event. The hospital presents a unique combination of risk factors – acute illness or presentation of symptoms, and 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. 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). 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 tool and focuses on suicide 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. 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. Non-psychiatric 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.

Measurable Elements of COP.B

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 when identified as “at risk” for suicide and/or self-harm.
3. The hospital conducts an environmental risk assessment to identify and minimize physical risks in the environment that could be used in a suicide or self-harm attempt.
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.
6. Staff are trained on screening criteria, screening tools, and suicide and self-harm risk reduction protocols and procedures.

DRAFT

Medication Management and Use (MMU)

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. ②

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. 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 h) 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. There is at least one documented review of the medication management system, addressing items a) through h) of the intent as appropriate, within the previous 12 months.
 - 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.
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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 super-bugs 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.¹ 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.²⁻⁴ Some estimate that more than 700,000 deaths occur worldwide per year due to antibiotic resistance.⁵

In addition to resistance and the growth of super-bugs, there are often side effects and/or complications to antibiotic treatment, including acquiring *Clostridium difficile*, 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.6 and PCI.6.1) 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.⁶

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, 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.⁷

Tracking the effectiveness of the program is an important element of the success of the program. **Examples** of identifying effectiveness may include evidence of a decrease in the inappropriate use of antibiotics and 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 that oversees and evaluates the effectiveness of the program for antibiotic stewardship.

Selection and Procurement

Standard MMU.2

There is a method for overseeing the hospital's medication list, how medications are used, and ensuring medications for prescribing or ordering are stocked; and there are processes in place for medications not stocked or normally available to the hospital or for times when the pharmacy is closed. ⑥

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. 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 life-saving 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. Decisions to add or to remove medications from the list are guided by criteria.
- 4. When medications are newly added to the list, there is a process or mechanism to collect, aggregate and monitor data on how the drug is used and any unanticipated adverse events.
- 5. There is a process for authorized staff to obtain medications during the night or when the pharmacy is closed.

Storage

Standard MMU.3

Medications are properly and safely stored. ②

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, investigational medications may require special storage and/or consent. In all locations where medications are stored, the following is evident:

- Medications are stored under conditions suitable for product stability, including medications stored on individual patient care units and ambulances (as applicable).
- 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.
- Concentrated electrolytes are not stored in patient care units excluding the exceptions identified in the

intent of IPSPG.3.2(scored at IPSPG.3.2).

- All medication storage areas, including medication storage areas on patient care units and ambulances (as applicable), are inspected according to hospital policy to ensure that medications are stored properly.
- 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 and access to such medications is limited, 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 inspected per hospital policy 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

The 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. 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.4.1)

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 include to this higher risk of errors include: look-a-like 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.

Consistency and uniformity in the approach to emergency resuscitation may significantly reduce the risks and improve patient outcomes. ISMP identifies strategies to improve the efficiency and accuracy of medication administration during an emergency resuscitation. (ISMP “Medication Safety Alert”, volume 16, issue 3). Examples of strategies include

- Utilize separate adult and pediatric emergency carts as needed based on the age and weight ranges of patients served.
- Areas that treat both adult and pediatric patients (including the emergency department and operating theatre) should have both carts available, with clear directions regarding their appropriate use.
- If universal emergency carts must be used, provide separate, labeled adult and pediatric emergency drug trays/drawers in the cart.
- Use emergency carts only for emergencies.
- In units that provide care to neonates (including obstetrical units), supply a designated neonatal emergency drug box/tray on the neonatal/pediatric emergency cart with medications and concentrations that are appropriate for neonates and match applicable protocols and dosing guidelines.
- Standardize common emergency cart equipment whenever possible throughout the organization.

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 in identifying and implementing strategies to improve the efficiency and accuracy of medication administration during emergency resuscitation.

Standard MMU.3.2

The hospital has a medication recall system. ⑥

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 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 managing unopened, expired, or 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. 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. A hospital may place limits on prescribing or ordering by an individual, such as for controlled substances, chemotherapy agents, or radioactive and investigational medications. Individuals permitted to prescribe and to order medications are known to the pharmaceutical service or others who dispense medications. In emergency situations, the hospital identifies any additional individuals permitted to prescribe or to order medications.

Measurable Elements of MMU.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 and 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 are medication errors. "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. 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:

- a) The data necessary to accurately identify the patient
- b) When generic or brand names are acceptable or required
- 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
- 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;
- precautions for ordering medications with look-alike or sound-alike names
- special types of orders, such as emergency, standing, or automatic stop, and any elements unique to such orders; and
- verbal, telephone, and text medication orders and the process to verify such orders (scored at IPSG.2, MEs 1 and 2).

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.

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, and 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.⁹⁻¹¹ **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; for example, compounded sterile products such as chemotherapy, total parenteral nutrition (TPN) and epidurals. Staff compounding 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, sterile compounding).

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 of safe practices for the use of single-dose and multidose vials, for example, ensuring all needles and syringes are single patient use only and never re-entering a vial with a used needle or used syringe.

Medications stored and dispensed from areas outside the pharmacy (**for example**, patient care units) comply with the same safety and cleanliness measures.

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. Guidelines for preparation of chemotherapy, TPN, and other sterile compounded medications are used in the medication preparation process.
- 4. 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.
- 5. Guidelines for use of single-use and multidose vials are identified and implemented in the medication processes.
- 6. Medications stored, prepared, and dispensed from areas outside the pharmacy (for example, patient care wards) comply with the safety and cleanliness measures required in the pharmacy.

Standard MMU.5.1

Medication prescriptions or orders are reviewed for appropriateness. ⑥

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 (*see* MMU.6.1, ME 1)

The first review is conducted by someone other than the ordering individual, such as a licensed pharmacist, or other licensed professional, such as a nurse or physician, competent in the knowledge required for a full appropriateness review. Each prescription or order, newly prescribed or ordered, 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 change; **for example**, when new drugs are prescribed and therapeutic duplication may be an issue. The hospital defines what patient-specific information is required for the appropriateness review of the order or prescription.

The appropriateness review is conducted by those individuals competent to do so by virtue of education and training, as specified by privileging for licensed independent practitioners or demonstrated competency for nurses or other professionals, in the review process. This individual may be the pharmacist during the normal operation hours of the pharmacy. The process to conduct an appropriateness review (the first review) for an order or prescription prior to dispensing includes evaluation by a trained professional 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.

Appropriateness reviews must be conducted even when circumstances are not ideal. **For example**, if the central pharmacy or a unit pharmacy is not open, and the drug will be dispensed from stock on the nursing unit, 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 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 have documented training in conducting the critical

elements of the appropriateness review and will be supported by reference materials, computer programs, and other resources. Thus, when a physician calls in a new medication order during the night for a patient, the trained individual will write down and read back the order and then conduct an appropriateness review for the identified critical elements. A second review will be required by a licensed pharmacist or other licensed professional, such as a nurse or physician competent in the knowledge required for a full appropriateness review, within 24 hours.

There may be circumstances in which the full appropriateness review is not practical, such as in an emergency or when the ordering physician is present for ordering, administering, and monitoring of the patient (**for example**, 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 review, there is a record (profile) for all medication administered to a patient except emergency medications and those administered as part of a procedure. This record may be kept in the pharmacy and/or be online for review when the pharmacy is closed. This information is essential to the appropriateness review.

When computer programs are used to cross-check drug/drug interactions and drug allergies, the programs are current and updated according to recommendations of the program manufacturers. In addition, when print reference materials are used, the most current versions of the materials are 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 by a licensed professional competent in the knowledge required to perform 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 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 by the designated licensed professional within 24 hours.
- 5. Review is facilitated by a record (profile) for all patients receiving medications, and this record is available at all times when the pharmacy is open or closed.
- 6. Computer programs and print reference materials, when used to cross-check drugs for drug/drug interactions and allergies, 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 life-saving. **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.

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. A hospital may place limits on medication administration by an individual, such as for controlled substances or radioactive and investigational medications. In emergency situations, the hospital identifies any additional individuals permitted to administer medications.

The medical record of each patient who receives medication contains a list of the medications prescribed or ordered for the patient and the dosage and times the medication was administered. Included are medications administered "as needed." If this information is recorded on a separate medication form, the form is inserted in the patient's medical record at discharge or transfer.

Measurable Elements of MMU.6

- 1. The hospital identifies those individuals, by job description or the privileging process, authorized to administer medications.
- 2. There is a process to place 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;
- 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.

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.

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 on a timely basis.
 - 6. Medications are administered as prescribed and noted in the patient's medical record.
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Standard MMU.6.2

Policies and procedures govern medications brought into the hospital for patient self-administration or as samples.
Ⓟ

Intent of MMU.6.2

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 how medication samples are managed, used, and documented.

Written documentation of the medications brought in by the patient/family and sample medications address

- a) receipt;
- 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.
 - 2. The hospital performs a risk-assessment for medications brought in by the patient 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 any medications brought into the hospital for or by the patient.
 - 5. The hospital establishes and implements a process that includes a) through e) of the intent for sample medications.
 - 6. The hospital establishes and implements a process to govern the availability, management, use, and documentation of medication samples.
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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. 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.

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 has a process for recording in the patient medical record, adverse effects related to medication use. and
- 4. The hospital has a 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.

Ⓢ

Intent of MMU.7.1

The hospital has a process to identify and to report medication errors and near misses. 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. 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 taking action on the reports are identified.
- 4. The hospital uses medication errors and near misses reporting information to improve medication use processes.

Prevention and Control of Infections (PCI)

Standards, Intents, and Measurable Elements

Responsibilities & Resources

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. The infection prevention and control program is supported by a team of individuals, as necessary, to ensure that the program is led by 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. Their qualification(s) depend on the activities they will carry out and may be met through

- formal education;
- formal training;
- clinical 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 towards meeting these priorities. This individual(s) identifies high-risk areas for infection prevention and control, including Central Sterile Services 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) is accountable for coordination with hospital leadership regarding priorities, resources, and quality improvement related to the infection prevention and control program.
 - 5. Infection prevention and control program results are reported 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). 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. That 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. 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. There is a designated mechanism for the coordination of the infection prevention and control program that involves infection prevention and control professionals.
 - 2. Coordination of infection prevention and control activities involves physicians and 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.
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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. Hospital leadership ensures that human resources are available to support the infection prevention and control program. This includes the appointment of qualified individual(s) to oversee the program and to provide oversight of high-risk areas (for example, 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 allocates, approves, and ensures that the resources intended for the infection prevention and control program are actually provided to the program 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. 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 Control Program

Standard PCI.4

The hospital designs and implements a comprehensive infection 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.

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, and visitors. 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, systems to identify infections and to investigate outbreaks of infectious diseases, implementation of a vaccine program for staff and patients, and oversight for improving the safe use of antimicrobials. The periodic assessment of risk and setting of risk-reduction goals guide the program.

Measurable Elements of PCI.4

- ❑ 1. There is a comprehensive program that crosses all levels of the hospital, to reduce the risk of health care–associated infections in patients.
- ❑ 2. There is a comprehensive program that crosses all levels of the hospital to reduce the risk of health care–associated infections in hospital staff.
- ❑ 3. The hospital has identified those processes associated with infection risk
- ❑ 4. The hospital has implemented 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 reduction program.

Standard PCI.5.1

The hospital identifies areas at high risk for infections by conducting a risk assessment and develops interventions to address these risks and monitors the effectiveness of the interventions.

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, data-driven 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

In addition, applying the scientific knowledge related to the control of infections through such strategies as the use of clinical practice guidelines, antibiotic stewardship programs, 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.

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, and 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 has established the focus of the program through the collection and tracking of data related to a) through e) in the intent.
2. The data collected in a) through e) are analyzed to identify priorities for reducing rates of infection.
3. Infection control strategies are implemented 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 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 Centers for Disease Control and Prevention (CDC) define 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. 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 Guideline for Sterilization and Disinfection 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, 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 where 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 or an endoscopy clinic. Cleaning, disinfection, and sterilization methods maintain the same standards wherever they are performed in the hospital. It is critical that staff follow standard practices to minimize infection risks. Staff processing medical/surgical equipment, devices, and supplies are oriented, trained, and competent in the practices of cleaning, disinfection, and sterilization 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, trained, and demonstrate competency in cleaning, disinfection, and sterilization and 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.
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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. ⑥

Intent of PCI.6.1

Certain single-use devices may be reused under specific circumstances when permitted by local and national laws and regulations. The types of single-use devices referenced in this standard include critical and semi-critical [medical] devices of the Spaulding Classification and 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. Additionally, chemicals used for reprocessing may corrode the device, and the process itself may damage the device.

The types of single-use devices referenced in this standard include critical and semi-critical [medical] devices of the Spaulding Classification and is not meant to include non-critical devices. Medical devices manufactured to be single-use devices may be either marked with a symbol such as (ⓧ), 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

- single-use devices and materials that may be reused;
- a process for identifying when a single-use device is no longer safe or suitable for reuse;
- the cleaning process for each device that starts immediately after use and follows a clear protocol;
- identification of patients on whom reusable medical devices have been used; and
- a process to manage adverse events resulting from 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. There is oversight of the process to grant or revoke approvals for the reuse of reprocessed single-use devices based on this data, hospital needs, and alternatives to reuse; the list of single-use devices approved for reuse is routinely reviewed to ensure 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. There is a 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, and this process is followed for each device.
- 4. The hospital identifies patients on whom reusable medical devices have been used.
- 5. 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.
- 6. The hospital implements a process consistent with national laws and regulations and professional standards that identifies the process for managing expired supplies.

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Environmental Cleanliness

Standard PCI.7

The infection prevention and control program identifies and implements standards from recognized infection 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, cleaning of waiting areas and other public spaces, cleaning of 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 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, 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. This data is used during ongoing education for environmental cleaning staff and to evaluate and change the cleaning and disinfection process and when indicated.

Measurable Elements of PCI.7

- 1. The hospital selects cleaning and disinfection standards and procedures from recognized infection 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 follow infection control guidelines.

- 4. Environmental cleaning and disinfection processes are monitored, and data is 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 are in compliance 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**, 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 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 are in compliance 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, body parts, and remains 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 blood-borne diseases. Incorrect handling and improper disposal of sharps and needles present a major staff safety hazard. Work practices influence the risk of injury and potential exposure to disease. Identifying and implementing evidence-based practices to reduce the risk of injury from sharps ensures that exposure to such injuries is minimal. Hospitals need to provide staff with education related to safe handling and management of sharps and needles.

Proper disposal of needles and sharps also reduces the risk of injury and exposure. Proper disposal includes the use of containers that are closable, puncture-proof, and leakproof on the sides and the bottom. Containers must be easily accessible to staff and should not be overfilled. Additionally, 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.

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.

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 ensure 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. 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, 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. Operation of the mortuary and postmortem area 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 non-intact skin, mucus membranes, eyes, nose, or mouth. Various pathogens, including Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus, can be transmitted through blood or body fluid exposure. 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. 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 and 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 post-exposure prophylaxis therapy. 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.

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. There is a process for reporting patient and staff exposures to blood and body fluids.
 - 3. There is 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. Incidents of patient and staff exposures to blood and body fluids are tracked and monitored.
 - 6. Reports of exposure incidents are reviewed, and actions are taken to minimize the risk of future exposures to blood and body fluids.
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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 principles such as first in, first out which helps ensure 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.

There are various nutritional products that have special storage and preparation requirements, such as human milk, baby formula, and other enteral nutrition products. 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. Food and nutrition products are stored in a manner that reduces the risk of infection, including those stored outside of the kitchen and food preparation areas.
- 2. Kitchen sanitation measures and guidelines for preparation areas are adopted and implemented to prevent the risk of cross contamination and infection.
- 3. The hospital prepares food and nutrition products using proper sanitation techniques.
- 4. The hospital has 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 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 when 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 regulation 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 micro-organisms and to successfully carry out cleaning, disinfection, and sterilization procedures. Cold water and hot must be stored and distributed at temperatures that minimize growth of water-borne 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. Additionally, 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 includes proper maintenance of inlets, outlets, fans, filters, diffusers, ductwork, humidifiers, and so on.

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 associated with demolition, construction, renovation, and routine facility maintenance.

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.

Measurable Elements of PCI.11

- 1. The hospital has a program developed that uses risk criteria to assess the impact of renovation or new

construction and implements the program when demolition, construction, renovation, or routine maintenance projects take place.

- ❑ 2. The risks and impact of the demolition, renovation, or construction on air and utility quality and infection prevention and control activities throughout the hospital are assessed.
- ❑ 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, isolation procedures, and transmission-based precautions 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.

In addition to the use of standard precautions, transmission-based precautions must be used to prevent infection transmission. Transmission-based precautions are initiated upon suspicion or diagnosis of infections and include

- 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; and
- Reverse/protective isolation to protect patients who are immunocompromised from infections that other patients or staff may be carrying.

Airborne infection isolation rooms (AIIR) 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 (TNPI) when airborne infection isolation is needed and there are no available or insufficient AIIRs. 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 TNPI 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. 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 or returned air may over-pressurize the air return system and may later the negative/positive pressure balance. The use of TNPI follows acceptable guidelines and must adhere to all building and fire codes, and discharge outflow is positioned in a location and height that it does not create exposure risks for staff, patients, and visitors.

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.

Measurable Elements of PCI.12

- 1. Patients with known or suspected contagious diseases are isolated and staff use transmission-based precautions in accordance with recommended guidelines.
- 2. Patients with immunosuppression or other increased risks for contracting a communicable disease are protected through isolation and the use of reverse/protective isolation in accordance with recommended guidelines.
- 3. Negative-pressure rooms are monitored routinely and available 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 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 tests 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. The World Health Organization (WHO) has identified the importance of detecting communicable disease outbreaks early and stopping the mortality, spread, and potential impact. An important element to detecting and limiting the spread of infection includes 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 in Epidemiology and Public Health Intervention Network (TEPHINET) and the US Centers for Disease Control and Prevention. In addition, organizations need to connect with the epidemiology department of their local public health agencies when available.¹⁷

It is 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. **For example**, signs and personal protective equipment (PPE) at patient entrances requesting patients to wear PPE if experiencing infectious disease symptoms; asking simple screening questions at the time of patient registration that potentially identify patients at a higher risk of infection with a communicable disease.

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;
- 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 tested at least annually to ensure proper response when an actual event occurs. Testing involves local, regional, and/or national authorities, when applicable; for example, a community-wide response drill or participation in table top 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 test. Debriefing following an annual test or actual event can identify vulnerable processes that may need to be reevaluated.

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 contact/entry into the hospital system and targets education on early recognition and prompt action.
3. The entire program is tested at least annually and when applicable, involves local regional, and/or national authorities.
4. At the conclusion of every test, debriefing of the test is conducted.
5. Follow-up actions identified from testing 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. 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,** donning 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 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 throughout the organization.

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 where it could be needed.
- 2. Staff are trained and correctly use personal protective equipment in each identified situation.
- 3. Surface disinfecting procedures are implemented 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. Monitoring data includes benchmarking infection rates internally and with external organizations and/or databases.

Measurable Elements of PCI.14

- 1. Infection prevention and control activities are integrated into the hospital's quality improvement and patient safety program.
 - 2. Monitoring data are collected and analyzed for the infection prevention and control activities and include epidemiologically important infections.
 - 3. Monitoring data are used to evaluate and support improvements to the infection prevention and control program at least annually/quarterly.
 - 4. Monitoring data includes benchmarking infection rates.
 - 5. Monitoring data are documented, and reports of data analysis and recommendations are provided 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. In addition, staff receive ongoing education and training related to emerging trends in infection prevention and control. The education program includes professional staff, clinical and nonclinical support staff, patients and families, and even tradespeople and other visitors. Patients and families are encouraged to participate in the implementation and use of infection prevention and control practices in the hospital.

The education is provided as part of the orientation of all new staff and is refreshed periodically, or at least when there is a change in the policies, procedures, and practices that guide the hospital's infection prevention and control program.

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. All staff receive ongoing education and training 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. Findings and trends from quality improvement activities are communicated to all staff and included as part of staff education.

Facility Management and Safety (FMS)

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. ⑨

Intent of FMS.1

Laws, regulations, building and fire safety codes, 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.

Some hospitals are located inside larger, multi-use 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 is in compliance 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 the national and local laws, regulations, building and fire safety codes, and other requirements, such as licenses and permits, that 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 and providing evidence of progress toward implementing the improvements.

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 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, implement, and maintain compliance with 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 multi-use 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 physical 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 must be effectively managed through a facility management and safety structure to reduce and control hazards and risks, prevent accidents and injuries, and maintain safe conditions.

Effective management includes multidisciplinary involvement and planning, education, and monitoring as follows:

- Hospital leadership plans the space, 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 report situations that pose risk.
- Performance criteria are used to evaluate systems and 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. 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, 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 wastes, fire safety, medical equipment, utility systems, and emergency and disaster management
- c) The facility management and safety programs are current and fully implemented
- d) Staff and others are trained on the programs
- 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 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 individual is responsible for a) through f) in the intent.
3. The 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

The hospital develops and documents a comprehensive, facility-wide risk assessment, at least annually, that integrates all seven facility management and safety programs. The seven programs include the following:

- Safety
- Security
- Hazardous materials and wastes
- Fire safety
- Medical equipment
- Utility systems
- Emergency and disaster management

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.

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 seven facility management and safety programs 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 effectiveness of the improvements are evaluated, and based on the results, changes are made to 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. 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 safety 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 goal is to prevent accidents, injuries, and harm; to reduce and control hazards and risks; and to maintain safe conditions for patients, staff, and others, including families, contractors, vendors, volunteers, trainees, and students, among others.

The hospital develops and implements a written safety program. As part of the safety program, the hospital conducts and documents an ongoing inspection of its physical facilities. The results of the inspection are reviewed and addressed in a documented 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 and 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), falls risks (for example, due to uneven or slippery floors or missing hand rails), and so on.

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. Part of prioritizing and planning 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, which is conducted and documented annually, and safety risks are identified and prioritized from the risk assessment.
- 4. Goals and improvements are identified and implemented, and data are monitored to ensure 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. 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 newborn nursery and the operating theatre must be secure and monitored. Children, elderly adults, and vulnerable patients not able to protect themselves or signal for help must be protected from harm. In addition, remote or isolated areas of the facility and grounds may require the use of security cameras.

Measurable Elements of FMS.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 ensures that all security risk areas and restricted areas are identified, documented, 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. Goals and improvements are identified and implemented for the security program, and data are monitored to ensure security risks are reduced or eliminated.

Hazardous Materials and Wastes

Standard FMS.7

The hospital develops and implements a program for the management of hazardous materials and wastes. ©

Standard FMS.7.1

The hospital's program for the management of hazardous materials and wastes 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 wastes includes the types, handling, storage, and disposal of hazardous wastes. ©

Intent of FMS.7 through FMS.7.2

The hospital develops and implements a written program for the management of hazardous materials and wastes that includes identifying and safely controlling these materials and wastes throughout the facility. As part of the hazardous materials and wastes 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 wastes.

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 wastes generated by the organization and how the wastes are identified (for example, color-coded and labeled waste bags/bins).

Hazardous wastes can be categorized by the following:

- Infectious
- Sharps
- Pathological and anatomical
- Pharmaceutical
- Chemicals/heavy metals/pressurized containers
- Genotoxic/cytotoxic
- Radioactive material

The hospital's hazardous materials and wastes program addresses hazardous materials and hazardous wastes and includes processes for

- the inventory of hazardous materials 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 types of hazardous wastes;
- safe handling and storage of hazardous wastes;
- tracking quantity of and proper disposal of hazardous wastes 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 in a safe manner must be immediately available at all times and include information about the physical data of the material (such as its boiling point, flashpoint, flammability, odor, 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 a safety data sheet (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 eye wash station may be necessary for immediate and continuous flushing to prevent or minimize injury. An eye wash 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 eye wash station may not be needed in all cases of hazardous material exposures. Hospitals should conduct a risk assessment to identify where in the organization eye wash 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 eye wash station may be appropriate depending on the types of risks and potential for exposures. For example, personal eye wash bottles may be appropriate in areas where exposure to a mild irritant is a risk, or where a person could use the bottles for immediate flushing as they make their way to a proper eye wash station or get to an area for medical attention. Hospitals that have eye wash 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 wastes.
- 2. A hazardous materials and wastes risk assessment is conducted and documented annually throughout the facility, and risks related to hazardous materials and wastes are identified and prioritized from the risk assessment.
- 3. Goals and improvements are identified and implemented, and data are monitored to ensure risks related to hazardous materials and wastes are reduced or eliminated.

Measurable Elements of FMS.7.1

- 1. The hazardous materials and wastes 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 wastes program establishes and implements procedures for safe handling, storage, and use of hazardous materials.
- 3. The hazardous materials and wastes program establishes and implements the proper protective equipment required during handling and use of hazardous materials.
- 4. The hazardous materials and wastes 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 wastes 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 wastes program establishes the types of hazardous wastes generated by the hospital and how they are identified.
- 2. The hazardous materials and wastes program establishes and implements procedures and the proper protective equipment required for safe handling and storage of hazardous wastes.
- 3. When required by local laws and regulations, the hazardous materials and wastes program documents the quantities of hazardous wastes generated by the hospital.
- 4. The hospital disposes of hazardous wastes safely or contracts with sources that ensure the proper disposal of hazardous wastes in dedicated hazardous waste sites or as determined by local laws and regulations.

Fire Safety

Standard FMS.8

The hospital develops 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. ⑥

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. The fire safety program also addresses nonfire 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 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 takes into account the risk posed to patients, staff, and others when determining the plan and timeframe for implementing improvements and/or interim measures. The ongoing risk assessment and timeframe 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 nonfire 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. Goals and improvements are identified and implemented, and data are monitored to ensure 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 nonfire 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 nonfire 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 nonfire 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 nonfire 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. (P)

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 non-functioning 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.
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Standard FMS.8.4

The hospital involves staff in regular exercises to test the fire safety program. (P)

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 nonfire emergencies;
- the process for testing all portions of the fire safety program during each 12-month period;
- 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.

Exercises to test the fire safety program can be accomplished in multiple ways. For example, to ensure staff know what to do, how to exit, where to assemble (the “assembly points”), and so on, the hospital can conduct evacuation exercises to test the fire safety program. Evacuation exercises in areas such as the intensive care unit, operating theater, or on high floors of the building may provide additional insights when evaluating the evacuation plan. Such exercises should take place during various shifts, including nights and weekends. However, evacuation exercises to test the fire safety program should not involve patients.

Another example of an exercise to test 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. Hospitals may also develop a written test for staff to take relating to fire safety as part of testing the program. Whatever the exercise chosen to test 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 test 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 test the fire safety program are documented, and staff who do not pass are reeducated and retested on the fire safety program.
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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. ⑥

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 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.

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. Goals and improvements are identified and implemented, and data are monitored to ensure 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. ⑥

Intent of FMS.9.2

The hospital has a process 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.

Measurable Elements of FMS.9.2

- ❑ 1. The hospital has a process for receiving and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures.
- ❑ 2. The hospital reports any deaths, serious injuries, or illnesses 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 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 services and 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. 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 utility systems and minimizes 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 control, environmental support, and communication. The utility management program includes strategies for utility maintenance that ensure that these key systems components, such as electric, 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 utility systems risk assessment is conducted and documented annually throughout the hospital, and utility systems risks are identified and prioritized from the risk assessment.
- 3. Goals and improvements are identified and implemented, and data are monitored to ensure 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. Utility systems and components are updated or replaced 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 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 crucial for meeting patient care needs.

An emergency power system is required for all hospitals that intend to provide continuous service under emergency conditions. Such a system provides sufficient power to maintain necessary functions during power failures. It also reduces the risks associated with such failures. Emergency and backup power sources are tested under planned circumstances that simulate actual load requirements. **For example**, for quarterly testing, requirements are that the test run for 30 minutes and should achieve 30% of the nameplate load. The 30-minute time frame does not include the time it takes for the warm-up or cool-down period. Hospitals may choose other methods for testing that meet industry standards.

Water quality can change suddenly from many causes, some of which occur outside of the hospital, such as a break in the supply line to the hospital. When there is a disruption in the usual source of water supplied to the organization, emergency 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 reduces the risks of utility system failures in these areas;
- plans emergency power and water sources for these areas and needs;
- tests the availability and reliability of emergency sources of power, water, and medical gases;
- documents the results of tests;
- ensures that 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, the amount of on-site fuel stored should take into account 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/a 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 nonpotable water is performed at least every six (6) months. Testing of potable and/or nonpotable 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, by local public health or water control authorities outside the hospital, or others judged competent to perform such tests. Whether performed by qualified hospital staff, 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 nonpotable 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, evaluates, and maintains a program for emergency and disaster management 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 or tsunami, or a 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 non-structural 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 non-structural

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 non-structural elements that are crucial for the safe operation of the hospital. An evaluation of structural and non-structural elements allows the hospital to identify vulnerabilities and develop plans for addressing these vulnerabilities and improving hospital safety and preparedness.

It is just as important to identify the probable effects of an emergency or disaster as it is to identify the types of emergencies and disasters likely to occur. This helps in planning the strategies that are needed in the event that the hospital experiences an emergency or disaster. **For example**, what is the likelihood that a natural disaster, such as an earthquake, will affect water and power? Could an earthquake prevent staff from responding to the disaster, either because roads are blocked or because they or their family members are also victims of the event? In such situations, staff responsibilities for their families and/or personal safety may make it difficult or impossible to be at the hospital responding to 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 non-structural 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;
- 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); and
- i) managing emergencies and disasters when personal responsibilities of staff conflict with the hospital's responsibility for providing patient care.

The emergency and disaster management program is tested by

- an annual test of the full program internally or as part of a communitywide 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 emergency and 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 and improvements 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 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 control;
- c) utilities;
- d) noise;
- e) vibration;
- f) hazardous materials and wastes;
- 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.

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 wastes, 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.

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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 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.

Management of Information (MOI)

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 the delivery of patient care, treatment, and services and for managing a safe and effective hospital. The ability to capture and disseminate information requires effective planning. Planning incorporates input from the sources who need or require data and information, including the following:

- Health care practitioners and other staff who provide clinical services
- The hospital's leadership and department/service leaders
- Individuals, services, and agencies outside the hospital who need or require data or information about the hospital's operations and clinical care processes

The planning also considers the hospital's mission, services, resources, technology, and staff. The priority information needs of these sources influence the hospital's information management processes and ability to implement those processes. The processes 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 plan but does require evidence of a planned approach that identifies the information needs and processes for meeting those needs.

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, and integrity of data and information through processes to manage and control access. ©

Standard MOI.2.1

The hospital maintains the confidentiality, security, 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 protecting confidential patient data and information. The balance between data sharing and data confidentiality is addressed.

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. 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, are utilized in the hospital to 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 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 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 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 back-up strategies such as off-site storage and/or cloud back-up services
- 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 server rooms and rooms for physical medical records are secured and accessible to only authorized individuals
- Ensuring 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. Compliance with the processes is monitored, and actions are taken 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. Goals and improvements are identified and implemented to address data security risks, and improvements are monitored to ensure risks are reduced or eliminated.
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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 patient medical records, data, and other information, which are retained for sufficient periods to comply with laws and regulations and to support patient care, management, legal documentation, research, and education, as applicable. The retention process for medical records, data, and other information, including text messages and emails that contain information for medical records, is consistent with 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, data, and other 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.
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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. Patients and families may not be familiar with or understand the 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 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 a 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 Ionized Ratio 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 upper-case and lower-case 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 also 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 also apply to electronic medical record systems and electronic communications, such as email and texting, that are used for communicating about patient care.

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 documents, patient rights documents, discharge instructions, and discharge summaries.
- 6. Uniform use of codes, symbols, and abbreviations across the hospital is monitored, and actions are taken to improve processes when needed.

Standard MOI.5

The data and information needs of those in and outside the hospital are met in a time frame and format that meets user expectations.

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 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.

Examples of dissemination strategies to meet user expectations include the following:

- Providing the specific data and information requested/required
- Providing reports with the frequency needed by the individual or organization
- Providing data and information in a format that facilitates its use
- Linking sources of data and information
- Providing interpretation or clarification of data

Measurable Elements of MOI.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 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;
- understand and implement tactics and strategies for the management of data, information, and

documentation during planned and unplanned downtime;

- use data and information to help in decision making;
- educate and support patients and families regarding participation in care processes; 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 emailed 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 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 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. ⑥

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
- 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, programs, and other documents that guide consistent and uniform clinical and nonclinical processes and practices are fully implemented. ⑥

Intent of MOI.7.1

Throughout the accreditation standards found in this manual, policies, procedures, programs, and other documents are required (noted with the icon ⑥). 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 programs 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 program 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 programs 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 programs are fully implemented and evident in the actions of individual staff members.
- 4. The implementation of policies, procedures, and programs 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. ⑥

Standard MOI.8.1

The medical record contains sufficient information to identify the patient, support the diagnosis, justify the treatment, and 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 an identifier unique to the patient, or some other mechanism is used to link the patient with his or her medical record. A single record and a single identifier enable the hospital to easily locate patient medical records and to document the care of patients over time.

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.

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 their 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 in the patient medical record is standardized to help promote 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 and condition; 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.

Measurable Elements of MOI.8

- 1. A medical record with an identifier 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 correction 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.
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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. 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.

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 the content, completeness, and legibility of patient medical records.

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 the 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, completeness, and legibility of the medical record and clinical information. Medical record content required by laws or regulations is included in the review process. The hospital's medical record review process includes medical records of 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, legibility, and completeness of the medical record.
- 4. Medical record content required by laws or regulations are 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

integrated and implemented properly, health information technology can pose potential risks to patient care.

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 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 IT systems, there may be several individuals who support this individual and help manage aspects of the program.

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 ensuring 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 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. 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 interface 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 or 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 of the contract is provided by the individual who oversees health information technology.

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 may have 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/burn-out, 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.
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Standard MOI.12

When mobile devices are used for texting, emailing, 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 emails, 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 emails 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 is kept secure and confidential. **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 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 or associated with the hospital.

Current 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 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. **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 email 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 email 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 requires 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.

The hospital implements a process to monitor the quality of communications conducted through text, email, and patient portals, and makes improvements where needed. The hospital collects data to monitor the process for clarifying questions that arise from messages received via text, email, 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 text messages and emails 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 emails, the hospital first obtains consent from patients to participate in the portal and/or receive text messages or emails.
- 5. When the hospital allows patient information to be communicated via text messages, email, and patient portals, the hospital has a process to ensure 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 only affect a single application. Hospitals must prepare all departments and services with training specific to tactics and interventions for managing downtime in their particular area. 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.

As more and more hospitals transition to different levels of electronic information management, the impact of downtime is becoming more challenging and potentially significant if the downtime is severe. Planned and unplanned downtime requires hospitals to develop a two-pronged business continuity approach. This approach includes identifying and implementing

- continuity strategies so that safe patient care continues during planned and unplanned interruptions; and
- downtime recovery tactics and data backup procedures to prevent data loss and maintain integrity of data.

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.

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. 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 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, 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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