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Joint Commission International Accreditation Standards for

Hospitals

Including Standards for Academic Medical Center Hospitals

5th Edition



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Hospitals

Including Standards for Academic Medical Center Hospitals

5th Edition

Joint Commission International

A division of Joint Commission Resources, Inc.

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JOINT COMMISSION INTERNATIONAL ACCREDITATION STANDARDS FOR HOSPITALS, 5TH EDITION	

Foreword

Joint Commission International (JCI) is proud to present this fifth edition of its international standards for hospitals. Our customers have told us clearly and repeatedly they want standards that are challenging, achievable, and focused on the safety and quality of patient care. We have listened and we believe these standards exceed those expectations.

In this edition, we are publishing fewer standards and requirements than we have since our second set of standards were published in 2002. We have combined similar requirements, eliminated others that we did not consider essential to better patient outcomes, and reorganized the content across many chapters to ensure a better, more logical flow of requirements. We have provided more examples of proper compliance within the standards' intents to ensure that our requirements are clear. We have also included two chapters of standards for Academic Medical Center Hospitals, consolidating all of our requirements for our hospital customers in one place.

We are thankful for the input and feedback we received from our esteemed Standards Advisory Panel, which reviewed, informed, and otherwise guided us through the development of these standards. We are grateful to our customers, who responded in record numbers to our field review, confirming that we were headed in the right direction with our proposed standards and making us think longer and more fully about other requirements, all of which eventually pushed us to do our jobs better and in a more patient-centric way.

We hope you appreciate the effort that we put into this edition of standards. As always, let us know what you think—your opinion is as much on these pages as ours is.

Paula Wilson
President and CEO
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Joint Commission International also thanks Ana Tereza Cavalcanti de Miranda, MD, PhD, MBA, Rio de Janeiro, Brazil, for her contributions to the Standards Advisory Panel.

Introduction

This fifth edition of the *Joint Commission International Accreditation Standards for Hospitals* contains the standards, intents, measurable elements (MEs), a summary of key changes to this edition of the Joint Commission International (JCI) hospital standards, a summary of key accreditation policies and procedures, a glossary of key terms, and an index. This Introduction is designed to provide you with information on the following topics:

- The origin of these standards
- How the standards are organized
- How to use this standards manual
- What is new in this edition of the manual

If, after reading this publication, you have questions about the standards or the accreditation process, please contact JCI:

+1-630-268-7400 JCIAccreditation@jcrinc.com

How were the standards developed and refined for this fifth edition?

A 13-member Standards Advisory Panel, composed of experienced physicians, nurses, administrators, and public policy experts, guided the development and revision process of the JCI accreditation standards. The panel consists of members from most major world regions. Its work is refined based on the following:

- Focus groups composed of JCI–accredited organization leaders and other health care experts conducted in 16 countries
- An international field review of the standards
- Input from experts and others with unique content knowledge
- Ongoing literature searches for key heath care practices

How are the standards organized?

The standards are organized around the important functions common to all health care organizations. The functional organization of standards is now the most widely used around the world and has been validated by scientific study, testing, and application.

The standards are grouped by functions related to providing patient care: those related to providing a safe, effective, and well-managed organization; and, for academic medical center hospitals only, those related to medical professional education and human subjects research programs. These standards apply to the entire organization as well as to each department, unit, or service within the organization. The survey process gathers standards compliance information throughout the entire organization, and the accreditation decision is based on the overall level of compliance found throughout the entire organization.

What are the Medical Professional Education and Human Subjects Research Programs standards and do they apply to my organization?

The Medical Professional Education (MPE) and Human Subjects Research Programs (HRP) standards for Academic Medical Center Hospitals were developed and first published in 2012 to recognize the unique resource such centers represent for health professional education and human subjects research in their community and country. These standards also present a framework for including medical education and human subjects research into the quality and patient safety activities of academic medical center hospitals. Unless deliberately included in the quality framework, education and research activities often are the unnoticed partners in patient care quality monitoring and improvement.

The standards are divided into two chapters, as medical education and clinical research are most frequently organized and administered separately within academic medical centers. For all hospitals meeting the eligibility criteria, compliance with the requirements in these two chapters, in addition to the other requirements detailed in this fifth edition manual, will result in an organization being deemed accredited under the JCI Standards for Academic Medical Center Hospitals.

Organizations with questions about their eligibility for Academic Medical Center Hospital accreditation should contact JCI Accreditation's Central Office at jciaccreditation@jcrinc.com.

Are the standards available for the international community to use?

Yes. These standards are available in the international public domain for use by individual health care organizations and by public agencies in improving the quality of patient care. The standards only can be downloaded at no cost from the JCI website for consideration of adapting them to the needs of individual countries. The translation and use of the standards as published by JCI requires written permission.

When there are national or local laws related to a standard, what applies?

When standard compliance is related to laws and regulations, whichever sets the higher or stricter requirement applies. **For example**, if a JCI standard on documenting services in the patient record is more stringent than a hospital's national standard, the JCI standard is applied.

How do I use this standards manual?

This international standards manual can be used to

- guide the efficient and effective management of a health care organization;
- guide the organization and delivery of patient care services and efforts to improve the quality and efficiency of those services;
- review the important functions of a health care organization;
- become aware of those standards that all organizations must meet to be accredited by JCI;
- review the compliance expectations of standards and the additional requirements found in the associated intent;
- become aware of the accreditation policies and procedures and the accreditation process; and
- become familiar with the terminology used in the manual.

JCI requirements by category are described in detail below. JCI's policies and procedures are also summarized is this manual. Please note that these are neither the complete list of policies nor every detail of each policy. Current JCI policies are published on JCI's public website, www.jointcommissioninternational.org.

A glossary of important terms and a detailed index follow the standards chapters.

JCI Requirement Categories

JCI requirements are described in these categories:

- Accreditation Participation Requirements (APR)
- Standards
- Intents
- Measurable Elements (MEs)

Accreditation Participation Requirements (APR)

The Accreditation Participation Requirements (APR) section, new to JCI in this edition, is composed of specific requirements for participation in the accreditation process and for maintaining an accreditation award. Hospitals must be compliant with the requirements in this section at all times during the accreditation process. However, APRs are not scored like standards during the on-site survey; hospitals are considered either compliant or not compliant with the APR. When a hospital is not compliant with a specific APR, the hospital will be required to become complaint or risk losing accreditation. (errata)

Standards

JCI standards define the performance expectation, structures, or functions that must be in place for a hospital to be accredited by JCI. JCI's International Patient Safety Goals (page) are considered standards and are evaluated as are standards in the on-site survey.

Intents

A standard's intent helps explain the full meaning of the standard. The intent describes the purpose and rationale of the standard, providing an explanation of how the standard fits into the overall program, sets parameters for the requirement(s), and otherwise "paints a picture" of the requirements and goals.

Measurable Elements (MEs)

Measurable elements (MEs) of a standard indicate what is reviewed and assigned a score during the on-site survey process. The MEs for each standard identify the requirements for full compliance with the standard. The MEs are intended to bring clarity to the standards and to help the organization fully understand the requirements, to help educate leaders and health care workers about the standards, and to guide the organization in accreditation preparation.

What is new in this fifth edition of the manual?

There are many changes to this fifth edition of the hospital manual. A thorough review is strongly recommended. In general, all of the significant changes—changes that, in the view of JCI and the experts and customers who helped develop the standards, "raise the bar" on compliance expectations—are listed in a table at the beginning of the chapter in which those standards appear.

In addition to requirement changes, JCI has edited nearly all of the text that appeared in the fourth edition for clarity, so it will be important for users to compare this and the fourth edition carefully to ensure a full understanding of the new requirements.

In response to the field's request to eliminate all but the most essential accreditation requirements, JCI has reduced the total number of standards by more than 10% and MEs by more than 5% in this edition.

Other changes include the following:

- A table at the front of each chapter detailing the key changes to that chapter in this edition (compared to the fourth edition standards). If a standard is not listed in the table, it has not changed since the fourth edition standards. Changes are classified in four ways:
 - o No significant change—Wording changes were made in the interest of clarity, but the requirements in the standard have not changed.

- o Renumbered—The standard moved from a different place in the same chapter or from another chapter and is, therefore, renumbered.
- Requirement change—A change(s) to one or more MEs, which will change the way an organization is evaluated.
- New standard—A new requirement that did not appear in the fourth edition standards
- New standards and established standards deemed by the field as more difficult to meet are supported with evidence-based references. With this new feature, JCI is beginning to build an evidence base for its standards that both cites important clinical evidence and provides assistance with compliance. References of various types—from clinical research to practical guidelines—are cited in the text of the standard's intent and are listed at the end of the applicable standard chapter.
- A new section, "Accreditation Participation Requirements" (APR). See JCI Requirement Categories for more information.
- Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a picon after the standard text. In previous editions, each required policy or procedure was specified in its own ME. In this edition, all policies and procedures will be scored together at MOI.9 and MOI.9.1.
- Examples that better illustrate compliance are provided in most standards' intents. To make the examples more obvious to the user, the term **for example** is printed in bold text.
- JCI's policies and procedures are summarized and moved from the front of the manual to their current
 location on page 253. This change reflects customer feedback that the policies and procedures, though
 important, are secondary in importance to the JCI standards, intents, and MEs. Starting in late 2013, JCI
 policies will be published on JCI's public website at
 http://www.jointcommissioninternational.org/accreditation-policies.
- The Medical Professional Education (MPE) and Human Subjects Research Programs (HRP) standards
 for Academic Medical Center Hospitals are now included in this manual. Academic medical center
 hospitals are evaluated on all of JCI's hospital requirements in addition to the MPE and HRP
 requirements. Hospitals not being surveyed for Academic Medical Center Hospital accreditation do not
 need to comply with MPE and HRP requirements.
- The "Management of Information" (MOI) chapter was changed from "Management of Communication and Information" (MCI) in the previous edition. Many communications-related requirements were consolidated with similar requirements in the "Access to Care and Continuity of Care" (ACC), "Governance, Leadership, and Direction" (GLD), and "Quality Improvement and Patient Safety" (QPS) chapters.
- Definitions of key terms used throughout the manual have been created or updated, and text including those terms has been reevaluated and revised to ensure that terminology is correct and clear. Many terms are defined within intents; look for these key terms in italics (for example, leadership). All key terms are defined in the Glossary in the back of this edition.
- Chapter overviews, presented for all chapters in past editions, are present only when necessary—specifically, in this edition, in the APR section and GLD chapter.
- Widespread wording changes for clarity, including frequently substituting the term program for plan or
 process. In past editions, JCI requirements called for hospitals to have a plan or a process for many clinical
 issues and matters. During the development of these standards, customer feedback indicated confusion
 over the definitions of plan and process, but program was considered more specific and clear.

How frequently are the standards updated?

Information and experience related to the standards will be gathered on an ongoing basis. If a standard no longer reflects contemporary health care practice, commonly available technology, quality management practices, and so forth, it will be revised or deleted. It is current practice that the standards are revised and published approximately every three years.

What does the "effective" date on the cover of this fifth edition of the standards manual mean?

The "effective" date found on the cover means one of two things:

- For hospitals already accredited under the fourth edition of the standards, this is the date by which they now must be in full compliance with all the standards in the fifth edition. Standards are published at least six months in advance of the effective date to provide time for organizations to come into full compliance with the revised standards by the time they are effective.
- For hospitals seeking accreditation for the first time, the effective date indicates the date after which all surveys and accreditation decisions will be based on the standards of the fifth edition. Any survey and accreditation decisions before the effective date will be based on the standards of the fourth edition.

General Eligibility Requirements

Any hospital may apply for Joint Commission International (JCI) accreditation if it meets all the following criteria:

- The hospital is located outside of the United States and its territories.
- The hospital is currently operating as a health care provider in the country, is licensed to provide care and treatment as a hospital (if required), and, at minimum, does the following:
 - o Provides a complete range of acute care clinical services—diagnostic, curative, and rehabilitative.
 - o In the case of a specialty hospital, provides a defined set of services, such as pediatric, eye, dental, and psychiatry, among others.
 - o For all types of hospitals, provides services that are available 365 days per year; ensures all direct patient care services are operational 24 hours per day, 7 days per week; and provides ancillary and support services as needed for emergent, urgent, and/or emergency needs of patients 24 hours per day, 7 days per week (such as diagnostic testing, laboratory, and operating theatre, as appropriate to the type of acute care hospital).
- The hospital provides services addressed by the JCI fifth edition hospital accreditation standards.
- The hospital assumes, or is willing to assume, responsibility for improving the quality of its care and services.
- The hospital is open and in full operation,* admitting and discharging a volume of patients that will permit the complete evaluation of the implementation and sustained compliance with all the JCI fifth edition hospital accreditation standards.
- The hospital meets the conditions described in the "Accreditation Participation Requirements" (APR) section of the JCI fifth edition hospital accreditation standards.

The applicant academic medical center hospital must meet each of the criteria above in addition to the following three criteria:

- 1) The applicant hospital is organizationally or administratively integrated with a medical school.
- 2) The applicant hospital is the principal site† for the education of both medical students (undergraduates) and postgraduate medical specialty trainees (for example, residents or interns) from the medical school noted in criterion 1.
- 3) At the time of application, the applicant hospital is conducting academic and/or commercial human subjects research under multiple approved protocols involving patients of the hospital.

*Definition of full operation:

- The hospital accurately identifies the following in its electronic application (E-App) at the time of application:
 - All clinical services currently provided for inpatients and outpatients. (Those clinical services that
 are planned and thus not identified in the E-App and begin operations at a later time will require a
 separate extension survey to evaluate those services.)
 - O Utilization statistics for clinical services showing consistent inpatient and outpatient activity levels and types of services provided for at least four months or more prior to submission of the E-App.
- All inpatient and outpatient clinical services, units, and departments identified in the E-App are available
 for a comprehensive evaluation against all relevant JCI standards for hospitals consistent with JCI's
 normal survey process for the size and type of organization (see, for example, the JCI fifth edition
 hospital survey process guide), such as
 - o patient tracer activities, including individual patient and systems tracers;

- o open and closed medical record review;
- o direct observation of patient care processes;
- o interviews of patients; and
- interviews with medical students/trainees.

Note: Contact JCI Accreditation prior to submitting an E-App to discuss the criteria and validate whether the hospital meets the above criteria for "in full operation" at least four months or more prior to submitting its E-App and at its initial survey. JCI may request documentation of the hospital's utilization statistics prior to accepting the E-App or conducting the on-site survey. In addition, JCI will not begin an on-site survey, may discontinue an on-site survey, or may cancel a scheduled survey when it determines the hospital is not "in full operation."

†Principal site means the hospital provides the majority of medical specialty programs for postgraduate medical trainees (**for example**, residents or interns) and not just one specialty, as in a single-specialty hospital (**for example**, an ophthalmologic hospital, dental hospital, or orthopedic hospital).

Note: If in its reasonable discretion JCI determines that the applicant hospital does not meet the published eligibility criteria, JCI will not accept the application or will not process the application for accreditation from the hospital and will notify the hospital of its decision.

Section I: Accreditation Participation Requirements



Accreditation Participation Requirements (APR)

Overview

This section, new to this accreditation manual, consists of specific requirements for participation in the Joint Commission International accreditation process and for maintaining an accreditation award.

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

Organizations are either compliant or not compliant with the APRs. When a hospital does not comply with certain APRs, the hospital may be asked to submit an SIP, or the noncompliance may result in being placed At Risk for Denial of Accreditation, or may lead to the loss of accreditation as with any refusal to permit performance of a survey. How the requirement is evaluated and the consequences of noncompliance are noted with each APR.

Please note that the APR requirements are not scored similarly to the standards chapters, and their evaluation does not directly impact the outcome of an on-site initial or triennial accreditation survey. Please also note that the following table, "History of These Requirements," is provided here because most of these requirements have existed in past editions of this manual, but not in the form of this section.

History of These Requirements

Requirement	Where Previously Published	Explanation
APR.1	Policies and procedures (4th edition)	Moves requirement from the "Reporting Requirements Between Surveys" section to this section
APR.2	Policies and procedures (4th edition)	Moves requirement from "Information Accuracy and Truthfulness Policy" section to this section
APR.3	Policies and procedures (4th edition)	Moves requirement from "Information Accuracy and Truthfulness Policy" section to this section
APR.4	Policies and procedures (4th edition)	Moves requirement from "JCI Focused Survey Policy" section of JCI accreditation manual (4th edition) to this section
APR.5	Accreditation survey process	Extends accreditation process for report review to JCI's requesting reports from agencies directly

Requirement	Where Previously Published	Explanation
APR.6	Policies and procedures (4th edition)	Moves requirement from "On-Site Survey Process" section to this section
APR.7	Intent of QPS.3 through QPS.3.3 (4th edition)	Moves requirement from "Quality Improvement and Patient Safety" chapter to this section; in addition, the selection and use of Library measures is integrated into the "Governance, Leadership, and Direction" chapter of this manual
APR.8	Policies and procedures (4th edition)	Moves requirement from "Information on Accreditation Status Available to the Public" section to this section
APR.9	Policies and procedures (4th edition)	Moves requirement from "Complaint Management Policy for Accredited Organizations" section to this section
APR.10	Accreditation contract	Expands accreditation contract language to include JCI review of interpreter credentials
APR.11	PFR.3 (4th edition)	Moves requirement from "Patient and Family Rights" chapter to this section
APR.12	Policies and procedures (4th edition)	Moves requirement from "Threat to Health and Safety Policy" section to this section

Requirements, Rationales, Evaluation Methods, and Consequences of Noncompliance

Requirement: APR.1

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

Rationale for APR.1

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

Evaluation of APR.1

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

Consequences of Noncompliance with APR.1

If the hospital fails to meet the requirements for the timely submission of data and information to JCI, the hospital will be considered At Risk for Denial of Accreditation and may be required to undergo a focused survey.

Failure to resolve this issue in a timely manner or at the time of the focused survey may result in Denial of Accreditation. These consequences address only compliance with the requirement itself and not the content of the hospital's submissions to JCI. **For example**, if information in a hospital's E-App leads to inaccuracies in the appropriate length of the survey and a longer survey is required, the hospital will incur the additional costs of the longer survey. In addition, if there is evidence that the hospital has falsified or withheld the information or intentionally deleted information submitted to JCI, the requirement at APR.2 and its consequences will apply.

Requirement: APR.2

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

Rationale for APR.2

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

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

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

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

Evaluation of APR.2

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

Consequences of Noncompliance with APR.2

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

Requirement: APR.3

The hospital reports within 15 days any changes in the hospital's profile (electronic database) or information provided to JCI via the E-App before and between surveys.

Rationale for APR.3

JCI collects core information regarding each hospital's profile in its E-App to understand ownership, licensure, scope and volume of patient services, and types of patient care facilities, among other factors. When any of these factors change, JCI must make a deliberate determination if the change is within or outside of the scope of a planned initial survey or the scope of a current accreditation award. Thus, the hospital notifies JCI before the change or within 15 days of changes in such core information from the hospital's profile, including, but not limited to, the following:

- A change in hospital ownership and/or name
- The revocation or restriction of operational licenses or permits, any limitation or closure of patient care services, any sanctions of professional or other staff, or other actions under laws and regulations brought by relevant health authorities

- Alteration or changes in use of patient care buildings, construction of new or expansion of patient care buildings, or the occupation of buildings in new locations in the community, to expand the types and volume of patient care services 25% or more than was stated in the hospital's profile or was not reported as a patient care location in the E-App, or was not included in the scope of the previous accreditation survey
- Intentional expansion of the hospital's capacity to provide services in the absence of new, renovated, or expanded facilities by 25% or greater, as measured by patient volume, scope of services, or other relevant measures
- The addition or deletion of one or more types of health care services, such as addition of a dialysis unit or discontinuation of trauma care
- The hospital has merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable JCI standards.

When significant change occurs, JCI may conduct a focused survey for all or a portion of the hospital again or for the first time in the case of new facilities or services. JCI accreditation does not automatically extend accreditation to new services and facilities without an on-site evaluation.

Evaluation of APR.3

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

Consequences of Noncompliance with APR.3

If the hospital does not provide notification to JCI in advance or within 15 days of these changes, the hospital will be placed At Risk for Denial of Accreditation and a focused survey will be conducted.

Requirement: APR.4

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

Rationale for APR.4

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

Evaluation of APR.4

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

Consequences of Noncompliance with APR.4

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

Requirement: APR.5

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

Rationale for APR.5

In order to conduct a thorough accreditation survey, JCI collects information on many aspects of hospital operations. External bodies other than JCI evaluate areas related to safety and quality—for example, fire safety

inspections, staff working conditions inspections, and evaluation of safety incidents or quality complaints by local authorities. These evaluations complement accreditation reviews but may have a different focus or emphasis. These evaluations may produce information JCI needs to make accreditation decisions.

Evaluation of APR.5

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

Consequences of Noncompliance with APR.5

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

Requirement: APR.6

The hospital allows JCI Accreditation Program staff and members of JCI's Board of Directors to observe the on-site survey.

Rationale for APR.6

JCI Accreditation Program staff have reason to observe new surveyors, evaluate new standards, and evaluate changes in the on-site survey process, among other activities. JCI's Board of Directors approves accreditation strategies and policies, which is best done with a full understanding of the accreditation process gained from such an observation.

Evaluation of APR.6

Observations can occur at any phase of the accreditation process related to any type of on-site survey. For observers other than staff and JCI's Board of Directors, the hospital will receive a request specific to that observer.

Consequences of Noncompliance with APR.6

A hospital will be charged for all the nonreimbursable travel expenses associated with the hospital's refusal to allow observation by a JCI Accreditation Program staff or Board member.

Requirement: APR.7

The hospital participates in the Joint Commission International Library of Measures quality improvement measurement system. The hospital's leadership selects clinical measures from the Library applicable to the hospital's patient populations and services. When Library measures are not applicable to the hospital's patient populations and services, the hospital consults with JCI staff regarding an exemption from the measure requirements of APR.7.

The hospital uses the current Library measure specifications and follows Library measure selection, use, and data submission requirements as found on the JCI Library of Measures website, which can be accessed directly from the JCI Direct Connect customer portal. The JCI Library of Measures website describes current requirements related to the following:

- 1) Any required minimum number of measures sets or individual measures that must be selected and implemented
- 2) The process for obtaining an exemption from APR.7 requirements when the Library measures are not applicable to the hospital's patient populations and services provided
- 3) The collection and aggregation process for Library measure data

- 4) The effective date and the process for submission of quarterly discharge data
- 5) The use of Library measure data in the accreditation process
- 6) The criteria for determining continued use or replacement of Library measures
- 7) How data quality issues are to be managed

Rationale for APR.7

The Joint Commission International Library of Measures provides uniform, precise specifications for the collection of data standardized to permit comparison over time within a hospital and for comparisons among hospitals.

The collection, analysis, and use of data are at the core of the JCI accreditation process. Data can support continuous improvement in a hospital. Data can also provide a continuous flow of information to JCI in support of the hospital's ongoing improvement in its continuous accreditation process.

Both of these purposes are best served when the hospital selects Library measures that address process and outcomes for which the data will guide improvement in the delivery of patient care. Measures that are convenient and easy rarely serve this important purpose; and also do not uphold JCI's expectation for the hospital to demonstrate continuous improvement in the accreditation process.

The selection and use of Library measures is integrated into the hospital's measurement priorities as described in Standards GLD.5, GLD.11, and GLD.11.1.

Evaluation of APR.7

The selection, use, and data submission for at least a minimum number of measures from the JCI Library of Measures is evaluated throughout all phases of accreditation, both during the on-site survey process and through evaluation of the data submitted during the continuous accreditation process.

Consequences of Noncompliance with APR.7

The hospital will be considered At Risk for Denial of Accreditation and a focused survey may be conducted if the hospital is found not to be in compliance with applicable requirements found on the JCI Library of Measures website.

Requirement: APR.8

The hospital accurately represents its accreditation status and the programs and services to which JCI accreditation applies.

Rationale for APR.8

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

Evaluation of APR.8

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

Consequences of Noncompliance with APR.8

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

Requirement: APR.9

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

To support this culture of safety, the hospital must communicate to staff that such reporting is permitted. In addition, the hospital must make it clear to staff that no formal disciplinary actions (**for example**, demotions,

reassignments, or change in working conditions or hours) or informal punitive actions (**for example**, harassment, isolation, or abuse) will be threatened or carried out in retaliation for reporting concerns to JCI.

Rationale for APR.9

To create a "safe" reporting environment, the hospital educates all staff that concerns about the safety or quality of patient care provided in the hospital may be reported to JCI. The hospital also informs its staff that it will take no disciplinary or punitive action because a staff member reports safety or quality-of-care concerns to JCI.

Evaluation of APR.9

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

Consequences of Noncompliance with APR.9

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

Requirement: APR.10 (errata) (clarification)

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

Rationale for APR.10

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

Evaluation of APR.10

The hospital will submit the licenses and resumes of the selected translators no later than six (6) weeks prior to the start of any JCI on-site survey. JCI Accreditation Program staff will obtain a signed conflict-of-interest statement from each translator. For other types of on-site evaluations, such as a focused survey, the surveyor and/or JCI Accreditation Program staff member will evaluate the credentials of the translators.

Consequences of Noncompliance with APR.10

When translators are found to be unqualified due to lack of professional license or a conflict of interest, the survey will be stopped until a suitable replacement can be found. The hospital is responsible for any additional costs related to the delay, including rescheduling of survey team members when necessary.

Requirement: APR.11

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

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

Rationale for APR.11

JCI standards for hospitals require hospitals to have a mechanism to receive and respond to complaints, conflicts, and other patient care quality and safety concerns in a timely manner. The hospital needs to inform the public it serves about how to access this process.

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

Evaluation of APR.11

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

Consequences of Noncompliance with APR.11

An SIP will be required when a hospital is found to not meet this requirement.

Requirement: APR.12

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

Rationale for APR.12

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

Evaluation of APR.12

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

Consequences of Noncompliance with APR.12

Immediate threats discovered on-site during a survey interrupt the survey until the threat can be resolved or until the hospital, survey team, and JCI Accreditation Program staff can mediate the issue. Until the issue is resolved, the hospital is placed At Risk for Denial of Accreditation and a focused survey is conducted.

Section II: Patient-Centered Standards



International Patient Safety Goals (IPSG)

Changes to the IPSG Chapter

Standard	Change	Explanation
IPSG.1	Requirement change	Eliminates two MEs for overall clarity of the requirements
IPSG.2	Requirement change	Expands intent to include two additional standards for verbal/telephone communications: reporting of critical results of diagnostic tests (IPSG.2.1; formerly Standard AOP.5.3.1, 4th edition) and handovers of patient care (IPSG.2.2, new standard); emphasizes the need for more focused compliance on three distinct communication-related issues
IPSG.2.1	Requirement change	Moves requirement from AOP.5.3.1 (4th edition) to highlight reporting of critical results of diagnostic tests as an important communication issue
IPSG.2.2	New standard	Introduces a new requirement for effective handovers of patient care within the hospital
IPSG.3 and IPSG.3.1	Requirement change	Divides IPSG.3 (4th edition) into two standards to clarify expectations for high-alert medications (including medications involved in a high percentage of errors/sentinel events and look-alike/sound-alike medications; IPSG.3) and concentrated electrolytes (IPSG.3.1), emphasizing more focused compliance on two distinct medication-related issues
IPSG.4 and IPSG.4.1	Requirement change	Divides IPSG.4 (4th edition) into two standards to clarify the purpose and content of the preoperative verification process and the approach for the time-out procedure
IPSG.5	Requirement change	Incorporates elements of PCI.9 (4th edition), thereby consolidating hand-hygiene requirements into one standard
IPSG.6	Requirement change	Clarifies the need to address fall risk assessment and reassessment in both inpatients and outpatients

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Goals, Standards, Intents, and Measurable Elements

Goal 1: Identify Patients Correctly

Standard IPSG.1

Intent of IPSG.1

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

The identification process used throughout the hospital requires at least two ways in which to identify a patient, such as the patient's name, identification number, birth date, a bar-coded wristband, or other ways. The patient's room number or location cannot be used for identification. These two different identifiers are utilized in all locations within the hospital; **for example**, in the ambulatory care or other outpatient location, the emergency department, the operating theatre, diagnostic departments, and the like.

Two different patient identifiers are required in any circumstance involving patient interventions. **For example**, patients are identified before providing treatments (such as administering medications, blood, or blood products; serving a restricted diet tray; or providing radiation therapy); performing procedures (such as insertion of an intravenous line or hemodialysis); and before any diagnostic procedures (such as taking blood and other specimens for clinical testing, or performing a cardiac catheterization or diagnostic radiology procedure). Identification of the comatose patient with no identification is also included.

Measurable Elements of IPSG.1

1.	Patients are identified using two patient identifiers, not including the use of the patient's room numbe
	or location.

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J	3.	Patients are id	lentified be	etore any c	liagnostic i	procedures. ((Also see F	AOP.5.7,	ME2	.)
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Goal 2: Improve Effective Communication

Standard IPSG.2

Standard IPSG.2.1

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

Output

Description:

Standard IPSG.2.2

The hospital develops and implements a process for handover communication.

Intent of IPSG.2 Through IPSG.2.2

Effective communication, which is timely, accurate, complete, unambiguous, and understood by the recipient, reduces errors and results in improved patient safety. Communication can be electronic, verbal, or written. Patient care circumstances that can be critically impacted by poor communication include verbal or telephone patient care orders, verbal or telephone communication of critical test results, and handover communications. Handover communications can also be referred to as handoff communications. The most error-prone communications are patient care orders given verbally and those given over the telephone, when permitted under local laws and regulations. Different accents, dialects, and pronunciations can make it difficult for the receiver to understand the order being given. For example, drug names and numbers that sound alike, such as erythromycin instead of azithromycin or fifteen instead of fifty can affect the accuracy of the order. Background noise, interruptions, and unfamiliar drug names and terminology often compound the problem. Once received, a verbal order must be transcribed as a written order, which adds complexity and risk to the ordering process.

The reporting of critical results of diagnostic tests is also a patient safety issue. Diagnostic tests include, but are not limited to, laboratory tests, radiology exams, nuclear medicine exams, ultrasound procedures, magnetic resonance imaging, and cardiac diagnostics. This includes critical results from any diagnostic tests performed at the bedside, such as point-of-care testing, portable radiographs, bedside ultrasounds, or transesophageal echocardiograms. Results that are significantly outside the normal range may indicate a high-risk or life-threatening condition. A formal reporting system that clearly identifies how critical results of diagnostic tests are communicated to health care practitioners and how the information is documented reduces patient risks. (Also see AOP.5.4)

Safe practices for verbal or telephone communications include the following:

- Limiting verbal communication of prescription or medication orders to urgent situations in which
 immediate written or electronic communication is not feasible. For example, verbal orders can be
 disallowed when the prescriber is present and the patient's chart is available. Verbal orders can be
 restricted to situations in which it is difficult or impossible for hard-copy or electronic order
 transmission, such as during a sterile procedure.
- The development of guidelines for requesting and receiving test results on an emergency or STAT basis, the identification and definitions of critical tests and critical values, to whom and by whom critical test results are reported, and monitoring compliance.
- Writing down (or entering into a computer) the complete order or test result by the receiver of the information; the receiver reading back the order or test result; and the sender confirming that what has been written down and read back is accurate. Permissible alternatives for when the read-back process may not always be possible may be identified, such as in the operating theatre and in emergent situations in the emergency department or intensive care unit. (Also see COP.2.2; MMU.4; MMU.4.1; and MOI.11, ME 1)

Handovers of patient care within a hospital occur

- between health care providers, such as between physicians and other physicians or health care providers, or from one provider to another provider during shift changes;
- between different levels of care in the same hospital such as when the patient is moved from an intensive care unit to a medical unit or from an emergency department to the operating theatre; and
- from inpatient units to diagnostic or other treatment departments, such as radiology or physical therapy.

Breakdowns in communication can occur during any handover of patient care and can result in adverse events.^{1,2} Background noises, interruptions, and other distractions from unit activities can inhibit clear communication of important patient information. Standardized, critical content for communication between the patient, family, caregiver, and health care providers can significantly improve the outcomes related to handovers of patient care.^{3–6} (*Also see* ACC.3)

Measurable Elements of IPSG.2

☐ 1. The complete verbal order is documented and read back by the receiver and confirmed by the individual giving the order.

	2.	The complete telephone order is documented and read back by the receiver and confirmed by the individual giving the order.
	3.	The complete test result is documented and read back by the receiver and confirmed by the individual giving the result.
Mε	ae	urable Elements of IPSG.2.1
		The hospital has defined critical values for each type of diagnostic test.
	2.	The hospital has identified by whom and to whom critical results of diagnostic tests are reported.
	3.	The hospital has identified what information is documented in the patient record.
		urable Elements of IPSG.2.2
_	1.	Standardized critical content is communicated between health care providers during handovers of patient care.
	2.	Standardized forms, tools, and methods support a consistent and complete handover process.

Goal 3: Improve the Safety of High-Alert Medications

3. Data from handover communications are tracked and used to improve approaches to safe handover

Standard IPSG.3

communication.

Standard IPSG.3.1

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

Output

Description:

Intent of IPSG.3 and IPSG.3.1

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 more frequently, and the harm they produce is likely to be more serious when they are given in error. This can lead to increased patient suffering and potentially additional costs associated with caring for these patients.

High-alert medications include

- medications that are involved in a high percentage of errors and/or sentinel events, such as insulin, heparin, or chemotherapeutics; and
- medications whose names, packaging and labeling, or clinical use, look alike and/or sound alike, such as Xanax and Zantac or hydralazine and hydroxyzine

There are many medication names that sound or look like other medication names. 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;
- similar strengths, dosage forms, and frequency of administration; and
- illegible prescriptions or misunderstanding during issuing of verbal orders.

Lists of high-alert medications and look-alike/sound-alike medications are available from organizations such as the World Health Organization (WHO) and the Institute for Safe Medication Practices (ISMP), as well as in the literature.

A frequently cited medication safety issue is the incorrect or unintentional administration of concentrated electrolytes (**for example**, potassium chloride [equal to or greater than 2 mEq/mL concentration], potassium phosphate [equal to or greater than 3 mmol/mL concentration], sodium chloride [greater than 0.9% concentration], and magnesium sulfate [equal to or greater than 50% concentration]). Errors can occur when staff are not properly oriented to the patient care unit, when contract nurses are used and not properly oriented, or during emergencies. The most effective means to reduce or to eliminate these occurrences is to develop a process for managing high-alert medications that includes removing the concentrated electrolytes from the patient care units to the pharmacy. (*Also see* MMU.3)

The hospital makes a list of all medications that pose a significant risk to patients using hospital data related to medication use within the hospital, adverse and near-miss events, and other relevant information. The list includes medications identified as high risk for adverse outcomes as well as those at risk for look-alike/sound-alike confusion. Information from the literature and/or Ministry of Health may also be useful in helping to identify which medications should be included.^{7–9} These medications are stored in a way that reduces the likelihood of inadvertent administration or ideally provides directions on the proper use of the medication. Strategies to improve the safety of high-alert medications may be tailored to the specific risk of each medication and should include consideration of prescribing, preparation, administration, and monitoring processes, in addition to safe storage strategies.^{10–14} The hospital also identifies any areas where concentrated electrolytes are clinically necessary as determined by evidence and professional practice, such as the emergency department or operating theatre, and identifies how they are clearly labeled and how they are stored in those areas in a manner that restricts access to prevent inadvertent administration.

Measurable Elements of IPSG.3

- ☐ 1. The hospital has a list of all high-alert medications, including look-alike/sound-alike medications, that is developed from hospital-specific data.
- 2. The hospital implements strategies to improve the safety of high-alert medications, which may include specific storage, prescribing, preparation, administration, or monitoring processes.
- 3. The location, labeling, and storage of high-alert medications, including look-alike/sound-alike medications, is uniform throughout the hospital.

Measurable Elements of IPSG.3.1

- ☐ 1. The hospital has a process that prevents inadvertent administration of concentrated electrolytes.
- 2. Concentrated electrolytes are present only in patient care units identified as clinically necessary.
- 3. Concentrated electrolytes that are stored in patient care units are clearly labeled and stored in a manner that promotes safe use.

Goal 4: Ensure Correct-Site, Correct-Procedure, Correct-Patient Surgery

Standard IPSG.4

Standard IPSG.4.1

The hospital develops and implements a process for the time-out that is performed in the operating theatre immediately prior to the start of surgery to ensure correct-site, correct-procedure, and correct-patient surgery.

Intent of IPSG.4 and IPSG.4.1

Wrong-site, wrong-procedure, wrong-patient surgery is an alarmingly common occurrence in hospitals. These errors are the result of ineffective or inadequate communication between members of the surgical team, lack of patient involvement in site marking, and lack of procedures for verifying the operative site. In addition, inadequate patient assessment, inadequate medical record review, a culture that does not support open communication among surgical team members, problems related to illegible handwriting, and the use of abbreviations are frequent contributing factors.

Surgery and invasive procedures include all procedures that investigate and/or treat diseases and disorders of the human body through cutting, removing, altering, or insertion of diagnostic/therapeutic scopes. Organizations need to identify all areas within the hospital where surgical and invasive procedures take place; **for example**, the cardiac catheterization lab, interventional radiology department, gastrointestinal lab, and the like. The approach the hospital takes to ensuring correct-site, correct-procedure, and correct-patient surgery applies to all areas of the hospital in which surgical and invasive procedures occur.

Evidence-based practices are described in The (US) Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person SurgeryTM. The essential processes found in the Universal Protocol are

- marking the surgical site;
- a preoperative verification process; and
- a time-out that is held immediately before the start of a procedure.

Marking the surgical and invasive procedure site involves the patient and is done with an instantly recognizable mark. The mark must be consistent throughout the hospital; must be made by the person performing the procedure; should take place with the patient awake and aware, if possible; and must be visible after the patient is prepped and draped. The surgical site is marked in all cases involving laterality, multiple structures (fingers, toes, lesions), or multiple levels (spine).

The purpose of the preoperative verification process is to

- verify the correct site, procedure, and patient;
- ensure that all relevant documents, images, and studies are available, properly labeled, and displayed; and
- verify that any required special medical technology and/or implants are present.

There are various elements of the preoperative verification process that can be completed before the patient arrives at the preoperative area—such as ensuring that documents, imaging and test results, and paperwork are properly labeled and available; and marking the surgical site. In fact, waiting until the time-out to complete the preoperative verification process may unnecessarily delay surgery if paperwork or imaging are not labeled and available when surgery is about to begin. It is more likely that portions of the preoperative verification may occur more than once and in more than one place. For example, the surgical consent may be obtained in the surgeon's office and then verification that it is completed may take place in the preoperative holding area; marking the surgical site may occur in the preoperative holding area; and verifying that the right medical technology is available may occur in the operating theatre.

The time-out, held immediately before the start of the procedure with all team members present, permits any unanswered questions or confusion to be resolved. The time-out is conducted in the location at which the procedure will be done, just before starting the procedure, and involves the entire operative team. The patient does not have to participate in the time-out procedure. The hospital determines how the time-out process is to be documented.

Measurable Elements of IPSG.4

- 1. The hospital uses an instantly recognizable mark for surgical- and invasive procedure–site identification that is consistent throughout the hospital.
- 2. Surgical- and invasive procedure–site marking is done by the person performing the procedure and involves the patient in the marking process.
- 3. The hospital uses a checklist or other process to document, before the procedure, that the informed consent is appropriate to the procedure; that the correct site, correct procedure, and correct patient are identified; and that all documents and medical technology needed are on hand, correct, and functional.

Measurable Elements of IPSG.4.1

- 1. The full surgical team conducts and documents a time-out procedure in the area in which the surgery/invasive procedure will be performed, just before starting a surgical/invasive procedure.
- 2. The components of the time-out include correct patient identification, correct side and site, agreement of the procedure to be done, and confirmation that the verification process has been completed.
- 3. When surgery is performed, including medical and dental procedures done in settings other than the operating theatre, the hospital uses uniform processes to ensure the correct site, correct procedure, and correct patient.

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

Standard IPSG.5

Intent of IPSG.5

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. Internationally acceptable 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. (Also see GLD.11.2)

The hospital adopts and implements currently published evidence-based hand-hygiene guidelines. Hand-hygiene guidelines are posted in appropriate areas, and staff are educated in proper hand-washing and hand-disinfection procedures. Soap, disinfectants, and towels or other means of drying are located in those areas where hand-washing and hand-disinfecting procedures are required. (Also see PCI.9)

Measurable Elements of IPSG.5

- 1. The hospital has adopted currently published, evidence-based hand-hygiene guidelines.
- 2. The hospital implements an effective hand-hygiene program throughout the hospital.
- ☐ 3. Hand-washing and hand-disinfection procedures are used in accordance with hand-hygiene guidelines throughout the hospital.

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

Standard IPSG.6

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

Output

Description:

Intent of IPSG.6

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

An example of a situational risk is the patient who arrives at the outpatient department from a long term care facility via ambulance for a radiologic examination. The patient may be at risk for falls in that situation when transferring from ambulance cart to exam table, or when changing positions while lying on the narrow exam table. Specific locations may present higher fall risks because of the services provided. For example, a physical therapy department (inpatient or outpatient) has many types of specialized equipment used by patients that may increase the risk of fall, such as parallel bars, freestanding staircases, and exercise equipment.

In the context of the populations it serves, the services it provides, and its facilities, the hospital should evaluate patient falls and take action to reduce the risk of falling and to reduce the risk of injury should a fall occur. A fall reduction program may include risk assessment and periodic reassessment of a particular patient population and/or of the environment in which care and services are provided (such as those conducted during periodic safety tours). The hospital has a responsibility to identify the locations (such as the physical therapy department), situations (such as patients arriving by ambulance, patient transfers from wheelchairs or carts, or the use of patient-lifting devices), and types of patients (such as patients with gait or balance disturbances, visual impairments, altered mental status, and the like) who may be at high risk for falls.

The hospital establishes a fall-risk reduction program based on appropriate policies and/or procedures. The program monitors both the intended and unintended consequences of measures taken to reduce falls. For **example**, the inappropriate use of physical restraints or fluid intake restriction may result in injury, impaired circulation, or compromised skin integrity. The program is implemented. (Also see AOP.1.4)

Measurable Elements of IPSG.6

- 1. The hospital implements a process for assessing all inpatients and those outpatients whose condition, diagnosis, situation, or location identifies them as at high risk for falls.
- 2. The hospital implements a process for the initial and ongoing assessment, reassessment, and intervention of inpatients and outpatients identified as at risk for falls based on documented criteria.
- 3. Measures are implemented to reduce fall risk for those identified patients, situations, and locations assessed to be at risk.

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Access to Care and Continuity of Care (ACC)

Changes to the ACC Chapter

Standard	Change	Explanation
ACC.1.1 and ACC.1.2	Renumbered	Renumbers standards from the 4th edition to improve overall chapter flow: ACC.1.1 (previously ACC.1.1.1) and ACC.1.2 (previously ACC.1.1.3)
ACC.2	Renumbered; Requirement change	Renumbers standard ACC.1.1 (4th edition); removes text from intent and deletes ME 5 (4th edition) to clarify requirements
ACC.2.1 and ACC.2.2	Renumbered	Renumbers standards from the 4th edition to improve overall chapter flow: ACC.2.1 (previously ACC.1.1.2) and ACC.2.2 (previously ACC.1.2)
ACC.2.2.1	New standard	Adds a new requirement for hospitals to manage the flow of patients throughout the hospital
ACC.2.3 and ACC.2.3.1	Requirement change	Renumbers and separates requirements of ACC.1.4 (4th edition) to emphasize the need for established criteria for both admissions to and discharges from units providing intensive or specialized services
ACC.3	Renumbered; Requirement change	Moves requirement from ACC.2 (4th edition) and revises intent and MEs to clarify elements of continuity and coordination of patient care processes
ACC.3.1– ACC.4.4	Renumbered; No significant change	Renumbers several standards from the 4th edition, some with minor text changes to improve clarity: ACC.3.1 (previously ACC.2.1); ACC.3.2 (previously MCI.8); ACC.4 (previously ACC.3); ACC.4.1 (previously PFE.4); ACC.4.2 (previously ACC.3.1); ACC.4.3 (previously ACC.3.2.1); ACC.4.3.1 (previously ACC.3.4); ACC.4.3.2 (previously ACC.3.2); ACC.4.4 (previously ACC.3.3)
ACC.4.5 and ACC.4.5.1	Renumbered; Requirement change	Renumbers and separates requirements of ACC.3.5 (4th edition) to emphasize the need to address follow-up processes for patients who notify hospital staff and those who do not notify staff before leaving against medical advice
ACC.5 and ACC.5.1	Renumbered; No significant change	Renumbers and reorganizes requirements and clarifies text of ACC.4, ACC.4.1, and ACC.4.3 (4th edition)
ACC.5.2	Renumbered	Moves requirement from ACC.4.2 (4th edition)
ACC.5.3	Renumbered	Moves requirement from ACC.4.4 (4th edition)
ACC.6	Renumbered; No significant change	Moves requirement from ACC.5 (4th edition); adds text to intent for clarity

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Screening for Admission to the Hospital

Standard ACC.1

Intent of ACC.1

Matching patient needs with the hospital's mission and resources depends on obtaining information on the patient's needs and condition through screening, usually at the point of first contact. The screening may be through triage criteria, visual evaluation, a physical examination, or the results of previously conducted physical, psychological, clinical laboratory, or diagnostic imaging evaluations. The screening can occur at a referring source, during emergency transport, or when the patient arrives at the hospital. It is important that decisions to treat, to transfer, or to refer are made only after the results of screening evaluations are available. Only those patients for whom the hospital has the clinical capability to provide the needed services, consistent with its mission, are considered for inpatient admission or registered for outpatient services. Certain screening exams or diagnostic tests may be required for every patient being admitted, or the hospital may identify specific screenings and tests for particular patient populations. For example, all patients with active diarrhea must have a screen for *Clostridium difficile*, or certain types of patients require screening for methicillin-resistant *Staphylococcus aureus*, such as all patients coming from long term care facilities. Specific screening tests or evaluations are identified when the hospital requires them prior to admission or registration. (*Also see* AOP.1)

Measurable Elements of ACC.1

- ☐ 1. Based on the results of screening, it is determined if the needs of the patient match the hospital's mission and resources. (Also see GLD.3.1, ME 1)
- ☐ 2. Patients are accepted only if the hospital can provide the necessary services and the appropriate outpatient or inpatient setting for care.
- 3. There is a process to provide the results of diagnostic tests to those responsible for determining if the patient is to be admitted, transferred, or referred.
- 4. Specific screening tests or evaluations are identified when the hospital requires them prior to admission or registration.
- 5. Patients are not admitted, transferred, or referred before the test results required for these decisions are available.

Standard ACC.1.1

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

Intent of ACC.1.1

Patients with emergent, urgent, or immediate needs (such as airborne infections) are identified by an evidence-based triage process. Once identified as emergent, urgent, or requiring immediate needs, these patients are assessed and receive care as quickly as necessary. Such patients may be assessed by a physician or other qualified individual before other patients, receive diagnostic services as rapidly as possible, and begin treatment to meet their needs. The triage process may include physiologic-based criteria, where possible and appropriate. The hospital trains staff to determine which patients need immediate care and how their care is given priority.

When the hospital is not able to meet the needs of the patient with an emergency condition and the patient requires transfer to a higher level of care, the transferring hospital must provide and document stabilizing treatment within its capacity prior to transport.

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1.	The hospital uses an evidence-based triage process to prioritize patients with immediate needs.
2.	Staff are trained to use the criteria.
3.	Patients are prioritized based on the urgency of their needs.
4.	Emergency patients are assessed and stabilized within the capacity of the hospital prior to transfer
5.	Stabilizing treatment provided prior to transport is documented in a record maintained by the transferring hospital. (<i>Also see</i> MOI.10.1.1)

Standard ACC.1.2

Intent of ACC.1.2

Patients are informed when there are known long waiting periods for diagnostic and/or treatment services or when obtaining the planned care may require placement on a waiting list. Patients are informed of the associated reasons for the delay or wait and are informed of available alternatives. This requirement applies to inpatient and outpatient care and/or diagnostic services; it does not apply to minor waits in providing outpatient care or inpatient care, such as when a physician is behind schedule. For some services, such as oncology or transplant, delays may be consistent with national norms for those services and thus different than the delays for such services as diagnostic.

Measurable Elements of ACC.1.2

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

Admission to the Hospital

Standard ACC.2

The hospital has a process for admitting inpatients and for registering outpatients. (9)

Intent of ACC.2

The process for admitting inpatients to the hospital for care and for registering outpatients for services is standardized. Staff are familiar with and follow the standardized process.

The process addresses

- registration for outpatient services or admission for inpatient services;
- admission directly from the emergency service to an inpatient unit; and
- the process for holding patients for observation.

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- 1. The outpatient registration process is standardized.
- The inpatient admitting process is standardized.
- ☐ 3. There is a process for admitting emergency patients to inpatient units.
- 4. There is a process for holding patients for observation.
- 5. Staff are familiar with and follow all of the admission and registration processes.

Standard ACC.2.1

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

Intent of ACC.2.1

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

Measurable Elements of ACC.2.1

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

Standard ACC.2.2

At admission as an inpatient, patients and families receive information on the proposed care, the expected outcomes of care, and any expected cost to the patient for care.

Intent of ACC.2.2

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

Measurable Elements of ACC.2.2

- ☐ 1. The patient and family are provided with information at admission.
- 2. The information includes proposed care.
- ☐ 3. The information includes expected outcomes of care.
- 4. The information includes any expected costs to the patient or family.

Standard ACC.2.2.1

The hospital develops a process to manage the flow of patients throughout the hospital.

Intent of ACC.2.2.1

Emergency department (ED) crowding and high hospital occupancy rates can lead to boarding patients in the ED or creating temporary inpatient holding areas. Managing the flow of patients throughout their care is essential to prevent crowding, which can undermine the timeliness of care and, ultimately, patient safety. 1–3 Effective management of systemwide processes that support patient flow (such as admitting, assessment and treatment, patient transfer, and discharge) can minimize delays in the delivery of care. 4–12 The components of the patient flow process address the following topics:

- a) The available supply of inpatient beds
- b) Facility plans for allocation of space, utilities, equipment, medical technology, and supplies to support temporary patient locations
- c) Staffing plans to support the addition of temporary patient locations and/or boarding in the ED
- d) The patient flow of areas where patients receive care, treatment, and services (such as inpatient units, laboratory, operating rooms, telemetry, radiology, and the postanesthesia care unit)
- e) The efficiency of the nonclinical services that support patient care and treatment (such as housekeeping and transportation)
- f) The provision for the same level of care as provided to patients admitted to an inpatient unit
- g) Access to support services (such as social work, religious or spiritual support, and the like)

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

Patients who come to a hospital ED for care are particularly vulnerable to boarding. ^{13,14} Boarding in the ED must be used as only a temporary solution to hospital crowding. Hospital plans should identify a time frame by which boarded patients will be transferred from the ED to a standard or temporary inpatient area. The expectations here are intended to guide hospitals in providing for a safe location, the orientation and training of staff, and the assessment, reassessment, and care (within its capabilities) of patients who are subject to boarding. ^{13,15–20}

Measurable Elements of ACC.2.2.1

- The hospital develops and implements a process that supports the flow of patients throughout the hospital that includes at least a) through g) of the intent.
 The hospital plans and provides for the care of patients needing admission who are boarded in the ED,
- including identifying a time limit for boarding.
- 3. The hospital plans and provides for care to patients when bed space is not available on the desired service or unit or elsewhere in the facility.
- 4. The individuals who manage patient flow processes review the effectiveness to identify and implement process improvements.

Standard ACC.2.3

Standard ACC.2.3.1

Discharge from units providing intensive or specialized services is determined by established criteria. ®

Intent of ACC.2.3 and ACC.2.3.1

Units or services that provide intensive care (**for example**, a postsurgical intensive care unit) or that provide specialized services (**for example**, the care of burn patients or organ transplant units) are costly and usually are limited in space and staffing. Each hospital must establish criteria for determining those patients who require the level of care provided in such units.

When considering admission to specialized units that utilize expensive resources, hospitals may restrict admission to only those patients with reversible medical conditions, and not provide admission to patients whose conditions are terminal. To ensure consistency, the criteria should utilize prioritization and diagnostic and/or objective parameters, including physiologic-based criteria. Individuals from the emergency, intensive, or specialized services participate in developing the criteria. The criteria are used to determine direct entry to the unit; for example, directly from the emergency department. The criteria are also used to determine admission into the unit from within the hospital or from outside the hospital (such as when a patient is transferred from another hospital).

Patients admitted to a specialized unit require reassessment and reevaluation to identify when the patient's condition has changed, such that specialized care may no longer be required. For example, when the patient's physiological status has stabilized and intensive monitoring and treatment are no longer necessary, or when the patient's status has deteriorated to the point that specialized care and services will no longer be provided, the patient may be discharged from the specialized unit or moved to a unit that provides a lower level of care (such as a medical/surgical unit, hospice, or palliative care unit). The criteria used for transfer from a specialized unit to a lower level of care should be the criteria that are used for admitting patients to the next level of care. For example, when the patient's condition has deteriorated such that intensive treatment is no longer considered helpful, the patient's admission to hospice or palliative care must be according to criteria for admission to those services.

When the hospital conducts research or provides specialized patient care services or programs, admission into such programs is through established criteria or an established protocol. Individuals from the research or other programs are involved in developing the criteria or protocol. Admission to such programs is documented in the patient's record and includes the criteria or protocol conditions under which the patient was admitted. (Also see ACC.3)

Measurable Elements of ACC.2.3

The hospital has established entry and/or transfer criteria for admission to intensive and specialized services or units, including research and other programs to meet special patient needs.
 The criteria utilize prioritization, diagnostic, and/or objective parameters, including physiologic-based criteria.
 Individuals from intensive/specialty units are involved in developing the criteria.
 Staff are trained to apply the criteria.
 The records of patients who are admitted to units providing intensive/specialized services contain evidence that they meet the criteria for services.

Measurable Elements of ACC.2.3.1

- 1. The hospital has established discharge and/or transfer criteria from intensive and specialized services or units to a different level of care, including research and other programs.
- 2. The criteria used for discharge or transfer should include the criteria used for admission to the next level of care.
- 3. Individuals from intensive or specialty units are involved in developing the criteria.
- ☐ 4. Staff are trained to apply the criteria.
- 5. The records of patients who are transferred or discharged from units providing intensive or specialized services contain evidence that they no longer meet the criteria for services.

Continuity of Care

Standard ACC.3

Intent of ACC.3

As patients move through the hospital from admission to discharge or transfer, several departments and services and many different health care practitioners may be involved in providing care. Throughout all phases of care, patient needs are matched with the required resources within and, when necessary, outside the hospital. Continuity is enhanced when all patient-care providers have the information needed from the patient's current and past medical experiences to help in decision making, and, when multiple decision makers are providing care, these decision makers agree on the care and services to be provided.

The patient's record(s) is a primary source of information on the care process and the patient's progress and thus is an essential communication tool. For this information to be useful and to support the continuity of the patient's care, it needs to be available during inpatient care, for outpatient visits, and at other times as needed and kept up to date. Medical, nursing, and other patient care notes are available to all of the patient's health care practitioners who need them for the care of the patient. (Also see AOP.2)

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

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

The leaders of the departments and services work together to design and to implement the processes of care coordination and continuity. These processes may be supported with the use of tools such as guidelines, clinical pathways, care plans, referral forms, checklists, and the like. The hospital identifies individuals responsible for coordinating services. These individuals may coordinate all patient care (**for example**, between departments) or may be responsible for coordinating the care of individual patients (**for example**, case manager). This care coordination is best accomplished by using established criteria or policies that determine the appropriateness of transfers within the hospital. (*Also see* IPSG.2.2; ACC.2.3; ACC.2.3.1; COP.8.3; COP.9.3, ME 2; ASC.7.2; and MOI.1)

Measurable Elements of ACC.3

1.	The leaders of departments and services design and implement processes that support continuity and coordination of care, including at least a) through e) identified in the intent. (Also see GLD.10)
2.	The patient's record(s) is available to those practitioners who are authorized to have access and need for the care of the patient. (Also see AOP.1.1)

- ☐ 3. The patient's record(s) is up to date to ensure communication of the latest information.
- 4. Continuity and coordination of care processes are supported by the use of tools, such as care plans, guidelines, or other such tools.
- ☐ 5. Continuity and coordination are evident throughout all phases of patient care.

Standard ACC.3.1

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

Intent of ACC.3.1

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

When a patient moves from one phase of care to another (**for example**, from surgical to rehabilitation), the individual responsible for the patient's care may change, or the same individual may continue overseeing the entire patient's care.

Measurable Elements of ACC.3.1

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

Standard ACC.3.2

Information related to the patient's care is transferred with the patient.

Intent of ACC.3.2

Patients may be transferred within the hospital from one service or inpatient unit to a different service or inpatient unit during their course of care and treatment. When the care team changes as a result of the transfer, continuity of patient care requires that essential information related to the patient be transferred with him or her. Thus, medications and other treatments can continue uninterrupted, and the patient's status can be monitored. To ensure that each care team receives the information needed to provide care, the patient's record(s) is transferred or information from the patient's record is summarized at transfer and provided to the care team receiving the patient. Such a summary includes the reason for admission, significant findings, diagnosis, procedures performed, medications and other treatments, and the patient's condition at transfer.

Measurable Elements of ACC.3.2

- 1. The patient's record or a summary of patient care information is transferred with the patient to another service or unit in the hospital.
- ☐ 2. The summary contains the reason for admission.
- ☐ 3. The summary contains the significant findings.

4. The summary contains any diagnosis made.
5. The summary contains any procedures performed.
6. The summary contains any medications and other treatments.
7. The summary contains the patient's condition at transfer.

Discharge, Referral, and Follow-Up

Standard ACC.4

Intent of ACC.4

Referring or discharging a patient to a health care practitioner outside the hospital, another care setting, home, or family is based on the patient's health status and need for continuing care or services. The patient's physician or individual responsible for his or her care must determine readiness for discharge based on the policies and relevant criteria or indications of referral and discharge established by the hospital. Criteria may also be used to indicate when a patient is ready for discharge. Continuing needs may mean referral to a medical specialist, rehabilitation therapist, or even preventive health needs coordinated in the home by the family. An organized process is required to ensure that any continuing needs are met by appropriate health care practitioners or outside organizations. The process includes referring patients to sources of care outside the region when required. When indicated, the hospital begins to plan for the continuing needs as early in the care process as possible. The family is included in the discharge planning process as appropriate to the patient and his or her needs. (*Also see* AOP.1.8) There is a process to guide when the hospital permits patients to leave the hospital for a period of time (such as on a weekend "pass").

Measurable Elements of ACC.4

- 1. Patients are referred and/or discharged based on their health status and needs for continuing care.
- 2. The patient's readiness for discharge is determined by the use of relevant criteria or indications that ensure patient safety.
- ☐ 3. Planning for referral and/or discharge begins early in the care process.
- 4. There is a process for patients being permitted to leave the hospital during the planned course of treatment on an approved pass for a defined period of time.

Standard ACC.4.1

Patient and family education and instruction are related to the patient's continuing care needs.

Intent of ACC.4.1

The hospital routinely provides education in areas that carry high risk to patients. Education supports the return to previous functional levels and maintenance of optimal health.

The hospital uses standardized materials and processes in educating patients on at least the following topics:

- Safe and effective use of all medications taken by the patient (not just discharge medications), including potential medication side effects
- Safe and effective use of medical technology

- Potential interactions between prescribed medications and other medications (including over-the-counter preparations) and food
- Diet and nutrition
- Pain management
- Rehabilitation techniques

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- 1. Patients and families are educated about the safe and effective use of all medications, potential side effects of medications, and prevention of potential interactions with over-the-counter medications and/or food. 2. Patients and families are educated about safe and effective use of medical technology.
- 3. Patients and families are educated about proper diet and nutrition.
- 4. Patients and families are educated about pain management.
- 5. Patients and families are educated about rehabilitation techniques.

Standard ACC.4.2

The hospital cooperates with health care practitioners and outside agencies to ensure timely referrals.

Intent of ACC.4.2

Timely referral to the practitioner, organization, or agency that can best meet the patient's continuing needs takes planning. The hospital becomes familiar with the health care practitioners in its community to understand the types of patients treated and services provided and to build formal or informal relationships with those practitioners. When patients come from a different community, the hospital attempts to make a referral to a qualified individual or agency in the patient's home community.

Also, patients may need support services and medical services at discharge. For example, patients may need social, nutritional, financial, psychological, or other support at discharge. The availability and actual use of these support services may, to a large degree, determine the need for continuing medical services. The discharge planning process includes the type of support service needed and the availability of such services.

Measurable Elements of ACC.4.2

- 1. The discharge planning process includes the need for both support services and continuing medical services.
- 2. Referrals outside the hospital are to specific individuals and agencies in the patient's home community whenever possible.
- ☐ 3. Referrals are made for support services.

Standard ACC.4.3

The complete discharge summary is prepared for all inpatients.

Intent of ACC.4.3

The discharge summary provides an overview of the patient's stay within the hospital. The summary can be used by the practitioner responsible for providing follow-up care. The summary includes the following:

- Reason for admission, diagnoses, and comorbidities
- Significant physical and other findings
- Diagnostic and therapeutic procedures performed

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

Measurable Elements of ACC.4.3

- 1. The discharge summary contains the reason(s) for admission, diagnoses, and comorbidities.
- ☐ 2. The discharge summary contains significant physical and other findings.
- ☐ 3. The discharge summary contains diagnostic and therapeutic procedures performed.
- 4. The discharge summary contains significant medications, including discharge medications.
- 5. The discharge summary contains the patient's condition/status at the time of discharge.
- ☐ 6. The discharge summary contains follow-up instructions.

Standard ACC.4.3.1

Patient education and follow-up instructions are given in a form and language the patient can understand.

Intent of ACC.4.3.1

For patients not directly referred or transferred to another health care practitioner, clear instructions on where and how to receive continuing care are essential to ensure optimal outcomes of care and that all care needs are met. The instructions include the name and location of sites for continuing care, any return to the hospital for follow-up, and when urgent care should be obtained. Families are included in the process when a patient's condition or abilities prevent him or her from understanding the follow-up instructions. Families are also included when they play a role in the continuing care process. The hospital provides the instructions to the patient and, as appropriate, his or her family in a simple, understandable manner. The instructions are provided in writing or in the form most understandable to the patient when the patient is not able to understand written instructions.

Measurable Elements of ACC.4.3.1

- 1. Follow-up instructions are provided in writing and in a form and language the patient can understand.
- ☐ 2. The instructions include any return for follow-up care.
- ☐ 3. The instructions include when to obtain urgent care.

Standard ACC.4.3.2

The clinical records of inpatients contain a copy of the discharge summary.

Intent of ACC.4.3.2

A summary of the patient's care is prepared at discharge from the hospital. Any qualified individual can compile the discharge summary, such as the patient's physician, a house officer, or a clerk.

A copy of the discharge summary is provided to the practitioner who will be responsible for the continuing or follow-up care of the patient. A copy is given to the patient when indicated by hospital or by common practice consistent with laws and culture. In cases in which details of a patient's follow-up care are unknown, such as with patients who are visiting from a different region or country, a copy of the discharge summary is given to the patient. The copy of the discharge summary is placed in the patient's record.

Measurable Elements of ACC.4.3.2

- ☐ 1. A discharge summary is prepared by a qualified individual.
- 2. A copy of the discharge summary is provided to the practitioner responsible for the patient's continuing or follow-up care.
- 3. A copy of the discharge summary is provided to the patient in cases in which information regarding the practitioner responsible for the patient's continuing or follow-up care is unknown.
- 4. A copy of the completed discharge summary is placed in the patient's record in a time frame identified by the hospital.

Standard ACC.4.4

Intent of ACC.4.4

When the hospital provides ongoing care and treatment for outpatients with complex diagnoses and/or who need complex care (**for example**, patients seen several times for multiple problems, multiple treatments, in multiple clinics, and/or the like), there may be an accumulated number of diagnoses and medications and an evolving clinical history and physical examination findings. It is important for any health care practitioner in all settings providing care to that outpatient to have access to information about the care being provided.

The process for providing this information to health care professionals includes

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

Measurable Elements of ACC.4.4

- ☐ 1. The hospital identifies the types of outpatients receiving complex care and/or with complex diagnoses who require an outpatient profile.
- ☐ 2. The information to be included in the outpatient profile is identified by the clinicians who treat those patients.
- ☐ 3. The hospital uses a process that will ensure the outpatient profile is available in an easy to retrieve and review format.
- 4. The process is evaluated to see if it meets the needs of the clinicians and improves the quality and safety of outpatient clinical visits.

Standard ACC.4.5

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

Standard ACC.4.5.1

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

Intent of ACC.4.5 and ACC.4.5.1

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

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

The hospital designs this process to be consistent with applicable laws and regulations. When applicable, the hospital reports cases of infectious disease and provides information regarding patients who may harm themselves or others to local and national health authorities as required.

Measurable Elements of ACC.4.5

_	1.	medical advice.
	2.	The process includes informing the patient of the medical risks of inadequate treatment.
	3.	The patient should be discharged according to the hospital discharge process.
	4.	If the family physician of a patient leaving against medical advice is known and has not been involved in the process, the physician is notified.
	5.	The hospital has a process to try to identify the reasons for patients leaving against medical advice.
	6.	The process is consistent with applicable laws and regulations, including requirements for reporting cases of infectious disease and cases in which patients may be a threat to themselves or others.
Me	ası	urable Elements of ACC.4.5.1
	1.	There is a process for the management of inpatients and outpatients who leave the hospital against medical advice without notifying hospital staff.
	2.	There is a process for the management of outpatients receiving complex treatment who do not return for treatment.
	3.	If the family physician is known and has not been involved in the process, the physician is notified.
	4.	The process is consistent with applicable laws and regulations, including requirements for reporting cases of infectious disease and cases in which patients may be a threat to themselves or others.

Transfer of Patients

Standard ACC.5

Patients are transferred to other organizations based on status, the need to meet their continuing care needs, and the ability of the receiving organization to meet patients' needs.

Intent of ACC.5

Transferring a patient to an outside organization is based on the patient's status and need for continuing health care services. Transfer may be in response to a patient's need for specialized consultation and treatment, urgent services, or less-intensive services, such as subacute care or longer-term rehabilitation. Criteria help to identify when a transfer is necessary in order to ensure that the patient's needs are met.

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

Measurable Elements of ACC.5

- ☐ 1. Transfers of patients are based on criteria developed by the hospital to address patients' needs for continuing care.
- 2. The referring hospital determines that the receiving organization can meet the needs of the patient to be transferred.
- 3. Formal or informal arrangements are in place with receiving organizations when patients are frequently transferred to the same organization(s).

Standard ACC.5.1

The referring hospital develops a transfer process to ensure that patients are transferred safely.

Intent of ACC.5.1

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

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

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

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

Measurable Elements of ACC.5.1

- ☐ 1. The hospital develops a transfer process that addresses how responsibility for continuing care is moved to another practitioner or setting.
- 2. The transfer process identifies who is responsible for monitoring the patient during transfer and the staff qualifications required for the type of patient being transferred.
- ☐ 3. The transfer process identifies the medications, supplies, and medical technology required during transport.
- 4. The transfer process addresses a follow-up mechanism that provides information about the patient's condition upon arrival to the receiving organization.
- 5. The transfer process addresses the situations in which transfer is not possible.
- ☐ 6. There is a process to evaluate the quality and safety of the transfer process.

Standard ACC.5.2

The receiving organization is given a written summary of the patient's clinical condition and the interventions provided by the referring hospital.

Intent of ACC.5.2

To ensure continuity of care, patient information is transferred with the patient. A copy of the discharge summary or other written clinical summary is provided to the receiving organization with the patient. The summary includes the patient's clinical condition or status, the procedures and other interventions provided, and the patient's continuing needs.

Measurable Elements of ACC.5.2

- 1. A patient clinical summary document is transferred with the patient.
- ☐ 2. The clinical summary includes patient status.
- □ 3. The clinical summary includes procedures and other interventions provided.
- 4. The clinical summary includes the patient's continuing care needs.

Standard ACC.5.3

The transfer process is documented in the patient's record.

Intent of ACC.5.3

The record of each patient transferred to another health care organization contains documentation of the transfer. The documentation includes the name of the organization and the name of the individual agreeing to receive the patient, the reason(s) for the transfer, and any special conditions for transfer (such as when space at the receiving organization is available, or the patient's status). Also, it is noted if the patient's condition or status changed during transfer (**for example**, the patient dies or requires resuscitation). Any other documentation required by hospital policy (**for example**, a signature of the receiving nurse or physician, the name of the individual who monitored the patient during transport) is included in the record.

Measurable Elements of ACC.5.3

1. The records of transferred patients note the name of the receiving health care organization and the name of the individual agreeing to receive the patient.

2.	The records of transferred patients contain documentation or other notes as required by the policy of the transferring hospital.
3.	The records of transferred patients note the reason(s) for transfer.
4.	The records of transferred patients note any special conditions related to transfer.

Transportation

Standard ACC.6

Intent of ACC.6

The hospital's process for referring, transferring, or discharging patients includes an understanding of the transportation needs of patients. For example, patients from long term care facilities or rehabilitative centers needing outpatient services or evaluation in the emergency department may arrive by ambulance or other medical vehicle. Upon completion of the service, the patient may require assistance with transportation back to his or her home or another facility. In other situations, patients may drive themselves to the hospital for a procedure that impairs their ability to drive themselves home (such as eye surgery, a procedure that requires sedation, and the like). Assessing the patient's transportation needs and ensuring that the patient has safe transportation is the hospital's responsibility. Depending on hospital policy and the laws and regulations of the region, the cost of the transportation may or may not be the responsibility of the hospital.

The type of transportation will vary and may be by ambulance or other vehicles owned by the hospital or by a source designated by the family, or the family and/or friends may provide the transportation. The transportation selected will depend on the patient's condition and status.

When the transport vehicles are owned by the hospital, they need to be in compliance with all applicable laws and regulations related to their operation, condition, and maintenance. The hospital identifies the transportation situations that have a risk of infection and implements strategies to reduce infection risk. (Also see PCI.7; PCI.7.1; PCI.7.1.1; PCI.7.2; PCI.7.3; PCI.8, ME 1; and PCI.9) The required drugs, medications, and other supplies needed within the vehicle are based on the types of patients transported. For example, simply taking geriatric patients home from outpatient visits is very different than transferring an infectious disease or burn patient to another hospital.

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

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

Measurable Elements of ACC.6

1.	There is an assessment of transportation needs when any patient is referred to another source of care,
	transferred to another care setting, or ready to go home following an inpatient admission or outpatient
	visit.

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3.	Transport vehicles owned by the hospital meet relevant laws and regulations related to their operation
	condition, and maintenance.

- 4. Transportation services, including contracted services, meet the hospital's requirements for quality and safe transport.
- 5. All vehicles used for transportation, contracted or hospital owned, comply with the infection control program and have appropriate medical technology, supplies, and medications to meet the needs of the patient being transported.
- 6. There is a process in place to monitor the quality and safety of transportation provided or arranged by the hospital, including a complaint process.

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Patient and Family Rights (PFR)

Changes to the PFR Chapter

Standard	Change	Explanation
PFR.1.1	Renumbered	Moves requirement from ACC.1.3 (4th edition)
PFR.1.2	Renumbered; Requirement change	Renumbers and combines requirements of PFR.1.1 and PFR.1.1.1 (4th edition); rewords standard and MEs to clarify requirements
PFR.1.3	Renumbered; Requirement change	Renumbers and combines requirements of PFR.1.2 and PFR.1.6 (4th edition); incorporates PFR.1.6, MEs 1 and 3 (4th edition), into new PFR.1.3, ME 3 to streamline and clarify requirements
PFR.1.4	Renumbered	Moves requirement from PFR.1.3 (4th edition)
PFR.1.5	Requirement change	Combines PFR.1.4 and PFR.1.5 (4th edition) and revises MEs to consolidate and clarify requirements
PFR.2	No significant change	Adds minor revisions to intent and MEs to clarify expectations regarding the hospital's support of the patient's right to seek a second medical opinion
PFR.2.1	Requirement change	Combines PFR.2.1 and PFR.2.1.1 (4th edition) and revises MEs to consolidate and clarify requirements
PFR.2.2	Requirement change	Combines PFR.2.2 and PFR.2.3 (4th edition) and revises MEs to consolidate and clarify requirements
PFR.2.3	Requirement change	Combines and renumbers PFR.2.4 and PFR.2.5 (4th edition) and revises MEs to consolidate and clarify requirements
PFR.4	Renumbered	Renumbers PFR.5 (4th edition)
PFR.5	Renumbered; Requirement change	Renumbers PFR.6.3 (4th edition) and adds an ME on informing patients and families about tests and treatments that require informed consent
PFR.5.1	Renumbered; Requirement change	Renumbers PFR.6 (4th edition) and adds two MEs regarding patients learning about the informed consent process in a manner and language they understand and uniform recording of informed consent
PFR.5.2	Renumbered; Requirement change	Combines and renumbers PFR.6.4 and PFR.6.4.1 (4th edition) and removes two MEs
PFR.5.3	Renumbered	Moves requirement from PFR.6.1 (4th edition)
PFR.5.4	Renumbered	Moves requirement from PFR.6.2 (4th edition)

Standard	Change	Explanation
PFR.6	Renumbered; Requirement change	Moves requirement from PFR.10 (4th edition), revises intent for clarity, and adds two MEs to further emphasize the need to ensure patient and family rights regarding organ and tissue donation
PFR.6.1	Renumbered; Requirement change	Moves requirement from PFR.11 (4th edition), revises intent for clarity, and removes and adds MEs to clarify requirements regarding organ and tissue procurement

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standard appeared in this chapter of the 4th edition standards but was deleted from this edition (listed with 4th edition numbers): PFR.4.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Standard PFR.1

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

Output

Description:

Intent of PFR.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 their 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.

The hospital respects the right of patients, and in some circumstances the right of the patient's family, to have the prerogative to determine 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.

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

Measurable Elements of PFR.1

- Hospital leadership works to protect and to advance patient and family rights.
- 2. Hospital leadership understands patient and family rights as identified in laws and regulations and in relation to the cultural practices of the community or individual patients served.
- 3. The hospital respects the right of patients, and in some circumstances the right of the patient's family, to have the prerogative to determine what information regarding their care would be provided to family or others, and under what circumstances.
- 4. All staff are knowledgeable about patient rights and can explain their responsibilities in protecting patient rights.

Standard PFR.1.1

The hospital seeks to reduce physical, language, cultural, and other barriers to access and delivery of services.

Intent of PFR.1.1

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. The hospital has identified those barriers and has implemented processes to eliminate or to reduce them for patients seeking care. The hospital also takes action to reduce the impact of these barriers on the delivery of services. (*Also see* COP.1, PFE.2.1, and GLD.12)

Measurable Elements of PFR.1.1

- ☐ 1. The department/service leaders and staff of the hospital identify the most common barriers in its patient population.
- ☐ 2. The department/service leaders develop and implement a process to overcome or limit barriers for patients seeking care.
- ☐ 3. The department/service leaders develop and implement a process to limit the impact of barriers on the delivery of services.

Standard PFR.1.2

The hospital provides care that is respectful of the patient's personal values and beliefs and responds to requests related to spiritual and religious beliefs.

Intent of PFR.1.2

Each patient brings his or her own set of values and beliefs to the care process. 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.

Strongly held values and beliefs can shape the care process and how patients respond to care. Thus, each health care practitioner seeks to understand the care and services he or she provides 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, 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 PFR.1.2

- ☐ 1. Patients' values and beliefs are identified.
- 2. Staff provide care that is respectful of the patient's values and beliefs.
- □ 3. The hospital responds to routine as well as complex requests related to religious or spiritual support.

Standard PFR.1.3

The patient's rights to privacy and confidentiality of care and information are respected.

Output

Intent of PFR.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. 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 does not need to be documented.

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 the patient 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.

The hospital has a policy that indicates if patients have access to their health information and the process to gain access when permitted.

Measurable Elements of PFR.1.3

 Staff members identify patient expectations and needs for privacy during car 	are and treatment.
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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. (Also see MOI.2 and MOI.7)
- 4. Patients are requested to grant permission for the release of information not covered by laws and regulations.

Standard PFR.1.4

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

Intent of PFR.1.4

The hospital communicates its responsibility, if any, for the patient's possessions to patients and families. When the hospital takes responsibility for any or all of the patient's personal possessions brought into the hospital, there is a process to account for the possessions and to ensure that they will not be lost or stolen. This process considers the possessions of emergency patients, same-day surgery patients, inpatients, those patients unable to make alternative safekeeping arrangements, and those incapable of making decisions regarding their possessions. (*Also see* FMS.4.1)

Measurable Elements of PFR.1.4

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

Standard PFR.1.5

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

Intent of PFR.1.5

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

Each hospital identifies its at-risk patient groups (such as children, disabled individuals, the elderly) and establishes processes to protect the rights of individuals in these groups. Vulnerable patient groups and the hospital's responsibility may be identified in laws and regulations. Staff members understand their responsibilities in these processes. Children, disabled individuals, the elderly, and other identified populations at risk are protected. Comatose patients and individuals with mental or emotional disabilities are also included. Such protection extends beyond physical assault to other areas of safety, such as abuse, negligent care, withholding of services, or providing assistance in the event of a fire. (Also see FMS.4.1 and FMS.7)

Measurable Elements of PFR.1.5

1.	The host	pital (develor	s and in	plements a	process to	protect all	patients fr	om assault.

	2.	Vulnerable	populations	that are at	additional	risks	are identified
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3.	The hospital develops and implements a process to protect vulnerable populations from other safet
	issues.

4. Remote or isolated areas of the facility are monitor	」 .	4 Remo	ate or isolated	areas of the	facility are	monitore
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	5	Staff members	understand	their re	snonsibilities	in the	protection	nrocesses
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Standard PFR.2

The hospital supports patients' and families' rights to participate in the care process.

O

Intent of PFR.2

Patients and families participate in the care process by making decisions about care, asking questions about care, requesting a second opinion, and even refusing diagnostic procedures and treatments. 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 their 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. (*Also see* COP.7.1, ME 5)

Measurable Elements of PFR.2

	1.	The hospital	supports and	promotes	patient and	family	partici	pation	in care	processes
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2.	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.

3. Staff members are trained on the policies and procedures and their role in supporting patient and family participation in care processes.

Standard PFR.2.1

Patients are informed about all aspects of their medical care and treatment.

Intent of PFR.2.1

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 on the proposed care and treatment. During the care process patients also have a right to be told of the outcomes of the planned care and treatment. In addition, it is important that they be told of any unanticipated outcomes of the care and treatment, such as unanticipated events during surgery or with prescribed medications or other treatments.

Patients and families understand that they have a right to this information and who is responsible for telling them. Patients and families understand the type of decisions that must be made about care and how to participate in those decisions. In addition, patients and families need to understand the hospital's process to obtain consent and which care processes, tests, procedures, and treatments require their consent.

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.

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.

Measurable Elements of PFR.2.1

1.	Patients are informed of their medical conditions and any confirmed diagnosis.
2.	Patients are informed of the planned care and treatment(s).

- 3. Patients are told when informed consent will be required and the process used to give consent.
- 4. Patients are informed about the expected outcomes of care and treatment.
- ☐ 5. Patients are informed about any unanticipated outcomes of care and treatment.
- Patients and families are informed about their right to participate in care decisions to the extent they wish.

Standard PFR.2.2

Intent of PFR.2.2

Patients, or those making decisions on their behalf, may decide not to proceed with the planned care or treatment or to continue 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 professionals 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, in particular 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 professionals 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 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 PFR.2.2

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.

	5.	The hospital	informs	patients	about	available	care and	treatment	alternatives.
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6.	The hospital guides health professionals on the ethical and legal considerations in carrying out patient
	wishes regarding treatment alternatives.

Standard PFR.2.3

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

Intent of PFR.2.3

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 the assessment and management of a patient's unique needs at the end of life. (Also see COP.7)

Measurable Elements of PFR.2.3

				l management of	

2.	The hospital respects and supports the patient's right to assessment and management of the dying
	patient's needs.

3.	The hospital's staff understand the personal, cultural, and societal influences on the patient's experiences with pain.
4.	The hospital's staff understand the personal, cultural, and societal influences on the patient's experiences with death and dying.

Standard PFR.3

Intent of PFR.3

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. (Also see SQE.11)

Measurable Elements of PFR.3

- 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.

Standard PFR.4

All patients are informed about their rights and responsibilities in a manner and language they can understand.

Intent of PFR.4

Admission as an inpatient or registration as an outpatient to a health care hospital can be frightening and confusing for patients, making it difficult for them to act on their rights and to understand their responsibilities in the care process. Thus, the hospital prepares a written statement of patient and family rights and responsibilities that is given to patients when they are admitted as inpatients or registered as outpatients to the hospital and is available each visit or throughout their stay. **For example**, the statement may be posted in the facility.

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 PFR.4

- 1. Information about patient rights and responsibilities is provided in writing to each patient.
- 2. The statement of patient rights and responsibilities is posted or otherwise available from staff at all times.
- 3. The hospital has a process to inform patients of their rights and responsibilities when written communication is not effective or appropriate.

General Consent

Standard PFR.5

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

Intent of PFR.5

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. Patients are also given information about those tests and treatments for which a separate informed consent will be obtained. The general consent notes if it is likely that students and trainees will participate in care processes. The hospital defines how a general consent is documented in the patient's record.

Measurable Elements of PFR.5

- 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 record.
- ☐ 3. Patients and families are informed about which tests and treatments require informed consent. (Also see PFR.5.1)

Informed Consent

Standard PFR.5.1

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

Intent of PFR.5.1

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. (Also see PFR.5, ME 3 and GLD.18)

Measurable Elements of PFR.5.1

- 1. The hospital develops and implements a clearly defined informed consent process.
- Designated staff are trained in the process.

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.

Standard PFR.5.2

Intent of PFR.5.2

When the planned care includes surgical or invasive procedures, anesthesia, procedural sedation, use of blood and blood products, or other high-risk treatments or procedures, a separate consent is obtained (also see ASC.3, ASC.3.3, ASC.5.1, and ASC.7.1). This consent process provides the information identified in PFR.5.3 and documents the identity of the individual providing the information. (Also see COP.8.5 and COP.9.1)

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

Measurable Elements of PFR.5.2

1.	Consent is obtained before 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.	
6.	The identity of the individual providing the information to the patient and family is noted in the patient's record.	

Standard PFR.5.3

Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.

Intent of PFR.5.3

Staff members clearly explain any proposed treatment(s) or procedures to the patient and the family. The information provided includes

- a) the patient's condition;
- b) the proposed treatment(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; and
- h) possible results of nontreatment. (Also see PFR.5.2)

Staff members also 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 procedures or treatment(s). Frequently, patients have questions about their primary care practitioners' experience, length of time with the hospital, and the like. The hospital needs to have a process to respond when patients request additional information about their primary care practitioners.

Measurable Elements of PFR.5.3

- ☐ 1. Patients are informed of elements a) through h) in the intent as relevant to their condition and planned treatment.
- 2. Patients know the identities of the physicians or other practitioners responsible for their care.
- 3. The hospital develops and implements a process to respond to a patient's request for additional information on the practitioner responsible for his or her care.

Standard PFR.5.4

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

Intent of PFR.5.4

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 record.

Measurable Elements of PFR.5.4

- 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 record.

Organ Donation

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 PFR.6

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

Standard PFR.6.1

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

Intent of PFR.6 and PFR.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. (Also see COP.9)

requirements.

of transplants.

implement choices to donate.

Me	as	urable Elements of PFR.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.
		urable Elements of PFR.6.1 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

3. Staff are trained in the contemporary issues and concerns related to organ donation and the availability

4. The hospital cooperates with relevant hospitals and agencies in the community to respect and to

Assessment of Patients (AOP)

Changes to the AOP Chapter

Standard	Change	Explanation
AOP.1	Requirement change	Adds requirements from AOP.1.1 (4th edition) to better align similar requirements; rewords standard, intent, and MEs for clarity
AOP.1.1	Renumbered; No significant change	Moves requirement from AOP.1.2 (4th edition) and adds text to intent to emphasize the need for health professionals to work together for effective patient assessment
AOP.1.2 and AOP.1.2.1	Renumbered; Requirement change	Renumbers AOP.1.3 and AOP.1.3.1 (4th edition) and incorporates requirements from AOP.1.4.1 and AOP.1.5 (4th edition) to better align similar standards; rewords standards, intents, and MEs for clarity
AOP.1.3	Renumbered; Requirement change	Renumbers AOP.1.4 (4th edition) and adds new language to standard, intent, and MEs requiring that the patient's medical history and physical examination be repeated if the initial assessment performed in an outpatient setting is greater than 30 days at the time of inpatient admission or outpatient procedure in the hospital
AOP.1.3.1	Renumbered; Requirement change	Moves requirement from AOP.1.5.1 and adds new language to standard, intent, and MEs to clarify the term <i>preoperative assessment</i> and describe the scope of the assessment, which includes the patient's medical, physical, psychological, spiritual/cultural, and discharge needs
AOP.1.4	Renumbered; Requirement change	Renumbers AOP.1.6 (4th edition) and incorporates requirements of AOP.1.10 (4th edition) to emphasize that patients should be screened for special needs (such as dental and vision) in addition to nutritional and functional needs
AOP.1.5	Renumbered	Renumbers AOP.1.7 (4th edition) and adds examples of screening questions to intent; rewords intent and MEs to clarify requirements
AOP.1.6	Renumbered; Requirement change	Renumbers AOP.1.8 (4th edition) and rewords ME 1 to clarify that the hospital needs to identify in writing which special patient populations require modified assessments; adds ME 3 to include language on local laws and regulations and professional standards, and their importance to the assessment process for special-needs populations
AOP.1.7	Renumbered	Renumbers AOP.1.9 (4th edition)
AOP.1.8	Renumbered; Requirement change	Renumbers AOP.1.11 (4th edition); adds text to intent and adds ME 3 to emphasize the need to identify and address special educational needs as part of discharge planning

Standard	Change	Explanation
AOP.2	Requirement change	Adds text to intent to clarify and add examples of non-acute patients who may not need daily physician assessments; combines ME 1 and ME 2 (4th edition)
AOP.3	Requirement change	Combines ME 1 and ME 5 (4th edition)
AOP.4	Requirement change	Incorporates standard AOP.4.1 (4th edition) to consolidate similar requirements and eliminates AOP.4.1, ME 2 (4th edition)
AOP.5	Requirement change	Incorporates standard AOP.5.11 (4th edition) and adds ME 4 regarding the hospital's ability to identify and contact experts in specialized diagnostic areas; combines ME 3 (4th edition) with ME 2 and clarifies expectation
AOP.5.1	Renumbered	Moves requirement from AOP.5.8 (4th edition)
AOP.5.2	Requirement change	Rewords standard, intent, and MEs to emphasize the need for all laboratory staff members to have the required education, training, qualifications, and experience; revises MEs to clarify requirements, including the need for a staffing plan to provide laboratory staffing during all hours of operation and during emergencies
AOP.5.3	Renumbered; Requirement change	Moves requirement from AOP.5.1 (4th edition) and revises standard, intent, and MEs to make a more direct association between the laboratory safety program and compliance with facility management and infection control programs
AOP.5.3.1	New standard	Establishes a new standard to emphasize the need to reduce special risks for laboratory staff related to infection control and biohazards
AOP.5.4	Renumbered	Renumbers AOP.5.3 (4th edition)
AOP.5.5	Renumbered; Requirement change	Renumbers AOP.5.4 and consolidates and rewords MEs for clarity of expectations
AOP.5.6	Renumbered	Moves requirement from AOP.5.5 (4th edition)
AOP.5.7	Renumbered; No significant change	Renumbers AOP.5.6 (4th edition) and inserts language specifically calling for "established and implemented" procedures for collecting, identifying, handling, transporting, and disposing of specimens
AOP.5.8	Renumbered	Renumbers AOP.5.7 (4th edition)
AOP.5.9 and AOP.5.9.1	Requirement change	Revises MEs to consolidate and clarify expectations; introduces a new ME 2 in AOP.5.9.1 regarding satisfactory performance of the laboratory's proficiency testing results in accordance with laws and regulations
AOP.5.10 and AOP.5.10.1	Requirement change; New standard	Expands AOP.5.10 (4th edition) and adds new standard AOP.5.10.1 to detail requirements for reference (contract) laboratories used by the hospital
AOP.5.11	New standard	Introduces a new standard specific to blood bank and transfusion services

Standard	Change	Explanation
AOP.6	Requirement change	Incorporates requirements of AOP.6.1 and AOP.6.10 (4th edition), including moving the requirement regarding the hospital's ability to contact experts in specialized diagnostic areas when needed to ME 3; combines ME 3 (4th edition) with ME 2 and clarifies expectations
AOP.6.1	Renumbered	Moves requirement from AOP.6.7 (4th edition) for better chapter flow
AOP.6.2	Renumbered	Renumbers AOP.6.3 (4th edition)
AOP.6.3	Renumbered; Requirement change	Renumbers AOP.6.2 (4th edition) and adds new language to standard, intent, and MEs regarding compliance with the facility management and infection control programs; eliminates MEs 3 and 4 (4th edition) and combines MEs 6 and 7 (4th edition)
AOP.6.5	Requirement change	Rewords MEs to clarify requirements; adds language specifying that manufacturers' recommendations should be followed when inspecting, testing, calibrating, and maintaining radiology equipment; incorporates ME 7 (4th edition) into ME 1
AOP.6.7	Renumbered; Requirement change	Renumbers AOP.6.8 (4th edition) and adds text to the MEs to emphasize the need for documentation as it relates to the quality control program for radiology and diagnostic imaging services
AOP.6.8	Renumbered	Renumbers AOP.6.9 (4th edition)

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a Θ icon after the standard text.

Standards, Intents, and Measurable Elements Standard AOP.1

Intent of AOP.1

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

- 1) Collecting information and data on the patient's physical, psychological, and social status, and his or her health history
- 2) Analyzing the data and information, including the results of laboratory and imaging diagnostic tests, to identify the patient's health care needs
- 3) Developing a plan of care to meet the patient's identified needs

When a patient has been registered or admitted to a hospital for inpatient or outpatient care/treatment, a complete assessment needs to be performed related to the reason(s) the patient has come for care. The specific

information the hospital requires at this stage, and the procedures for getting it, depend on the patient's needs and the setting in which care is being provided (**for example**, inpatient or outpatient care). Hospital policies and procedures define how this process functions and what information needs to be gathered and documented. (*Also see* ACC.1)

To consistently assess patient needs, the hospital defines, in policies, the minimum content of assessments to be performed by physicians, nurses, and other clinical disciplines. Assessments are performed by each discipline within its scope of practice, licensure, applicable laws and regulations, or certification. Only qualified individuals conduct the assessments. Any assessment forms used for assessments reflect this policy. The hospital defines assessment activities in both inpatient and outpatient settings in which care is provided. (Also see ASC.3.2, ME 1 and ASC.4, ME 1) The hospital defines those elements common to all assessments and defines any differences, when permitted, in the scope of general medical and specialty services assessments. The assessment defined in policy may be completed by more than one qualified individual and at different points in time. All the content must be available when treatment is initiated. (Also see AOP.1.2 and AOP.1.2.1)

Measurable Elements of AOP.1

- 1. The minimum content of assessments for inpatients is defined for each clinical discipline that performs assessments and specifies the required elements of the history and physical examination.
- 2. The minimum content of assessments for outpatients is defined for each clinical discipline that performs assessments and specifies the required elements of the history and physical examination.
- 3. Only qualified individuals permitted by licensure, applicable laws and regulations, or certification perform the assessment. (Also see SQE.10)
- 4. The hospital identifies the information to be documented for the assessments.

Standard AOP.1.1

Intent of AOP.1.1

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

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

To provide this information, the initial assessment includes an evaluation of the patient's medical status through a physical examination and health history. The psychological assessment determines the patient's emotional status (**for example**, if he or she is depressed, fearful, or belligerent and may harm him- or herself or others). Gathering social information on a patient is not intended to "classify" patients. Rather, a patient's social, cultural, family, and economic contexts are important factors that can influence his or her response to illness and treatment. Families can be very helpful in these areas of assessment and in understanding the patient's wishes and preferences in the assessment process. Economic factors are assessed as part of the social assessment or assessed separately when the patient and his or her family will be responsible for the cost of all or a portion of the care while an inpatient or following discharge. Many different qualified individuals may be involved in the assessment of a patient. The most important factors are that the assessments are complete and available (*also see* ACC.3, ME 2) to those caring for the patient.

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

professionals responsible for the patient work together. (*Also see* COP.8.4; COP.8.7; COP.9.2; and MOI.10, ME 2)

Measurable Elements of AOP.1.1

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

- 2. Each patient receives an initial psychological assessment as indicated by his or her needs.
- 3. Each patient receives an initial social and economic assessment as indicated by his or her needs.
- 4. The initial assessment results in an initial diagnosis.

Standard AOP.1.2

Standard AOP.1.2.1

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

Intent of AOP.1.2 and AOP.1.2.1

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

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

In an emergency, the initial medical and nursing assessments may be limited to the patient's apparent needs and condition. Also, when there is no time to record the complete history and physical examination of an emergency patient requiring surgery, a brief note and the preoperative diagnosis are recorded before surgery. (Also see MOI.10.1, ME 3)

Measurable Elements of AOP.1.2

1.	The initial medical assessment, including health history, physical exam, and other assessments required
	by the patient's condition, is performed and documented within the first 24 hours of admission as an
	inpatient or sooner as required by patient condition.

Ц	2.	The initial	l medical	assessment	results in	a list o	t spec1t	ic medic	al diagnoses	that include	s primary	and
		associated	l conditio	ns requiring	g treatmen	t and n	nonitor	ing.				

3.	The initial nursing assessment is performed and documented within the first 24 hours of admission as
	an inpatient or sooner as required by patient condition.

4.	The initial nursing assessment results in a list of specific patient nursing needs or conditions that requir	e
	nursing care, interventions, or monitoring.	

Measurable Elements of AOP.1.2.1

- ☐ 1. The medical assessment of emergency patients is based on their needs and condition and documented in the patient record.
- ☐ 2. The nursing assessment of emergency patients is based on their needs and condition and documented in the patient record.
- 3. Before surgery is performed, there is a brief note and preoperative diagnosis documented for emergency patients requiring emergency surgery. (Also see ASC.7)

Standard AOP.1.3

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

Intent of AOP.1.3

When the initial medical assessment is conducted in a physician's private office or other outpatient setting prior to care in the hospital as an inpatient, it must be within the previous 30 days. If at the time of admission as an inpatient the medical assessment is greater than 30 days old, the medical history must be updated and the physical examination repeated. For medical assessments performed and documented 30 days or less prior to admission, any significant changes in the patient's condition since the assessment are noted at admission. This updating and/or reexamination can be accomplished by any qualified individual. (Also see AOP.1.2 and AOP.1.2.1 regarding the time frame and documentation requirements for initial assessments conducted in the hospital)

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

Measurable Elements of AOP.1.3

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

Standard AOP.1.3.1

A preoperative assessment is documented before anesthesia or surgical treatment and includes the patient's medical, physical, psychological, and spiritual/cultural needs.

Intent of AOP.1.3.1

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

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

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

Measurable Elements of AOP.1.3.1

- 1. Patients for whom surgery is planned have a preoperative assessment performed before the surgery.
- ☐ 2. The preoperative assessment includes the patient's medical, physical, psychological, spiritual/cultural, and discharge needs.
- ☐ 3. The preoperative assessment of surgical patients is documented in the patient record before surgery.

Standard AOP.1.4

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

Intent of AOP.1.4

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

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

In each case, the screening criteria are developed by qualified individuals able to further assess and, if necessary, to provide any required patient treatment. **For example**, screening criteria for nutritional risk may be developed by nurses who will apply the criteria, dietitians who will supply the recommended dietary intervention, and nutritionists able to integrate nutritional needs with the other needs of the patient. (*Also see* COP.4 and COP.5)

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

Measurable Elements of AOP.1.4

INIE	:a5	urable Elements of AOP.1.4
	1.	Qualified individuals develop and implement criteria to identify patients who require further nutritional assessment.
	2.	Patients at risk for nutritional problems receive a nutritional assessment.
	3.	Qualified individuals develop and implement criteria to identify patients who require further functional assessment.
	4.	Patients in need of a functional assessment are referred for such an assessment.
	5.	When the need for additional specialized assessments is identified, patients are referred within the hospital or outside the hospital.

6. Specialized assessments conducted within the hospital are completed and documented in the patient's record.

Standard AOP.1.5

All inpatients and outpatients are screened for pain and assessed when pain is present.

Intent of AOP.1.5

During the initial assessment and during any reassessments, a screening procedure is used to identify patients with pain. **Examples** of questions that may be used in a screening exam include the following:

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

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

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

Measurable Elements of AOP.1.5

- ☐ 1. Patients are screened for pain.
- 2. When pain is identified from the initial screening exam, a comprehensive assessment of the patient's pain is performed.
- 3. The assessment is recorded in a way that facilitates regular reassessment and follow-up according to criteria developed by the hospital and the patient's needs.

Standard AOP.1.6

The hospital conducts individualized initial assessments for special populations cared for by the hospital.

Output

Description:

Intent of AOP.1.6

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

- Children
- Adolescents
- Frail elderly
- Terminally ill/dying patient
- Patients with intense or chronic pain
- Women in labor
- Women experiencing terminations in pregnancy

- Patients with emotional or psychiatric disorders
- Patients suspected of drug and/or alcohol dependency
- Victims of abuse and neglect
- Patients with infectious or communicable diseases
- Patients receiving chemotherapy or radiation therapy
- Patients whose immune systems are compromised

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

Measurable Elements of AOP.1.6

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

Standard AOP.1.7

Dying patients and their families are assessed and reassessed according to their individualized needs.

Intent of AOP.1.7

Assessments and reassessments need to be individualized to meet patients' and families' needs when patients are at the end of life. Assessments and reassessments should evaluate, as indicated by the patient's condition,

- a) such symptoms as nausea and respiratory distress;
- b) factors that alleviate or exacerbate physical symptoms;
- c) current symptom management and the patient's response;
- d) patient and family spiritual orientation and, as appropriate, any involvement in a religious group;
- e) patient and family spiritual concerns or needs, such as despair, suffering, guilt, or forgiveness;
- f) patient and family psychosocial status, such as family relationships, the adequacy of the home environment if care is provided there, coping mechanisms, and the patient's and family's reactions to illness;
- g) the need for support or respite services for the patient, family, or other caregivers;
- h) the need for an alternative setting or level of care; and
- i) survivor risk factors, such as family coping mechanisms and the potential for pathological grief reactions.

Measurable Elements of AOP.1.7

- ☐ 1. Dying patients and their families are assessed and reassessed for those elements in a) through i) of the intent, according to their identified needs.
- 2. Assessment findings guide the care and services provided. (Also see AOP.2, ME 2)
- ☐ 3. Assessment findings are documented in the patient record.

Standard AOP.1.8

The initial assessment includes determining the need for discharge planning.

Intent of AOP.1.8

Continuity of care requires special preparation and considerations for some patients, such as for discharge planning. The hospital develops a mechanism, such as a list of criteria, to identify those patients for whom discharge planning is critical due to age, lack of mobility, continuing medical and nursing needs, or assistance with activities of daily living, among others. As arrangements for discharge may take some time, the assessment process and planning process are initiated as soon as possible after admission as an inpatient. (*Also see* ACC.4)

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

Measurable Elements of AOP.1.8

- 1. There is a process to identify those patients for whom discharge planning is critical.
- 2. Planning for discharge for these patients begins soon after admission as inpatients.
- ☐ 3. Discharge planning includes identifying special educational needs and developing and implementing a plan to address those needs.

Standard AOP.2

Intent of AOP.2

Reassessment by all the patient's health care practitioners is key to understanding whether care decisions are appropriate and effective. Patients are reassessed throughout the care process at intervals based on their needs and plan of care or as defined in hospital policies and procedures. The results of these reassessments are noted in the patient's record for the information and use of all those caring for the patient. (Also see ACC.3)

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

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

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

Some non-acute patients may not need daily physician assessments; **for example**, a stable psychiatric patient receiving group therapy sessions, or a patient who is past the acute phase of illness or surgery and who is receiving only rehabilitative treatment. The hospital identifies, in writing, those patients who do not require daily assessments.

Measurable Elements of AOP.2

- 1. Patients are reassessed to determine their response to treatment and plan for continued treatment and/or discharge. (Also see COP.5, ME 3; ASC.6.1; and MMU.7, ME 1)
- 2. Patients are reassessed at intervals based on their condition and when there has been a significant change in their condition, plan of care, or individual needs. (*Also see* AOP.1.7, ME 2)

ш	3.	A physician reassesses patients at least daily, including weekends, during the acute phase of their care and treatment.
	4.	For non-acute patients, the hospital defines, in writing, the circumstances in which, and the types of patients or patient populations for which, a physician's assessment may be less than daily and identifies the minimum reassessment interval for these patients.
	5.	Reassessments are documented in the patient record.

Intent of AOP.3

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

Measurable Elements of AOP.3

- Individuals qualified to conduct patient assessments and reassessments are identified and have their responsibilities defined in writing. (Also see SQE.1.1, ME 2)
- 2. Only those individuals permitted by licensure, applicable laws and regulations, or certification perform patient assessments.
- ☐ 3. Emergency assessments are conducted by individuals qualified to do so.
- 4. Nursing assessments are conducted by individuals qualified to do so.

Standard AOP.4

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

Intent of AOP.4

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

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

Measurable Flements of AOP 4

1.	Patient assessment data and information are analyzed and integrated.
2.	Those responsible for the patient's care participate in the process.

☐ 3. Patient needs are prioritized based on assessment results.

Laboratory Services

Standard AOP.5

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

Intent of AOP.5

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

Laboratory services, including those required for emergencies, may be provided within the hospital, by agreement with another organization, or both. Laboratory services are available after normal hours for emergencies. In addition, the hospital is able to identify and to contact experts in specialized diagnostic areas, such as parasitology, virology, or toxicology, when needed.

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

Measurable Elements of AOP.5

٦.	1	Laboratory	certices me	et applicable loca	Land national	l etandarde	lawe and	regulations
_	1.	Laboratory	SCI VICCS IIIC	et annucabie ioca	i anu nauona	i stanuarus.	iaws, aiiu	ice manons.

- 2. Laboratory services are available to meet the needs related to the hospital's mission and patient population, the community's health care needs, and emergency needs, including after normal hours.
- ☐ 3. Experts in specialized diagnostic areas are contacted when needed.
- 4. Outside sources are selected based on an acceptable record and compliance with laws and regulations.
- 5. Patients are informed about any relationships between the referring physician and outside sources of laboratory services. (*Also see* GLD.12.1, ME 1)

Standard AOP.5.1

A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service. ®

Intent of AOP.5.1

Clinical laboratory services are under the direction of an individual who is qualified by virtue of documented training, expertise, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the laboratory facility and the services provided in the laboratory as well as tests performed outside the laboratory, such as the testing performed at bedside (point-of-care testing). The oversight of services outside the laboratory includes ensuring consistent hospitalwide policies and practices, such as training and supply management, among others. It does not include daily supervision of those activities. Daily supervision remains the responsibility of the leaders of the department or unit in which the testing is conducted.

When this individual provides clinical consultation or medical opinion, he or she is a physician, preferably a pathologist. Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals. Responsibilities of the laboratory leader include

developing, implementing, and maintaining policies and procedures;

- administrative oversight;
- maintaining any necessary quality control program;
- recommending outside sources of laboratory services; and
- monitoring and reviewing all laboratory services.

Measurable Elements of AOP.5.1

	1.	The cl	inical lab	orato	ry, and	d oth	ier lab	oratory	y servic	es thre	ough	out the l	nospital	, are unc	der the	direc	ction
		and ov	ersight o	of one	or m	ore c	qualific	ed indi	viduals.	(Also	see G	LD.9, N	IE 1)				
_	_	-	., .,						,							~	

]	2.	Responsibilities for developing,	implementing, and	l maintaining policies	and procedures a	re defined and
		carried out.				

	3.	Responsibilities	for	administrative	oversight a	re defined	and	carried	out.
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- 4. Responsibilities for maintaining quality control programs are defined and carried out.
- 5. Responsibilities for recommending reference (contract) laboratory services are defined and carried out. (Also see GLD.6, ME 4 and GLD.6.1, ME 3)
- Responsibilities for monitoring and reviewing all laboratory services within and outside the laboratory are defined and carried out.

Standard AOP.5.2

All laboratory staff have the required education, training, qualifications, and experience to administer and perform the tests and interpret the results.

Intent of AOP.5.2

The hospital identifies the education, training, qualifications, and experience of laboratory staff members performing and interpreting laboratory tests, those who are approved to perform point-of-care screening tests at the bedside, and those who direct or supervise staff who perform testing. Supervisory staff and technical staff are oriented to their work. Technical staff are given work assignments consistent with their training and experience. In addition, the laboratory implements a staffing program that allows staff to perform tests promptly and to ensure laboratory staffing during all hours of operation and for emergencies. (Also see SQE.4)

Measurable Elements of AOP.5.2

	1	All laboratory sta	ff have the requir	ed credentials to	administer	norform or	d interpret tests
_	Ι.	All laboratory sta	ff have the requir	ed credentials to	o administer.	perform, ar	ia interpret tests.

2.	Staff performing point-of-care testing have the required qualifications and training to administer
	point-of-care tests.

3.	A staffing program is implemented that allows staff to perform tests promptly and to provide staffing
	during all hours of operation and during emergencies.

L		l. 1	Laboratory	v supervisor	v staff are	e identified	land h	nave the 1	proper o	malifications a	and experience
_	-		Laborator	y supervisor	y starr arc	. ideiidiida	andi	iave tire p	proper q	quantications i	and experience.

Standard AOP.5.3

Intent of AOP.5.3

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

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

The laboratory safety management program includes

- compliance with standards addressing facility management and infection control programs;
- compliance with local and regional laws and regulations;
- availability of safety devices appropriate to the laboratory's practices and hazards encountered;
- the orientation of all laboratory staff to safety procedures and practices; and
- in-service education for new procedures and newly acquired or recognized hazardous materials. (Also see PCI.5, FMS.4, FMS.4.1, and FMS.5)

Measurable Elements of AOP.5.3

- 1. A laboratory safety program addresses potential safety risks in the laboratory and other areas outside the laboratory where laboratory services are provided.
- 2. The program is part of the hospital's facility management and infection control programs and reports to the hospital safety structure at least annually and when any safety events occur.
- 3. Identified safety risks are addressed by specific processes and/or devices to reduce the safety risks.
- 4. Laboratory staff are oriented to safety procedures and practices and receive ongoing education and training for new practices and procedures. (*Also see* FMS.11, ME 1; GLD.9, ME 4; and SQE.8, MEs 3 and 4)

Standard AOP.5.3.1

Intent of AOP.5.3.1

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

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

When problems with practice are identified, or accidents occur, corrective actions are taken, documented, and reviewed.^{1–5} (*Also see* PCI.7.2)

Measurable Elements of AOP.5.3.1

☐ 1. The laboratory has a defined process for reducing the risks of infection.

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

Intent of AOP.5.4

The hospital defines the time period for reporting laboratory test results. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergency tests and after-hours and weekend testing needs are included. Results from urgent tests, such as those from the emergency department, operating theatres, and intensive care units, are given special attention in the quality measurement process. In addition, when laboratory services are by contract with an outside organization, the reports are also timely, as set forth by hospital policy or the contract. (*Also see* IPSG.2.1)

Measurable Elements of AOP.5.4

- ☐ 1. The hospital has established the expected report time for results.
- ☐ 2. The timeliness of reporting of urgent/emergency tests is measured.
- 3. Laboratory results are reported within a time frame to meet patient needs. (Also see ASC.7, ME 1)

Standard AOP.5.5

All equipment and medical technology used for laboratory testing is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities. $^{\textcircled{D}}$

Intent of AOP.5.5

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

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

Testing, maintenance, and calibration frequency are related to the laboratory's use of its equipment and medical technology and its documented history of service. (Also see FMS.8 and FMS.8.1)

Measurable Elements of AOP.5.5

- ☐ 1. The laboratory develops, implements, and documents a program to manage laboratory equipment and medical technology.
- ☐ 2. The program identifies how laboratory equipment and medical technology are selected and acquired.
- 3. There is a documented inventory of all laboratory equipment and medical technology.

4.	Laboratory equipment and medical technology are inspected and tested when new and according to age, use, and manufacturers' recommendations thereafter and the inspections are documented.
5.	Laboratory equipment and medical technology are calibrated and maintained according to manufacturers' recommendations, and the calibration and maintenance are documented.
6.	The hospital has a system in place for monitoring and acting on laboratory equipment and medical technology hazard notices, recalls, reportable incidents, problems, and failures

Intent of AOP.5.6

The hospital has identified those reagents and supplies necessary to regularly provide laboratory services to its patients. A process to order or to secure those essential reagents and other supplies is effective. All reagents are stored and dispensed according to defined procedures. The evaluation of all reagents ensures accuracy and precision of results. Written guidelines ensure the complete and accurate labeling of reagents and solutions and the accuracy and precision of all results. (Also see AOP.5.9 and FMS.5)

Measurable Elements of AOP.5.6

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

Standard AOP.5.7

Procedures for collecting, identifying, handling, safely transporting, and disposing of specimens are established and implemented. $^{\textcircled{p}}$

Intent of AOP.5.7

Procedures are established and implemented for

- ordering tests;
- collecting and identifying specimens;
- transporting, storing, and preserving specimens; and
- receiving, logging in, and tracking specimens.

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

Measurable Elements of AOP.5.7

- 1. Procedures are established and implemented for the ordering of tests.
- 2. Procedures are established and implemented for the collection and identification of specimens. (*Also see* IPSG.1, ME 3)
- ☐ 3. Procedures are established and implemented for the transport, storage, and preservation of specimens.

4.	Procedures are	established	and imp	plemented	for the	receipt ar	nd tracking	of spec	imens.

5.	The pr	rocedures	are followed	ed when	reference	(contract) laborator	y services	are used.

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

Intent of AOP.5.8

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

Measurable Elements of AOP.5.8

,	aboratory has established reference ranges for each test performed.

	2.	The range	is	included	in	the	clinical	record	at th	ne time	test	results	are	report	ed.
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☐ 3. Ranges are furnished when tests are p	performed by reference	(contract) laboratory	services.
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- 4. Ranges are appropriate to the hospital's geography and demographics.
- ☐ 5. Ranges are reviewed and updated as needed.

Standard AOP.5.9

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

Standard AOP.5.9.1

There is a process for proficiency testing of laboratory services.

Intent of AOP.5.9 and AOP.5.9.1

Well-designed quality control systems are essential to providing excellent pathology and clinical laboratory services. Quality control procedures include

- validation of the test methods used for accuracy, precision, and reportable range;
- daily surveillance of results by qualified laboratory staff;
- testing of reagents (also see AOP.5.6);
- rapid corrective action when a deficiency is identified; and
- documentation of results and corrective actions.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognized by internal mechanisms. Thus, the laboratory participates in an approved proficiency-testing program when available. Alternatively, when approved programs are not available, the laboratory exchanges samples with a laboratory in another organization for purposes of peer comparison testing. The laboratory maintains a cumulative record of participation in a proficiency-testing process. Proficiency testing, or an alternative, is carried out for all specialty laboratory programs when available. (*Also see* AOP.5.10 and GLD.11)

Measurable Elements of AOP.5.9

- ☐ 1. The hospital establishes and implements a quality control program for the clinical laboratory.
- 2. The program includes the validation of test methods.

3.	The program includes the daily surveillance and documentation of test results.
4.	The program includes testing of reagents.
5.	The program includes rapid correction and documentation of deficiencies.
	The laboratory participates in a proficiency-testing program, or an alternative, for all specialty laboratory services and tests.
2.	For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with laws and regulations.
3.	The laboratory maintains records of its participation in a proficiency-testing program.

Reference (contract) laboratories used by the hospital are licensed, accredited, or certified by a recognized authority.

Standard AOP.5.10.1

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

Intent of AOP.5.10 and AOP.5.10.1

When the hospital uses the services of a reference laboratory (also know as a *contract laboratory*)—whether for select tests or to provide all laboratory services—the following information is required:

- a) A copy of a license from a recognized licensing authority
- b) A copy of the certificate or letter of accreditation or certification from a recognized laboratory accreditation or certification program*
- c) Documentation that the reference (contract) laboratory participates in an outside proficiency-testing program (*Also see* AOP.5.9.1)

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

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

Measurable Elements of AOP.5.10

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

Measurable Elements of AOP.5.10.1

☐ 1. The frequency and type of performance expectation data from reference laboratories are determined by the hospital.

2.	The qualified individual responsible for the laboratory or a qualified designee reviews the performance expectation data from reference laboratories.
3.	The responsible individual or qualified designee takes action based on the results.
4.	An annual report of the data from reference laboratories is provided to hospital leadership to facilitate management of contracts and contract renewals.

Blood Bank and/or Transfusion Services

Standard AOP.5.11

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

Intent of AOP.5.11

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

- a) blood donor selection;
- b) blood collection;
- c) blood storage;
- d) compatibility testing; and
- e) blood distribution.

Quality control processes for all blood bank services are established, implemented, and documented to ensure the safety of blood bank and transfusion services. Blood donor and transfusion services are guided by laws and regulations and recognized standards of practice.^{2,6–16}

Measurable Elements of AOP.5.11

- ☐ 1. A qualified individual is responsible for blood bank and/or transfusion services. (Also see COP.3.3, ME 1 and GLD.9, ME 1)
- ☐ 2. The blood bank has established, implemented, and documented processes for a) through e) of the intent. (Also see COP.3.3, ME 2)
- ☐ 3. Quality control measures are in place for all blood bank and transfusion services and are established, implemented, and documented.
- 4. The blood bank and transfusion services comply with applicable laws and regulations and recognized standards of practice.

Radiology and Diagnostic Imaging Services

Standard AOP.6

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

Intent of AOP.6

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

Radiology and diagnostic imaging services, including those required for emergencies, may be provided within the hospital, by agreement with another organization, or both. Radiology and diagnostic imaging services are available after normal hours for emergencies. In addition, the hospital can identify and contact experts in specialized diagnostic areas, such as radiation physics, radiation oncology, or nuclear medicine, when necessary. The hospital maintains a roster of such experts.

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

Measurable Elements of AOP.6

1.	Radiology and	diagnostic	imaging	services	meet	applicable	local	and 1	national	standards,	laws,	and
	regulations.											

- 2. Adequate, regular, and convenient radiology and diagnostic imaging services are available to meet the needs related to the hospital's mission and patient population, the community's health care needs, and emergency needs, including after normal hours.
- ☐ 3. The hospital contacts experts in specialized diagnostic areas when needed.
- 4. Outside sources are selected based on recommendations of the laboratory leader and an acceptable record of timely performance and compliance with applicable laws and regulations.
- 5. Patients are informed about any relationships between the referring physician and outside sources of radiology and/or diagnostic imaging services. (Also see GLD.12.1, ME 1)

Standard AOP.6.1

A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services. ®

Intent of AOP.6.1

Radiology and diagnostic imaging services, provided at any location in the hospital, are under the direction of an individual who is qualified by documented education, training, expertise, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the radiology and diagnostic imaging facility and the services provided. When this individual provides clinical consultation or medical opinion, he or she is a physician, preferably a radiologist. When radiation therapy or other special services are provided, they are under the direction of appropriately qualified individuals.

The radiology and diagnostic imaging leader's responsibilities include

- developing, implementing, and maintaining policies and procedures;
- administrative oversight;
- maintaining any necessary quality control program;
- recommending outside sources of radiology and diagnostic imaging services; and
- monitoring and reviewing all radiology and diagnostic imaging services. (Also see GLD.9)

Measurable Elements of AOP.6.1

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

2.	Responsibilities for developing, implementing, and maintaining policies and procedures are defined and carried out.
3.	Responsibilities for administrative oversight are defined and carried out.
4.	Responsibilities for maintaining quality control programs are defined and carried out.
5.	Responsibilities for recommending outside sources of radiology and diagnostic imaging services are defined and carried out. (Also see GLD.6, ME 4)
6.	Responsibilities for monitoring and reviewing all radiology and diagnostic imaging services are defined and carried out.

Individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results.

Intent of AOP.6.2

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

Measurable Elements of AOP.6.2

 Juo	diable Element of Alexander
1.	Those individuals who perform diagnostic and imaging studies or direct or supervise the studies are identified.
2.	Staff with proper qualifications and experience perform diagnostic and imaging studies.
3.	Staff with proper qualifications and experience interpret study results.
4.	Properly qualified staff verify and report the results of studies.
5.	There is an adequate number of staff to meet patient needs. (Also see GLD.9, ME 2 and SQE.6, ME 2)
6.	Supervisory staff have proper qualifications and experience.

Standard AOP.6.3

Intent of AOP.6.3

The hospital has an active radiation safety program that includes all components of the hospital's radiology and diagnostic imaging services, including radiation oncology and the cardiac catheterization laboratory. The radiation safety program reflects the risks and hazards encountered. The program addresses safety practices and prevention measures for radiology and diagnostic imaging staff, other staff, and patients. The program is coordinated with the hospital's safety management program.

The radiation safety management program includes

- compliance with applicable standards, laws, and regulations;
- compliance with standards addressing facility management and infection control programs;
- availability of safety protective devices appropriate to the practices and hazards encountered;

- the orientation of all radiology and diagnostic imaging staff to safety procedures and practices; and
- in-service education for new procedures and newly acquired or recognized hazardous materials. (*Also see* FMS.4, FMS.4.1, and FMS.5)

Measurable Elements of AOP.6.3

- 1. A radiation safety program is in place that addresses potential safety risks and hazards encountered within or outside the department.
- ☐ 2. The safety program is part of the hospital's facility management and infection control programs, and the program provides reports to the hospital safety structure at least annually and when any safety events occur.
- ☐ 3. Identified radiation safety risks are addressed by specific processes or devices that reduce safety risks (such as lead aprons, radiation badges, and the like).
- 4. Radiology and diagnostic imaging staff are oriented to safety procedures and practices and receive ongoing education and training for new procedures, equipment, and medical technology. (*Also see* FMS.11.1, ME 1; GLD.9, ME 4; and SQE.8, MEs 3 and 4)

Standard AOP.6.4

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

Intent of AOP.6.4

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

Measurable Elements of AOP.6.4

- 1. The hospital has established the expected report time for results.
- ☐ 2. The timeliness of reporting of urgent/emergency studies is measured.
- 3. Radiology and diagnostic imaging study results are reported within a time frame to meet patient needs. (Also see ASC.7, ME 1)

Standard AOP.6.5

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

Intent of AOP.6.5

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

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

documenting the management program.

Testing, maintenance, and calibration frequency are related to the use of the equipment and medical technology and its documented history of service. (Also see FMS.8 and FMS.8.1)

Measurable Elements of AOP.6.5

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

Standard AOP.6.6

X-ray film and other supplies are regularly available.

Intent of AOP.6.6

The hospital has identified the film, reagents, and supplies necessary to regularly provide radiology and diagnostic imaging services to its patients. A process to order or to secure essential film, reagents, and other supplies is effective. All supplies are stored and dispensed according to defined procedures that incorporate the manufacturers' recommendations. The periodic evaluation of reagents according to manufacturers' recommendations ensures accuracy and precision of results. (Also see AOP.6.8 and FMS.5)

Measurable Elements of AOP.6.6

- ☐ 1. Essential x-ray film, reagents, and supplies are identified.
- ☐ 2. Essential x-ray film, reagents, and supplies are available.
- ☐ 3. All supplies are stored and dispensed according to guidelines.
- 4. All supplies are periodically evaluated for accuracy and results.
- 5. All supplies are completely and accurately labeled.

Standard AOP.6.7

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

Output

Description:

Intent of AOP.6.7

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

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

Measurable Elements of AOP.6.7

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

Standard AOP.6.8 (clarification)

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

Intent of AOP.6.8

When the hospital uses outside sources of radiology and diagnostic imaging services, it regularly receives and reviews the quality control results for those outside sources. Qualified individuals review the quality control results. When diagnostic imaging quality control of outside sources is difficult to obtain, the department/service leader develops an alternative approach for quality oversight. (Also see AOP.6.6)

Measurable Elements of AOP.6.8

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

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Care of Patients (COP)

Changes to the COP Chapter

Standard	Change	Explanation
COP.1	No significant change	Rewords standard and MEs minimally for clarity
COP.2.1	Requirement change	Revises text of standard and intent and adds examples of measurable goals to intent; revises MEs to clarify expectations, including removing ME 3 and ME 5 (4th edition), combining ME 6 and ME 7 (4th edition), and adding new ME 4 and ME 5
COP.2.2	Requirement change	Rewrites standard and adds text to intent for clarity; revises ME 1 to emphasize the need for a uniform process for prescribing patient orders
COP.2.3	Requirement change	Adds text to standard, intent, and MEs for clarity; adds new ME 2 to require that the person requesting, and the reason for requesting, the procedure or treatment are documented in the patient's record
COP.3	Requirement change	Eliminates multiple, individual standards by incorporating the following standards from the 4th edition: COP.3.1, COP.3.2, COP.3.4, COP.3.5, COP.3.6, COP.3.7, COP.3.8, and COP.3.9; rewrites ME 2 and adds MEs 4 and 5 to more clearly identify expectations for the care of high-risk patients in the hospital
COP.3.1	New standard	Introduces new requirement for staff training to recognize and respond to changes in a patient's condition
COP.3.2	New standard	Adds new requirement to emphasize the need for resuscitation services to be available and consistent throughout the hospital
COP.3.3	Requirement change	Revises intent and MEs to emphasize the need for a qualified individual and clinical guidelines and procedures to guide the safe and consistent handling, use, and administration of blood and blood products
COP.4	Requirement change	Adds ME 4 from COP.4.1 (4th edition) to emphasize the need for timely distribution of food and honoring special requests
COP.5	No significant change	Adds minimal text to intent for clarity; incorporates ME 4 (4th edition) into ME 3
COP.6	Requirement change	Adds text to intent to clarify expectations; adds ME 2 on communication with patients regarding potential pain from planned treatments, procedures, or examinations

Standard	Change	Explanation
COP.8– COP.9.3	New standards	Introduces several standards to emphasize the need for safety and quality of organ and tissue transplant services

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standard appeared in this chapter of the 4th edition standards but was deleted from this edition (listed with 4th edition numbers): COP.2.4.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Care Delivery for All Patients

Standard COP.1

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

Intent of COP.1

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

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

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

Measurable Elements of COP.1

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

Standard COP.2

There is a process to integrate and to coordinate the care provided to each patient.

Intent of COP.2

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

The patient's record facilitates and reflects the integration and coordination of care. In particular, each practitioner records observations and treatments in the patient's record. Also, any results or conclusions from collaborative patient care team meetings or similar patient discussions are written in the patient's record. (Also see AOP.4)

Measurable Elements of COP.2

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- 2. Care delivery is integrated and coordinated among settings, departments, and services.
- ☐ 3. The results or conclusions of any patient care team meetings or other collaborative discussions are documented in the patient's record.

Standard COP.2.1

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

Intent of COP.2.1

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

The planning process is collaborative and uses the data from the initial assessment and from periodic reassessments performed by physicians, nurses, and other health care practitioners to identify and to prioritize the treatments, procedures, nursing care, and other care to meet the patient's needs.^{1–4} The patient and family are involved in the planning process with the health care team.^{2,4,5} The plan of care is developed within 24 hours of admission as an inpatient. Based on the reassessment of the patient performed by the patient's health care practitioners, the plan of care is updated as appropriate to reflect the evolving condition of the patient. The plan of care is documented in the patient's record.

The plan of care for a patient must be related to his or her identified needs. Those needs may change as the result of clinical improvement or new information from a routine reassessment (**for example**, abnormal laboratory or radiography results), or they may be evident from a sudden change in the patient's condition (**for example**, loss of consciousness) (also see COP.8.7 and COP.9.3). The plan of care is revised based on these changes and is documented in the record as notes to the initial plan, or they may result in a new plan of care.

One method of developing care plans is to identify and establish measurable goals. Measurable goals can be selected by the responsible physician in collaboration with the nurse and other health care practitioners. Measurable goals are observable, achievable targets related to patient care and expected clinical outcomes. They must be realistic, specific to the patient, and time-based to provide a means for measuring progress and outcomes related to the plan of care. **Examples** of measurable, realistic goals include the following:

• The patient will resume and maintain an adequate cardiac output as indicated by a heart rate, rhythm, and blood pressure that are within normal limits.

- The patient will demonstrate proper self-administration of insulin injections prior to hospital discharge.
- The patient will be able to walk from his bed to the visitor lounge with a standard walker, bearing weight as tolerated on the affected leg.

Note: A single, integrated plan of care that identifies measurable goals expected by each health care practitioner is preferable. It is good practice for the plan of care to reflect individualized, objective, and measurable goals to facilitate reassessment and revision of the plan of care. (*Also see* PFE.4)

Measurable Elements of COP.2.1

- 1. The care for each patient is planned by the responsible physician, nurse, and other health care practitioners within 24 hours of admission as an inpatient.
- 2. The plan of care is individualized based on the patient's initial assessment data and identified needs.
- 3. The plan of care is updated or revised and reviewed by the multidisciplinary team based on the reassessment of the patient by the health care practitioners.
- 4. The initial plan of care and any revisions to the plan of care are documented in the patient's record.
- 5. The plan of care for each patient is reviewed when initially developed and when revised based on changes in the patient's condition by the multidisciplinary team and documented in the patient's record.
- 6. The planned care is provided for each patient and documented in the patient's record by the health professional providing the care. (*Also see* COP.2.3; ASC.3; ASC.5; and MOI.10.1, ME 4)

Standard COP.2.2

The hospital develops and implements a uniform process for prescribing patient orders.

Output

Description:

Intent of COP.2.2

Many patient care activities require a qualified individual to prescribe an order for that activity that must be documented in the patient record. Such activities may include, **for example**, orders for laboratory testing, administration of medications, specific nursing care, nutrition therapy, rehabilitative therapy, and the like. Patient care activities requiring orders are ordered by individuals qualified to do so. Such orders must be easily accessible if they are to be acted on in a timely manner. Locating orders on a common sheet or in a uniform location in patient records facilitates the carrying out of orders. Documented orders help staff understand the specifics of an order, when the order is to be carried out, and who is to carry out the order. Orders can be written on an order sheet that is transferred to the patient's record periodically or at discharge, or a computerized order entry system may be used in hospitals that are using electronic patient records.

Each hospital decides

- which orders must be written/documented rather than verbal;
- which diagnostic imaging and clinical laboratory test orders must provide a clinical indication/rationale;
- any exceptions in specialized settings, such as emergency departments and intensive care units;
- who is permitted to prescribe orders; and
- where orders are to be located in the patient record. (*Also see* IPSG.2, MMU.4, MMU.4.1, MMU.4.2, MMU.4.3, MOI.10, and MOI.11)

Measurable Elements of COP.2.2

- ☐ 1. The hospital develops and implements a uniform process for prescribing patient orders.
- 2. Diagnostic imaging and clinical laboratory test orders include a clinical indication/rationale when required for interpretation.
- ☐ 3. Orders are prescribed only by those qualified to do so.
- 4. Orders are found in a uniform location in patient records.

Standard COP.2.3

Clinical and diagnostic procedures and treatments performed, and the results or outcomes, are documented in the patient's record.

Intent of COP.2.3

Clinical and diagnostic procedures and treatments performed, and the results or outcomes, are documented in the patient's record. **Examples** of such procedures and treatments include endoscopies, cardiac catheterization, radiation treatment, computerized tomography (CT) exams, and other invasive and noninvasive diagnostic procedures and treatments. Information about who requested the procedure or treatment and the reason for the procedure or treatment are included in the documentation. (*Also see* COP.2.1 and ASC.7.2)

Measurable Elements of COP.2.3

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

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

Standard COP.3

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

Intent of COP.3

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

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

Policies, guidelines, and procedures for managing the care of these patients are important tools for staff to understand and respond in a thorough, competent, and uniform manner. Hospital leadership is responsible for

- identifying the patients and services considered high risk in the hospital;
- using a collaborative process to develop guidelines and procedures for care; and
- training staff in implementing the guidelines and procedures.

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

• how planning will occur, including the identification of differences between adult and pediatric populations, or other special considerations;

- the documentation required for the care team to work and to communicate effectively;
- special consent considerations, if appropriate;
- patient-monitoring requirements;
- special qualifications or skills of staff involved in the care process; and
- the availability and use of specialized medical technology.

When serving any of the high-risk patients or providing any of the high-risk services identified below, the hospital establishes and implements guidelines and procedures for the services provided for and the patients served. (Also see PCI.8 and PCI.8.1) The high-risk services are for

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

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

Hospital leadership also identifies additional risk as the result of any procedures or plan of care (**for example**, the need to prevent deep vein thrombosis, decubitus ulcers, and ventilator-associated infections in patients on life support; neurological and circulatory injury in restrained patients; blood exposure in dialysis patients; central line infections; and falls). Such risks, when present, need to be addressed and prevented by educating staff and developing appropriate policies, guidelines, and procedures. (*Also see* PFR.5.2.) The hospital uses measurement information to evaluate the services provided to high-risk patients and integrates that information into the hospital's overall quality improvement program.

Measurable Elements of COP.3

- ☐ 1. Hospital leadership has identified the high-risk patients and services.
- 2. When high-risk services are provided by the hospital, leadership establishes and implements guidelines and procedures for those services and for the care of high-risk patients, for at least a) through i) of the intent. (Also see MOI.10.1, ME 4)
- 3. Staff have been trained and use the guidelines and procedures for care.
- 4. Hospital leadership identifies additional risks that may affect high-risk patients and services.
- □ 5. Evaluation of the high-risk services is included in the hospital's quality improvement program.

Recognition of Changes to Patient Condition

Standard COP.3.1

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

Intent of COP.3.1

Staff who do not work in critical care areas may not have adequate knowledge and training to assess and monitor patients with critical conditions. However, a significant number of patients outside of critical care areas experience critical inpatient events. Often, a patient will exhibit early warning signs (for example, a worsening of

vital signs or a subtle change in neurological status) shortly before experiencing significant clinical decline, resulting in a major event. The literature identifies physiological criteria that can assist staff in early detection of deteriorating patients.^{6–11} A majority of patients who experience cardiopulmonary or respiratory arrest demonstrate clinical deterioration prior to arrest. When staff are able to identify these patients early and request additional assistance from specially trained individuals, clinical outcomes improve.

All clinical staff require education and training to provide the knowledge and skills to recognize and intervene when patient assessments identify physiological signs that are outside of the normal range, indicating a potential for patient deterioration. Early response to changes in a patient's condition is critical to potentially preventing further deterioration. Hospitals that develop a systematic approach to early recognition and intervention of patients whose condition is deteriorating may reduce cardiopulmonary arrests and patient mortality. (Also see SQE.3)

Measurable Elements of COP.3.1

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

Resuscitation Services

Standard COP.3.2

Resuscitation services are available throughout the hospital.

Intent of COP.3.2

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

Successful resuscitation of patients in cardiopulmonary arrest is dependent on critical interventions, such as early defibrillation and accurate implementation of advanced life support.^{11–14} These services must be available to all patients, 24 hours a day, every day. Essential to providing these critical interventions is the quick availability of standardized medical technology, medications for resuscitation, and staff properly trained in resuscitation.¹⁴ Basic life support must be implemented immediately upon recognition of cardiac or respiratory arrest, and a process must be in place for providing advanced life support in fewer than 5 minutes. This could include reviews of actual in-hospital resuscitations as well as mock cardiac arrest response training. Resuscitation services available within the hospital, including medical technology and properly trained staff, must be based on clinical evidence and the population served (**for example**, if the hospital has a pediatric population, medical technology for pediatric resuscitation must be available). (*Also see* ASC.3, ME 4; SQE.8.1; GLD.9, ME 2; and FMS.8)

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

Measurable Elements of COP.3.2

- ☐ 1. Resuscitation services are available and provided to all patients 24 hours a day, every day, throughout all areas of the hospital.
 - 2. Medical technology for resuscitation and medications for basic and advanced life support are standardized and available for use based on the needs of the population served.
- 3. In all areas of the hospital, basic life support is implemented immediately upon recognition of cardiac or respiratory arrest, and advanced life support is implemented in fewer than 5 minutes.

Standard COP.3.3

Intent of COP.3.3

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

- a) procurement of blood from the blood bank or blood storage area;
- b) patient identification;
- c) blood administration;
- d) monitoring of the patient; and
- e) identification and response to signs of potential transfusion reactions.

An individual with the education, knowledge, and expertise to oversee the blood and blood products administration ensures that processes, procedures, and clinical guidelines for transfusions are defined and implemented.^{15–18} (*Also see* QPS.8, ME 2)

Measurable Elements of COP.3.3

- ☐ 1. An individual with education, knowledge, and expertise oversees the administration of blood and blood products. (*Also see* AOP.5.11, ME 1)
- 2. Clinical guidelines and procedures are established and implemented for the handling, use, and administration of blood and blood products. (*Also see* AOP.5.11, ME 2)
- 3. Clinical guidelines and procedures address the processes for a) through e) in the intent.

Food and Nutrition Therapy

Standard COP.4

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

Intent of COP.4

Appropriate food and nutrition are important to patients' well-being and recovery. Food choices take into consideration the patient's age, cultural and dietary preferences, and planned care, which may include special dietary needs such as low cholesterol, diabetic diet, and clear liquids, depending on the patient's diagnosis. The patient participates in planning and selecting foods, and the patient's family may, when appropriate, participate in providing food, consistent with cultural, religious, and other traditions and practices and compatible with the patient's diagnosis. Based on the patient's assessed needs and plan of care, the patient's physician or other qualified caregiver orders food or other nutrients for the patient. When the patient's family or others provide food to the patient, they are educated about foods that are contraindicated according to the patient's care needs

and plans, including information about any medications associated with food interactions. When possible, patients are offered a variety of food choices consistent with their nutritional status. (*Also see* AOP.1.4)

Measurable Elements of COP.4

1.	A variety of food choices or nutrition, consistent with the patient's condition, care, and needs, is
	regularly available.
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2. Prior to patients being fed, all inpatients have orders for food in their
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- ☐ 3. The order is based on the patient's nutritional status and needs.
- 4. The distribution of food is timely, and special requests are met.
- □ 5. When families provide food, they are educated about the patients' diet limitations.

Standard COP.5

Patients at nutrition risk receive nutrition therapy.

Intent of COP.5

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

Measurable Elements of COP.5

- ☐ 1. Patients assessed at nutrition risk receive nutrition therapy.
- ☐ 2. A collaborative process is used to plan, to deliver, and to monitor nutrition therapy.
- 3. The patient's response to nutrition therapy is monitored and documented in the patient record. (Also see AOP.2, ME 1)

Pain Management

Standard COP.6

Patients are supported in managing pain effectively.

Intent of COP.6

Pain can be a common part of the patient experience and may be associated with the condition or illness for which the patient is being treated. Pain may also be an expected part of certain treatments, procedures, or examinations. As part of care planning, patients are informed about the likelihood of pain when it is an anticipated effect from treatments, procedures, or examinations and what options for pain management are available. Whatever the origin of pain, unrelieved pain has adverse physical and psychological effects. Thus, patients in pain have the right to appropriate assessment and management of pain. (Also see PFR.2.3 and AOP.1.5)

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

- a) identifying patients with pain during initial assessment and reassessments;
- b) providing information to patients about pain that may be an expected result of treatments, procedures, or examinations;

- c) providing management of pain, regardless of the origin of pain, according to guidelines or protocols and in conjunction with patient goals for pain management;
- d) communicating with and educating patients and families about pain and symptom management in the context of their personal, cultural, and religious beliefs; and
- e) educating health care practitioners about pain assessment and management.

Measurable Elements of COP.6

- 1. Based on the scope of services provided, the hospital has processes to identify patients in pain.
- 2. When pain is an expected result of planned treatments, procedures, or examinations, patients are informed about the likelihood of pain and options for pain management.
- ☐ 3. Patients in pain receive care according to pain management guidelines and according to patient goals for pain management.
- 4. Based on the scope of services provided, the hospital has processes to communicate with and to educate patients and families about pain.
- 5. Based on the scope of services provided, the hospital has processes to educate staff about pain.

End-of-Life Care

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

The hospital's goal for providing care at the end of life considers the settings in which care or service is provided (such as a hospice or palliative care unit), the type of services provided, and the patient population served. The hospital develops processes to manage end-of-life care. These processes

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

Standard COP.7

The hospital addresses end-of-life care.

Intent of COP.7

Patients who are dying have unique needs for respectful, compassionate care. To accomplish this, all staff are made aware of the unique needs of patients at the end of life. Concern for the patient's comfort and dignity should guide all aspects of care during the final stages of life. End-of-life care provided by the hospital includes

- a) providing appropriate treatment for any symptoms according to the wishes of the patient and family;
- b) sensitively addressing such issues as autopsy and organ donation;
- c) respecting the patient's values, religion, and cultural preferences;
- d) involving the patient and family in all aspects of care; and
- e) responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family.

To accomplish these goals, all staff are educated about the unique needs of patients and their families at the end of life. The hospital evaluates the quality of the end-of-life care provided by evaluating family and staff perceptions of the care provided. (Also see PFR.2.3)

Measurable Elements of COP.7

- 1. Staff are educated about the unique needs of patients and their families at the end of life.
- ☐ 2. End-of-life care provided by the hospital addresses dying patients' needs, at least including evaluation of elements a) through e) in the intent.
- ☐ 3. The quality of the end-of-life care is evaluated by family and staff.

Standard COP.7.1

Care of the dying patient optimizes his or her comfort and dignity.

Intent of COP.7.1

The hospital ensures appropriate care of those in pain or dying by

- taking interventions to manage pain and primary or secondary symptoms;
- preventing symptoms and complications to the extent reasonably possible;
- taking interventions that address patient and family psychosocial, emotional, and spiritual needs regarding dying and grieving;
- taking interventions that address patient and family religious and cultural concerns; and
- involving the patient and family in care decisions.

Measurable Elements of COP.7.1

- ☐ 1. Interventions are taken to manage pain and primary or secondary symptoms.
- ☐ 2. Symptoms and complications are prevented to the extent reasonably possible.
- ☐ 3. Interventions address patient and family psychosocial, emotional, and spiritual needs regarding dying and grieving.
- 4. Interventions address patient and family religious and cultural concerns.
- 5. The patient and family are involved in care decisions. (Also see PFR.2)

Hospitals Providing Organ and/or Tissue Transplant Services

Note: The following standards are intended to be used during those times when patients and/or families request information about organ and tissue donation and/or when organ/tissue procurement is performed. For hospitals providing organ and/or tissue transplant services, standards COP.8 through COP.9.3 apply. Please contact the JCI Accreditation Office with inquiries. **(errata)**

Transplantation of organs is often a lifesaving procedure, and organ and tissue transplants are sometimes the only options for treatment of a wide range of diseases. Recent advances in transplantation have led to a greater success rate for transplanted organs and tissues. ^{19,20} However, transplantation is not free from risk. Transmission of infections from the donor to the recipient is a well-documented safety concern. ^{21–24} Diseases with documented transmission from infected donors subsequent to transplant include, to name a few, HIV, hepatitis B and C, and Creutzfeldt-Jakob disease (CJD). ^{22–24} Recipients may also contract bacterial or fungal infections through contamination during transportation, storage, or handling. ^{23–25}

Leadership's commitment to creating a culture conducive to organ and tissue donation can have significant impact on the overall success of the hospital's organ and tissue procurement efforts. These standards address the hospital's organizationwide responsibilities for organ and tissue donation and procurement. This includes any individual who has been determined medically suitable for donation by the organ-procurement organization. If the hospital has the necessary resources to support the recovery of organs and tissues after cardiac death, non–heart-beating donors are included in the organ procurement effort.

Standard COP.8

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

Intent of COP.8

The organ/tissue transplant program requires staff with specialized education and training and other resources in order to provide safe, high-quality care. Staff education and training must be specific to the responsibilities and requirements of organ/tissue transplant. Other essential resources include supplies, patient rooms with ventilation required for the type of transplant procedure (for example, positive pressure ventilation), required pharmaceuticals for the type of transplant procedure, laboratory testing to ensure that tissue/organs are not contaminated, and other resources as identified by the program service leader. In addition, resources related to information management systems are necessary to assist with the collection of data associated with risks, outcomes, and other information that support the quality of the transplant program. (Also see GLD.1.1, ME 3; GLD.7; and GLD.9, ME 2)

Measurable Elements of COP.8

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

Standard COP.8.1

A qualified transplant program leader is responsible for the transplant program.

Intent of COP.8.1

The responsibility of a hospital offering organ and tissue transplant services is to provide safe, high-quality care to transplant donors and recipients. At the core of this responsibility is an infrastructure capable of supporting all transplant program activities. A key element of the infrastructure is an individual(s) responsible for oversight of the organ/tissue transplant program. Acting on a full-time or part-time basis, this individual(s) provides that oversight as part of his or her assigned responsibilities or job description. This individual(s) is qualified in transplant management through education, training, experience, licensure, and/or certification. The required qualifications depend on the activities carried out. (*Also see* GLD.9, ME 1)

Measurable Elements of COP.8.1

- 1. One or more individuals oversees the organ/tissue transplant program.
- 2. The individual(s) is qualified for the program's scope and complexity.
- ☐ 3. The individual(s) fulfills the program's oversight responsibilities as defined by the transplant program.

Standard COP.8.2

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

Intent of COP.8.2

The success of a transplant program and positive outcomes for transplant recipients and living donors as well are dependent on a team of health care providers who have clinical knowledge and expertise in organ-specific transplantation. The nursing, psychological, pharmacological, and nutritional needs of an organ recipient and a living organ donor are unique. As related to the type of transplant, a multidisciplinary team consists of individuals from

- medicine;
- nursing;
- nutrition;
- pharmacology;
- social services; and
- psychological services.

This team should have the qualifications, training, and experience to provide care and services to transplant recipients and living donors. (Also see GLD.9, ME 3)

Measurable Elements of COP.8.2

- ☐ 1. The transplant program documents the composition of the tissue/organ-specific transplant team.
- The transplant program documents the team members' responsibilities.
- ☐ 3. Based on the services provided by the transplant team, the team includes individuals experienced in medicine, nursing, nutrition, pharmacology, social services, psychological services, and transplant coordination.
- 4. The transplant program evaluates team members for qualifications, training, and experience at the time each individual is being considered for the transplant team.

Standard COP.8.3

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

Intent of COP.8.3

Transplant services carry unique and critical risks to organ/tissue recipients and, in the cases of living donors, to the donor as well. An important component in ensuring safe, high-quality care through all phases of the donor/recipient process is identifying an individual with overall responsibility for coordination and continuity of the live donor's and recipient's care. This individual may be a physician, registered nurse, or other qualified health care professional. (Also see ACC.3)

Measurable Elements of COP.8.3

1.	The individual responsible for the coordination of the live donor's and transplant recipient's care is
	identified and available through all phases of transplant care.

2.	The clinical transplant coordinator facilitates continuity of care for transplant patients (candidates and
	recipients) through the pre-transplant, transplant, and discharge phases of transplantation.

3.	The clinical transplant coordinator facilitates continuity of care for living donors during evaluation,
	donation, and discharge phases of donation.

4.	The coordination of organ/transplant activities is communicated to all staff involved in the transplan
	program activities.

Standard COP.8.4

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

Intent of COP.8.4

There are multiple areas for consideration when a decision needs to be made about allocating organs to recipients. Consideration may be given to the imminent need of the patient for a transplant, the benefit the patient may gain from the transplant, the availability of alternative treatments, the expected improvement in the patient's quality of life, and the amount of resources required for successful treatment.

Because human organs and tissues available for transplant are limited, criteria for recipient selection are developed. Criteria for transplant recipient selection helps identify the most appropriate patient and limits the potential for bias. Thus, criteria for access to organs and tissues are defined in a transparent manner, based on an objective evaluation of medical needs.

In addition, there are organ-specific criteria that must be taken into account in the decision for allocating an organ. **For example**, the viability of an organ outside of the body varies from organ to organ. Thus consideration must be given to the length of time it may take for an organ to reach the recipient. (Also see AOP.1.1)

Measurable Elements of COP.8.4

- ☐ 1. The transplant program documents organ-specific candidate selection criteria.
- ☐ 2. The results of a medical evaluation are included in the determination of suitability for transplantation.
- 3. The transplant program documents organ compatibility confirmation in the transplant candidate's medical record.

Standard COP.8.5

Intent of COP.8.5

To consent, a patient must be informed of those factors related to the planned care required for an informed decision. Factors that could affect the success of the graft or the candidate's health as a recipient include, but are not limited to,

- a) the donor's history;
- b) condition of the organ(s) used;
- c) age of the organ(s); and
- d) the potential risk of contracting infectious disease(s) if disease(s) cannot be detected in an infected donor.

In addition, there may be psychological, ethical, financial, and other factors that are unique to the transplant patient than for other patients, such as the need for immunosuppressive medications and the projected survival rate. The patient needs to be informed of all special considerations as part of the consent process. The transplant program also follows the hospital's policy for informed consent as well as local and regional laws and regulations. (Also see PFR.5.2)

Measurable Elements of COP.8.5

☐ 1. The transplant program follows the hospital's policy when obtaining informed consent from transplant candidates.

Ц	2.	In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of potential psychosocial risks.
	3.	In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of organ donor risk factors that could affect the success of the graft or the candidate's health as a recipient, including, but not limited to, a) through d) of the intent.
	4.	In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of the transplant center's observed and expected one-year survival rate.
	5.	In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate about immunosuppressive drugs and potential associated costs.
	6.	In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective transplant candidate of alternative treatments.

Standard COP.8.6

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

Intent of COP.8.6

To reduce the risk of organ rejection, the transplant surgeon must ensure the compatibility of the donor organ(s) to the recipient. The most frequently used tests for compatibility include blood typing and crossmatching and tissue typing. The transplant surgeon ensures that testing for compatibility occurs before organ recovery and organ transplantation takes place.

Transmission of infectious diseases and malignancies is a potential risk for recipients of donor tissues and organs. Therefore, the level of safety, efficacy, and quality of human cells, tissues, and organs for transplantation must be ensured. Evaluation of organ and tissue donors may identify those donors who have a higher risk for infection with a potentially harmful pathogen. Donor screening of clinical history and donor testing for communicable diseases can significantly reduce the incidence of donor transmission of disease. Donor screening should include evaluation of medical history, behavioral risk factors, and a physical examination. Donor testing should include tests for HIV, hepatitis B, hepatitis C, and other recommended tests.

For any transplantation of human material, traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed-on means of coding to identify tissues and cells used in transplantation are essential for full traceability. (*Also see* GLD.11.2)

Measurable Elements of COP.8.6

IVIE	as	urable Elements of COP.8.6
	1.	The transplant team follows written organ recover protocols, which include reviewing the donor data recipient blood type, and other vital data to ensure compatibility before organ recovery takes place.
	2.	The transplant surgeon is responsible for confirming, in writing, the medical suitability of donor organs for transplantation into the recipient.
	3.	When an organ arrives at the transplant center, the transplanting surgeon and at least one other licensed health care professional at the transplant center verify that the donor's blood type and other vital data are compatible with the recipient prior to transplantation.
	4.	The transplant surgeon is responsible for confirming that donor evaluation and donor testing for infectious diseases and malignancy have been completed before organ recovery and organ transplant occur.

5. When an organ arrives at the transplant center, the transplanting surgeon and at least one other licensed health care professional at the transplant center verify that evaluation and testing of the donor organ shows no evidence of disease and the condition of the organ is suitable for transplant.

Standard COP.8.7

Individualized patient care plans guide the care of transplant patients.

Intent of COP.8.7

The care of the patient receiving an organ or tissue transplant is different based on the type of organ or tissue being transplanted. In addition, the patient's health history has an impact on his or her recovery. Individualized care plans are developed to guide the care of transplant patients. (Also see AOP.1.1 and COP.2.1)

Measurable Elements of COP.8.7

- ☐ 1. The transplant program has documented organ-specific clinical practice guidelines for the pre-transplant, transplant, and discharge phases of transplantation.
- 2. Each transplant patient is under the care of a multidisciplinary patient care team coordinated by the patient's primary transplant physician throughout the pre-transplant, transplant, and discharge phases of transplantation.
- 3. Transplant candidates are evaluated for the suitability of other medical and surgical therapies that may yield short- and long-term survival rates comparable to transplantation.
- 4. Transplant candidates receive a psychological evaluation.
- 5. The transplant program updates clinical information in the transplant patient's medical record on an ongoing basis.

Transplant Programs Using Living Donor Organs

Standard COP.9

Transplant programs that perform living donor transplantation protect the rights of prospective or actual donors.

Intent of COP.9

The growing demand for and limited supply of organs from deceased donors have resulted in increased efforts to promote live organ donation. Living donor standards for the selection of suitable candidates for donation, informed consent, and care following the donation do not universally exist. Living donors face difficult decisions and are at potential risk for lifelong complications and should not feel coerced or pressured into organ donation. To help with decisions and to ensure that the living donor's rights are protected, an individual with knowledge of living organ donation, transplantation, medical ethics, and informed consent must be identified. (Also see PFR.1 and PFR.6)

Measurable Elements of COP.9

- 1. The living organ donor has the right to make a decision about donation in a setting free of coercion and pressure.
- 2. An individual with knowledge of living organ donation, transplantation, medical ethics, and informed consent is identified as an advocate for the living donor.
- ☐ 3. The individual appointed as the living donor advocate is not involved in routine transplantation activities.

4. The individual appointed as the living donor advocate informs, supports, and respects the living donor in a culturally appropriate manner during decision making.

Standard COP.9.1

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

Intent of COP.9.1

The prospective donor needs to thoroughly understand all aspects of the donation process, particularly to understand the risks and benefits associated with being a living donor. Many living donors give their organ to a family member or acquaintance; however, some living donors do not influence the placement of their donated organ. A very important aspect of obtaining informed consent is to ensure that the prospective donor is willing to donate and has not been coerced or promised compensation, and understands that he or she may decline to donate at any time. (*Also see PFR.5.2*)

Measurable Elements of COP.9.1

_	1.	living donor can understand.
	2.	In addition to the information provided to any surgical patient as part of the informed consent process the transplant program informs the prospective living donor of potential psychological risks of donation.
	3.	In addition to the information provided to any surgical patient as part of the informed consent process

- 3. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective living donor of potential complications and risks associated with living organ donation.
- 4. In addition to the information provided to any surgical patient as part of the informed consent process, the transplant program informs the prospective living donor of potential future health problems.
- 5. The transplant program informs the prospective living door of alternative treatments for the transplant candidate.
- ☐ 6. The transplant program informs the prospective living donor of the donor's right to opt out of donation at any time during the donation process.

Standard COP.9.2

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

Intent of COP.9.2

Organ donors must be evaluated for suitability, both physical and psychological, as an organ donor. The medical evaluation determines the donor's physical ability to donate and identifies any immediate health risks and possible future health risks. The psychological evaluation will be conducted by a psychiatrist, psychologist, or social worker with experience in transplantation to determine decision-making capacity, screen for any preexisting psychiatric illness, and evaluate any potential coercion. The donor must also be evaluated for his or her ability to comprehend the donation process and the potential outcomes, including possible adverse outcomes. (Also see AOP.1.1)

Measurable Elements of COP.9.2

☐ 1. The transplant program documents defined organ-specific living donor selection criteria.

2. The transplant program's living donor selection criteria are consistent with laws and regulations and the principles of medical ethics.
 3. The results of a medical evaluation related to the living donor's own physical health are included in the determination of suitability for donation.
 4. The results of medical tests identifying infectious diseases or malignancies are included in the determination of suitability for donation.
 5. The results of a psychological evaluation are included in the determination of suitability for donation.
 6. The transplant program documents organ compatibility confirmation in the living donor's medical record.

Standard COP.9.3

Individualized patient care plans guide the care of living donors.

Intent of COP.9.3

In addition to the general health care needs of patients undergoing surgical procedures, the living donor has unique treatment and health care needs that require specific consideration. Individualized care plans are developed and implemented for all living donors. (Also see COP.2.1)

Measurable Elements of COP.9.3

- ☐ 1. Transplant programs performing living donor transplants are guided by documented living donor guidelines for care in the evaluation, donation, and discharge phases of donation. (Also see GLD.11.2)
- ☐ 2. Transplant programs performing living donor transplants provide multidisciplinary care by a team coordinated by a physician to each donor throughout the donor evaluation, donation, and discharge phases of donation. (Also see ACC.3)
- ☐ 3. The living donor candidate receives ongoing psychological support following donation.

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Anesthesia and Surgical Care (ASC)

Note: The anesthesia and surgery standards are applicable in any setting in which anesthesia and/or procedural sedation are used, and surgical and other invasive procedures that require consent (*also see* PFR.5.2) are performed. Such settings include hospital operating theatres, day surgery and day hospital units, dental and other outpatient clinics, emergency services, intensive care areas, and others. These standards do not address the use of minimal sedation (anxiolysis). Definitions of the levels of sedation can be found in the Glossary.

Changes to the ASC Chapter

Standard	Change	Explanation
ASC.1	Requirement change	Adds language to intent and a new ME 5 regarding the need for a contract for outside sedation and anesthesia services; adds a description of sedation and anesthesia to intent
ASC.2	Requirement change	Deletes MEs 3 and 4 (4th edition) and renumbers MEs 5 and 6 (4th edition) as MEs 3 and 4
ASC.3– ASC.3.2	Requirement change	Divides ASC.3 (4th edition) into three separate standards to emphasize the importance of standardization (ASC.3), qualifications of practitioners (ASC.3.1), and professional practice guidelines (ASC.3.2) as they relate to procedural sedation
ASC.3.3	New standard	Adds a requirement for discussing the risks, benefits, and alternatives of procedural sedation with the patient, family, and other decision makers, similar to the requirement regarding anesthesia in ASC.5.1
ASC.4	No significant change	Provides additional information to describe the preanesthesia assessment and combines MEs 3 and 4 (4th edition) into a revised ME 3
ASC.5	Requirement change	Combines ASC.5 and ASC.5.2 (4th edition) and adds text to ME 2 to include documentation of the anesthesia agent, dose (when applicable), and anesthetic technique in the patient's anesthesia record
ASC.5.1	Requirement change	Adds a new ME 2 to emphasize the need for postoperative analgesia education
ASC.6	Renumbered; Requirement change	Incorporates requirements of ASC.5.3 and ASC.7.3 (4th edition) into one standard (renumbered as ASC.6) and adds clarification that monitoring should be consistent with professional practice guidelines
ASC.6.1	Renumbered	Renumbers ASC.6 (4th edition)
ASC.7	No significant change	Adds text to intent to clarify that the patient's assessment should also be used to guide the identification of significant findings during monitoring

Standard	Change	Explanation
ASC.7.2	Requirement change	Rewords standard, intent, and MEs to better detail requirements of surgery documentation in the patient's record
ASC.7.3	Renumbered	Renumbers ASC.7.4 (4th edition) and adds text to expand on what is included in a postsurgical plan of care; combines and rewords MEs for clarity
ASC.7.4	New standard	Adds a new requirement regarding the special considerations needed in planning surgical care that involves the implanting of medical devices

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a Θ icon after the standard text.

Standards, Intents, and Measurable Elements

Organization and Management

Standard ASC.1

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

Intent of ASC.1

Sedation and anesthesia are commonly viewed as a continuum from minimal sedation to full anesthesia. A patient's response may move along that continuum during which a patient's protective airway reflexes are at risk. Sedation and anesthesia use are complex processes that must be integrated into patient care planning. Sedation and anesthesia require complete and comprehensive patient assessment, continued patient monitoring, and objective recovery criteria.

The hospital has a system for providing sedation and anesthesia services required by its patient population, clinical services offered, and health care practitioners' needs. Sedation and anesthesia services meet all applicable local and national standards, laws, and regulations. Sedation and anesthesia services are available after normal hours of operation for emergencies.

Sedation and anesthesia services (including services required for emergencies) may be provided by the hospital, by agreement with an outside source (**for example**, an individual anesthesiologist or anesthesia group practice), or both. Any use of outside anesthesia sources is based on the recommendation of the leader of sedation and anesthesia services. Outside sources meet applicable laws and regulations and have acceptable quality and patient safety records as defined in a contract for services. (*Also see* GLD.6 and GLD.6.1)

Measurable Elements of ASC.1

- Sedation and anesthesia services meet professional standards and applicable local and national standards, laws, and regulations.
- ☐ 2. Sedation and anesthesia services are available to meet patient needs.

3.	Sedation and anesthesia services are available for emergencies after normal hours of operation.
4.	Outside sedation and anesthesia sources are selected based on the recommendations of the leader of sedation and anesthesia services, acceptable records of performance, and compliance with applicable laws and regulations.
5.	There is a contract for outside sedation and anesthesia services.

Standard ASC.2

A qualified individual(s) is responsible for managing the sedation and anesthesia services.

Intent of ASC.2

Sedation and anesthesia services are under the direction of one or more individuals who are qualified by documented training, expertise, and experience, and are consistent with applicable laws and regulations. This individual(s) assumes professional responsibility for the anesthesia services provided. Responsibilities include

- developing, implementing, and maintaining policies and procedures;
- providing administrative oversight;
- maintaining any necessary quality control program;
- recommending outside sources of sedation and anesthesia services; and
- monitoring and reviewing all sedation and anesthesia services.

Measurable Elements of ASC.2

1.	Sedation and anesthesia services are uniform throughout the hospital.
2.	Sedation and anesthesia services are under the direction of one or more qualified individuals. (Also see GLD.9)

3. Responsibilities for recommending outside sources of sedation and anesthesia services are defined and carried out.

☐ 4. Responsibilities for monitoring and reviewing all sedation and anesthesia services are defined and carried out.

Sedation Care

Standard ASC.3

The administration of procedural sedation is standardized throughout the hospital.

Output

Description:

Intent of ASC.3

Procedural sedation, which includes moderate and deep sedation, involves any sedation administered intravenously, regardless of the dosage. Procedural sedation is often performed in many areas of the hospital outside of the operating theatre. Because procedural sedation, like anesthesia, poses significant potential risks to patients, the administration of sedation must be uniform throughout the hospital. The qualifications of staff participating in the procedure, the medical technology, the supplies, and the monitoring must be the same wherever procedural sedation is provided in the hospital. Thus hospitals must develop specific guidelines for how and where sedation may be used.

Standardization of procedural sedation is supported by policies and procedures and identifies

- a) areas in the hospital where procedural sedation may occur;
- b) special qualifications or skills of staff involved in the procedural sedation process;
- c) the differences between pediatric, adult, and geniatric populations or other special considerations;

- d) availability and use of specialized medical technology; and
- e) obtaining informed consent for both the procedure and sedation. (Also see PFR.5.2)

Emergency medical technology and supplies appropriate for the age and history of the patient and the type of procedure being performed must be readily available.

Measurable Elements of ASC.3

- ☐ 1. The administration of procedural sedation is standardized throughout the hospital.
- 2. Standardization of procedural sedation includes identifying and addressing at least a) through e) in the intent.
- ☐ 3. Emergency medical technology and supplies are readily available and customized to the type of sedation being performed and the age and medical condition of the patient.
- 4. An individual with advanced life-support training must be immediately available when procedural sedation is being performed. (*Also see* COP.3.2)

Standard ASC.3.1

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

Intent of ASC.3.1

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

- a) techniques and various modes of sedation;
- b) pharmacology of sedation drugs and the use of reversal agents;
- c) monitoring requirements; and
- d) response to complications. (Also see SQE.10)

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

- e) monitoring requirements;
- f) response to complications;
- g) use of reversal agents; and
- h) recovery criteria. (Also see SQE.3)

Measurable Elements of ASC.3.1

- Health care practitioners responsible for providing procedural sedation are competent in at least a) through d) of the intent.
- 2. The individual responsible for patient monitoring during procedural sedation is competent in at least elements e) through h) in the intent.
- ☐ 3. Procedural sedation competencies for all staff involved in sedation are documented in the personnel files.

Standard ASC.3.2

Intent of ASC.3.2

The degrees of sedation occur on a continuum from mild to deep sedation, and a patient may progress from one degree to another. Many factors influence the patient's response to sedation and can affect the degree to which a patient is sedated. Factors include the medications administered, the route and dosages, the age of the patient (pediatric, adult, or geriatric), and the patient's medical history. **For example**, history of impairment of major organs, current medications that may interact with sedating medications, drug allergies, previous adverse response to anesthesia or sedation, and substance abuse may each have an impact on patient response to procedural sedation. If the patient's physical status is high risk, consideration is given to the additional clinical needs of the patient and the appropriateness of procedural sedation.

The presedation assessment helps identify any factors that may impact the patient's response to procedural sedation and also helps to identify what findings from monitoring during and after the procedure may be significant. The responsible, qualified practitioner conducts a presedation assessment of the patient to

- a) identify any airway problems that may influence the type of sedation used;
- b) evaluate at-risk patients for appropriateness of procedural sedation;
- c) plan the type of sedation and the level of sedation the patient will need based on the procedure being performed;
- d) safely administer sedation; and
- e) interpret findings from patient monitoring during procedural sedation and recovery.

The scope and content of this assessment are based on professional guidelines and are defined in hospital policy.

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

Once the procedure has been completed, patients may continue to be at risk for complications due to delay in the full absorption of the sedating drug, respiratory depression, and/or lack of stimulation from the procedure. Patients continue to require monitoring until they have reached near their baseline level of consciousness and hemodynamic parameters. Objective criteria help identify patients who are recovered and/or ready for discharge. (Also see QPS.8, ME 6)

Measurable Elements of ASC.3.2

- 1. There is a presedation assessment performed and documented that includes at least a) through e) to evaluate risk and appropriateness of procedural sedation for the patient. (Also see AOP.1, MEs 1 and 2)
- A qualified individual monitors the patient during the period of sedation and documents the monitoring.
- □ 3 Established criteria are used and documented for the recovery and discharge from procedural sedation.

Standard ASC.3.3

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

Intent of ASC.3.3

The procedural sedation planning process includes educating the patient, his or her family, or decision maker on the risks, benefits, and alternatives related to procedural sedation. This discussion occurs as part of the process to obtain consent for procedural sedation as required in PFR.5.2. A qualified individual provides this education.

Measurable Elements of ASC.3.3

- The patient, family, and/or decision makers are educated on the risks, benefits, and alternatives of procedural sedation.
- ☐ 2. The patient, family, and/or decision makers are educated about postprocedure analgesia.
- ☐ 3. A qualified individual provides the education.

Anesthesia Care

Standard ASC.4

A qualified individual conducts a preanesthesia assessment and preinduction assessment.

Intent of ASC.4

Because anesthesia carries a high level of risk, administration is carefully planned. The patient's preanesthesia assessment is the basis for that plan, for identifying what findings from monitoring during anesthesia and recovery may be significant, and for the use of postoperative analgesia. The preanesthesia assessment provides information needed to

- identify any airway problems;
- select the anesthesia and to plan anesthesia care;
- safely administer an anesthetic based on patient assessment, identified risks, and type of procedure;
- interpret findings from patient monitoring during anesthesia and recovery; and
- provide information for the use of analgesia following surgery.

An anesthesiologist or another qualified individual conducts the preanesthesia assessment. The preanesthesia assessment may be carried out some time prior to admission or prior to the surgical procedure or shortly before the surgical procedure, as in emergency and obstetrical patients. The preinduction assessment is separate from the preanesthesia assessment, as it focuses on the physiological stability and readiness of the patient for anesthesia and occurs *immediately* prior to the induction of anesthesia. When anesthesia must be provided emergently, the preanesthesia assessment and preinduction assessment may be performed immediately following one another, or simultaneously, but are documented independently. (*Also see* ASC.6)

Measurable Elements of ASC.4

- 1. A preanesthesia assessment is performed for each patient. (Also see AOP.1, MEs 1 and 2)
- 2. A separate preinduction assessment is performed to reevaluate patients immediately before the induction of anesthesia.
- 3. The two assessments are performed by an individual(s) qualified to do so and documented in the patient record.

Standard ASC.5

Each patient's anesthesia care is planned and documented, and the anesthesia and technique used are documented in the patient's record.

Intent of ASC.5

Anesthesia care is carefully planned and documented in the anesthesia record. The plan includes information from other patient assessments and identifies the anesthesia to be used, the method of administration, other medications and fluids, monitoring procedures, and anticipated postanesthesia care. The anesthesia agent, dose (when applicable), and anesthetic technique are documented in the patient's anesthesia record. (*Also see* COP.2.1; QPS.8, ME 6; and MOI.10.1)

Measurable Elements of ASC.5

- 1. The anesthesia care of each patient is planned and documented in the patient's record.
- 2. The anesthesia agent, dose (when applicable), and anesthetic technique are documented in the patient's anesthesia record.
- ☐ 3. The anesthesiologist and/or nurse anesthetist and anesthesia assistants are identified in the patient's anesthesia record.

Standard ASC.5.1

The risks, benefits, and alternatives related to anesthesia are discussed with the patient, his or her family, or those who make decisions for the patient.

Intent of ASC.5.1

The anesthesia planning process includes educating the patient, his or her family, or decision maker on the risks, benefits, and alternatives related to the planned anesthesia and postoperative analgesia. This discussion occurs as part of the process to obtain consent for anesthesia as required in PFR.5.2. An anesthesiologist or a qualified individual provides this education.

Measurable Elements of ASC.5.1

- ☐ 1. The patient, family, and/or decision makers are educated on the risks, benefits, and alternatives of anesthesia.
- ☐ 2. The patient, family, and/or decision makers are educated about postoperative analgesia.
- ☐ 3. The anesthesiologist or another qualified individual provides and documents the education.

Standard ASC.6

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

Intent of ASC.6

Physiological monitoring provides reliable information about the patient's status during anesthesia (general, spinal, regional, and local) and the recovery period. Results of monitoring trigger key intraoperative decisions as well as postoperative decisions, such as return to surgery, transfer to another level of care, or discharge. Monitoring information guides medical and nursing care and identifies the need for diagnostic and other services. Monitoring findings are entered into the patient's record.

Monitoring methods depend on the patient's preanesthesia status, the anesthesia choice, and the complexity of the surgical or other procedure performed during anesthesia. In all cases, however, the overall monitoring during anesthesia and surgery is consistent with professional practice and defined in hospital policy. The results of monitoring are documented in the patient's record. (Also see ASC.4)

Measurable Elements of ASC.6

1. The frequency and type of monitoring during anesthesia and surgery are based on the patient's preanesthesia status, the anesthesia used, and the surgical procedure performed.

2.	Monitoring of the patient's physiological status is consistent with professional practice.

☐ 3. The results of monitoring are documented in the patient's record.

Standard ASC.6.1

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

©

Intent of ASC.6.1

Monitoring during the anesthesia period is the basis for monitoring during the postanesthesia recovery period. The ongoing, systematic collection and analysis of data on the patient's status in recovery support decisions about moving the patient to other settings and less-intensive services. Recording of monitoring data provides the documentation to support discontinuing recovery monitoring or the discharge decisions. When the patient is transferred directly from the operating theatre to a receiving unit, monitoring and documentation are the same as would be required in the recovery room.

Discharge from the postanesthesia recovery areas or discontinuation of recovery monitoring is by one of the following alternative ways:

- a) The patient is discharged (or recovery monitoring is discontinued) by a fully qualified anesthesiologist or other individual authorized by the individual(s) responsible for managing the anesthesia services.
- b) The patient is discharged (or recovery monitoring is discontinued) by a nurse or similarly qualified individual in accordance with postanesthesia criteria developed by hospital leadership, and the patient's record contains evidence that criteria are met.
- c) The patient is discharged to a unit that is capable of providing postanesthesia or postsedation care of selected patients, such as a cardiovascular intensive care unit or neurosurgical intensive care unit, among others.

The time of arrival at and discharge from the recovery area (or the time recovery begins and the time of discontinuation of recovery monitoring) are documented in the patient's clinical record. (Also see AOP.2)

Measurable Elements of ASC.6.1

- ☐ 1. Patients are monitored during the postanesthesia recovery period.
- ☐ 2. Monitoring findings are documented in the patient's clinical record.
- 3. Patients are discharged from the postanesthesia unit (or recovery monitoring is discontinued) in accordance with the alternatives described in a) through c) in the intent.
- 4. Time recovery is started and time recovery phase is complete are recorded in the patient's record.

Surgical Care

Standard ASC.7

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

Intent of ASC.7

Because surgery carries a high level of risk, its use is carefully planned. The patient's assessment(s) is the basis for selecting the appropriate surgical procedure and for identifying what findings during monitoring may be significant. The assessment(s) provides information necessary to

- select the appropriate procedure and the optimal time;
- perform procedures safely; and

interpret findings of patient monitoring.

Procedure selection depends on the patient's history, physical status, and diagnostic data as well as the risks and benefits of the procedure for the patient. Procedure selection considers the information from the admitting assessment, diagnostic test, and other available sources. The assessment process is carried out in a shortened time frame when an emergency patient needs surgery. (Also see AOP.1.2.1, ME 3)

The surgical care planned for the patient is documented in the patient's record, including a preoperative diagnosis. The name of the surgical procedure alone does not constitute a diagnosis. (Also see AOP.1.3.1 and MOI.10.1)

Measurable Elements of ASC.7

1.	The assessment information used to develop and to support the planned invasive procedure is
	documented in the patient's record by the responsible physician before the procedure is performed.
	(Also see AOP.5.4, ME 3; and AOP.6.4, ME 3)

- 2. Each patient's surgical care is planned based on the assessment information.
- 3. A preoperative diagnosis and the planned procedure are documented in the patient's record by the responsible physician prior to the procedure.

Standard ASC.7.1

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

Intent of ASC.7.1

Patients and their families or decision makers receive adequate information to participate in care decisions and to provide the informed consent required in PFR.5.2. The information includes

- the risks of the planned procedure;
- the benefits of the planned procedure;
- the potential complications; and
- the surgical and nonsurgical options (alternatives) available to treat the patient.

In addition, when blood or blood products may be needed, information on the risks and alternatives is discussed. The patient's surgeon or other qualified individual provides this information.

Measurable Elements of ASC.7.1

1.	The patient, family, and decision makers are educated on the risks, benefits, potential complications
	and alternatives related to the planned surgical procedure.

- ☐ 2. The education includes the need for, risk and benefits of, and alternatives to blood and blood-product use.
- □ 3. The patient's surgeon or other qualified individual provides and documents the education.

Standard ASC.7.2

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

Intent of ASC.7.2

A patient's postsurgical care depends on the events and findings of the surgical procedure. The most important issue is that all actions and results essential to the patient's condition are entered in the patient's record. This information could be presented in the form of a template—either paper or electronic—or an operative report, such as a written operative progress note. To support a continuum of postsurgical supportive care, the

information about the surgery is recorded in the patient's record immediately after surgery, prior to the patient being transferred from the surgical or the postanesthesia recovery area. The documented information about the surgery includes at least

- a) postoperative diagnosis;
- b) name of operative surgeon and assistants;
- c) procedures performed and description of each procedure findings;
- d) perioperative complications;
- e) surgical specimens sent for examination;
- f) amount of blood loss and amount of transfused blood;
- g) registry number of all implantable devices; and
- h) date, time, and signature of responsible physician.

Some information may be contained in other notations in the record. **For example**, amount of blood loss and transfused blood may be recorded in the anesthesia record, or information about implantable devices may be shown using a manufacturer's preprinted sticker.

The time immediately after surgery is defined as "upon completion of surgery, before the patient is transferred to the next level of care." This definition ensures that pertinent information is available to the next caregiver. If the surgeon accompanies the patient from the operating theatre to the next unit or area of care, the operative note, template, or progress note can be written in that unit or area of care. (*Also see* ACC.3; COP.2.3; and QPS.8, ME 5)

Measurable Elements of ASC.7.2

- 1. Surgical reports, templates, or operative progress notes include at least a) through h) from the intent.
- 2. The hospital identifies information that may routinely be recorded in other specific areas of the record.
- 3. The surgical report, template, or operative progress note is available immediately after surgery before the patient is transferred to the next level of care.

Standard ASC.7.3

Patient care after surgery is planned and documented.

Intent of ASC.7.3

Each patient's postsurgical medical and nursing care needs differ depending on the surgical procedure performed and the medical history of the patient. In addition, some patients may require care from other services, such as physical therapy or rehabilitation. Therefore, it is necessary to plan for that care, including the level of care, care setting, follow-up monitoring or treatment, and the need for medication or other treatment and services.

Postsurgical care planning can begin before surgery based on the patient's assessed needs and condition and the type of surgery being performed. The postsurgical plan of care also includes the patient's immediate postoperative needs. The planned care is documented in the patient's record within 24 hours and verified by the responsible service to ensure continuity of services during the recovery or rehabilitative period.

The postsurgical needs may change as the result of clinical improvement or new information from a routine reassessment, or they may be evident from a sudden change in the patient's condition. The postsurgical plan of care is revised based on these changes and documented in the record as notes to the initial plan or as a revised or new plan of care. (Also see COP.2.1)

Measurable Elements of ASC.7.3

☐ 1. The postsurgical care provided by medical, nursing, and others meets the patient's immediate postsurgical needs.

2. The continuing postsurgical plan(s) is documented in the patient's record within 24 hours by the responsible surgeon or verified by a co-signature from the responsible surgeon on the documented plan entered by the surgeon's delegate.
 3. The continuing postsurgical plan of care includes medical, nursing, and others as needed based on the patient's needs.
 4. When indicated by a change in the patient's needs, the postsurgical plan of care is updated or revised

Standard ASC.7.4

Intent of ASC.7.4

Many surgical procedures involve the implantation of a prosthesis, such as a hip, or a medical device such as a pacemaker, insulin pump, or remote monitoring device. These types of surgical procedures require that routine surgical care must be modified to consider special factors such as

- a) selection of device based on available science and research;
- b) modifications to the surgical checklist to ensure that implants are present in the operating theatre and special considerations in marking the surgical site;
- c) the qualifications and training of any outside technical staff required during the implant procedure;
- d) an understanding of and reporting process for device-related adverse events;

based on the reassessment of the patient by the health care practitioners.

- e) unique infection control considerations;
- f) any special discharge instructions to the patient; and
- g) the traceability of devices in the event of a recall.^{1–5}

These special considerations may be incorporated into guidelines, protocols, operating policies, or other documents to guide the surgical team and result in consistent processes and outcomes. (Also see FMS.8.1 and SQE.10)

Measurable Elements of ASC.7.4

- ☐ 1. The hospital's surgical services define the types of implantable devices that are included within its scope of services.
- 2. Policies and practices include a) through g) in the intent.
- 3. Medical device implants are included in the department's monitoring priorities.

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Medication Management and Use (MMU)

Changes to the MMU Chapter

Standard	Change	Explanation
MMU.1	Requirement change	Revises standard and MEs to incorporate requirements of MMU.1.1 (4th edition)
MMU.2	Requirement change	Adds text to standard and intent and revises MEs to incorporate requirements of MMU.2.2 (4th edition)
MMU.2.1	Requirement change	Rewords intent for clarity and deletes ME 2 (4th edition)
MMU.3	No significant change	Rewords intent and MEs to clarify expectations and emphasize the need for proper storage of medications inside and outside of the pharmacy (such as on patient care units); incorporates MMU.2.1, ME 2 (4th edition), regarding protection of medications from loss or theft
MMU.3.1	No significant change	Rewords standard, intent, and MEs for clarification of requirements; incorporates MMU.3, ME 5 (4th edition) regarding medications brought into the hospital by patients
MMU.3.3	No significant change	Rewords and consolidates MEs for clarity
MMU.4	Requirement change	Rewords MEs for clarity; deletes ME 3 (4th edition)
MMU.4.1	Requirement change	Rewrites standard, intent, and MEs for clarity and to separate requirements for a complete medication order from processes that need to be in place when an order does not meet the requirements; expands number of MEs from two (4th edition) to four
MMU.5	No significant change	Adds examples to intent to clarify requirements; adds additional text to ME 3 for clarity
MMU.5.1	Requirement change	Rewrites intent and MEs to clarify expectations; identifies that properly trained staff other than pharmacists may perform the medication review for appropriateness; adds language to MEs 1 and 5 to specify that the requirement applies when the pharmacy is open or closed
MMU.5.2	No significant change	Rewords ME 2 for clarity and combines MEs 4 and 5 (4th edition)
MMU.6.1	No significant change	Inserts word prescription in standard text for clarity
MMU.6.2	No significant change	Rewords MEs for clarity
MMU.7	No significant change	Rewords MEs for clarity
MMU.7.1	No significant change	Rewords standard and MEs for clarity

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Organization and Management

Standard MMU.1

Medication use in the hospital is organized to meet patient needs, complies with applicable laws and regulations, and is under the direction and supervision of a licensed pharmacist or other qualified professional.

Intent of MMU.1

Medications, as an important resource in patient care, must be organized effectively and efficiently. 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. (*Also see* GLD.9)

To ensure efficient and effective medication management and use, the hospital conducts a systems review at least once a year. The annual review pulls together all information and experience related to medication management. That information and experience includes, **for example**, the following:

- How well the system is working related to
 - the selection and procurement of medications;
 - o storage;
 - o ordering and transcribing;
 - o preparing and dispensing; and
 - o administration and monitoring
- Monitoring resulting from any changes in the formulary, such as addition of drugs
- Monitoring of medication errors and near misses
- Any education needs identified
- Consideration of new evidence-based practices

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 identifies how medication use is organized and managed 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.
 4. There is at least one documented review of the medication management system within the previous 12 months.
 5. The pharmacy or pharmaceutical service and medication use comply with applicable laws and regulations.
 6. Appropriate sources of drug information are readily available to those involved in medication use.

Selection and Procurement

Standard MMU.2

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.

On occasion, medications not stocked or readily available to the hospital are needed. 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. (Also see MMU.3.2, ME 1)

Measurable Elements of MMU.2

- 1. There is a list of medications stocked in the hospital or readily available from outside sources.
- ☐ 2. The process used to develop the list (unless determined by regulation or an authority outside the hospital) includes representation from all those who prescribe and manage medications in the hospital.
- 3. There is a process for obtaining medications during the night or when the pharmacy is closed.

Standard MMU.2.1

There is a method for overseeing the hospital's medication list and medication use.

Intent of MMU.2.1

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. 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 monitor 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.

Measurable Elements of MMU.2.1

- 1. There is a method for overseeing medication use in the hospital.
- 2. Health care practitioners involved in ordering, dispensing, administering, and patient-monitoring processes are involved in evaluating and maintaining the medication list.
- ☐ 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 monitor how the drug is used and any unanticipated adverse events.
- 5. The list is reviewed at least annually based on safety and efficacy information.

Storage

Standard MMU.3

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. 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.
- b) Controlled substances are accurately accounted for according to applicable laws and regulations.
- c) Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and warnings. (*Also see* FMS.5)
- d) Concentrated electrolytes are not stored in care units unless clinically necessary, and when stored in care units there are safeguards in place to prevent inadvertent administration (scored at IPSG.3.1).
- e) All medication storage areas, including medication storage areas on patient care units, are periodically inspected according to hospital policy to ensure that medications are stored properly.
- f) Medications are protected from loss or theft throughout the hospital. (Also see FMS.4.1)

Measurable Elements of MMU.3

Note: Each element a) through f) found in the intent is scored separately, as they represent critical or high-risk areas.

- Medications are stored under conditions suitable for product stability, including medications stored on individual patient care units.
- 2. Controlled substances are accurately accounted for according to applicable laws and regulations.
- 3. Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and warnings.
- 4. All medication storage areas, including medication storage areas on patient care units, are periodically inspected to ensure that medications are stored properly.

5. Medications are protected from loss or theft throughout the hospital.

Standard MMU.3.1

Intent of MMU.3.1

There are some types of medications that, because of their safety risk (radioactive medications), unusual circumstances (brought in by the patient), opportunity for abuse or misuse (sample medications and emergency medications), or their special nature (applicable nutritional products), require special processes for storage and control of use. Written documentation addresses the receipt process, the identification of the medication, the storage, and any distribution. (*Also see* FMS.4.1)

Measurable Elements of MMU.3.1

1.	The hospital establishes and implements a process for how nutrition products requiring spe	ecial
	considerations are stored.	

- ☐ 2. The hospital establishes and implements a process for how radioactive, investigational, and similar medications are stored. (Also see FMS.5)
- ☐ 3. The hospital establishes and implements a process for how sample medications are stored and controlled.
- 4. The hospital establishes and implements a process for how medications brought in by the patient are identified and stored.

Standard MMU.3.2

Emergency medications are available, monitored, and safe when stored out of the pharmacy. (9)

Intent of MMU.3.2

When patient emergencies occur, quick access to appropriate emergency medications is critical. Each hospital plans the location of emergency medications and the medications to be supplied in these locations. For example, agents to reverse anesthesia are found in the operating theatres. Emergency cabinets, carts, bags, or boxes can be used for this purpose. 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. Thus, the hospital understands the balance between ready access and security for locations where emergency medications are stored. (Also see FMS.4.1)

Measurable Elements of MMU.3.2

- 1. Emergency medications are available in the units where they will be needed or are readily accessible within the hospital to meet emergency needs. (*Also see* MMU.2)
- ☐ 2. The hospital establishes and implements a process for how emergency medications are stored, maintained, and protected from loss or theft.
- ☐ 3. Emergency medications are monitored and replaced in a timely manner after use or when expired or damaged.

Standard MMU.3.3

The hospital has a medication recall system. ®

Intent of MMU.3.3

The hospital has a process for identifying, retrieving, and returning or safely and properly destroying medications recalled by the manufacturer or supplier. There is a policy or procedure that addresses any use of or the destruction of medications known to be expired or outdated.

Measurable Elements of MMU.3.3

- ☐ 1. There is a medication recall system in place.
- 2. The hospital establishes and implements a process for use of medications known to be expired or outdated.
- ☐ 3. The hospital establishes and implements a process for the destruction of medications known to be expired or outdated.

Ordering and Transcribing

Standard MMU.4

Intent of MMU.4

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. As illegible medication prescriptions or orders jeopardize patient safety and may delay treatment, the hospital addresses actions to reduce illegibility. A listing of all current medications is recorded in the patient's 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. (Also see IPSG.2 and COP.2.2)

Measurable Elements of MMU.4

- 1. The hospital establishes and implements a process for the safe prescribing, ordering, and transcribing of medications in the hospital.
- 2. The hospital establishes and implements a process for managing illegible prescriptions and orders, including measures to prevent continued occurrence.
- 3. Staff are trained in correct prescribing, ordering, and transcribing processes.
- 4. Patient records contain a list of current medications taken prior to admission, and this information is made available to the pharmacy and the patient's health care practitioners.
- 5. 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 defines the elements of a complete order or prescription.

①

Intent of MMU.4.1

To reduce the variation and improve patient safety, the hospital defines the required elements of a complete order or prescription. The elements addressed include at least the following:

- a) The data necessary to accurately identify the patient
- b) The essential elements of all orders or prescriptions

- c) When generic or brand names are acceptable or required
- d) Whether or when indications for use are required on a PRN (pro re nata, or "as needed") or other medication order
- e) The types of orders that are weight based or otherwise adjusted, such as for children, frail elderly, and other similar populations

There are processes in place to manage

- medication orders that are incomplete, illegible, or unclear;
- special types of orders, such as emergency, standing, or automatic stop, and any elements unique to such
 orders; and
- verbal and telephone medication orders and the process to verify such orders (scored at IPSG.2, ME 1).

Thus, this standard sets hospitalwide expectations for medication orders. The processes are reflected in complete orders entered in the patient record, the pharmacy or dispensing unit receiving the information needed for dispensing, and the administration of the medication based on a complete order. (Also see COP.2.2 and MOI.10)

Measurable Elements of MMU.4.1

Note: Elements a) through e) found in the intent are scored together, as they represent aspects of the hospital's policy on complete orders.

- ☐ 1. The required elements of complete medication orders or prescriptions include at least a) through e) identified in the intent.
- 2. The hospital develops and implements a process to manage medication orders that are incomplete, illegible, or unclear.
- ☐ 3. The hospital develops and implements a process to manage special types of orders, such as emergency, standing, or automatic stop, and any elements unique to such orders.
- 4. The hospital develops and implements a process to monitor the completeness and accuracy of medication orders and prescriptions.

Standard MMU.4.2

The hospital identifies those qualified individuals permitted to prescribe or to order medications.

Intent of MMU.4.2

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. (Also see COP.2.2, SQE.10, and MOI.11)

Measurable Elements of MMU.4.2

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.

Ш	3.	Individual	ls permitted	l to prescri	be and	to orc	ler med	lication	ns are	known	to tl	ne pl	harmac	eutical	service	or
		others wh	o dispense	medication	ıs.											

Standard MMU.4.3

Medications prescribed and administered are written in the patient's record.

Intent of MMU.4.3

The 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 record at discharge or transfer. (Also see COP.2.2)

Measurable Elements of MMU.4.3

- ☐ 1. Medications prescribed or ordered are recorded for each patient.
- 2. Medication administration is recorded for each dose.
- 3. Medication information is kept in the patient's record or inserted into his or her 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. 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. Medications stored and dispensed from areas outside the pharmacy (for example, patient care units) comply with the same safety and cleanliness measures. Staff preparing compounded sterile products (such as IVs and epidurals) are trained in the principles of medication preparation and aseptic technique. Similarly, laminar airflow hoods are available and used when indicated by professional practices (for example, cytotoxic medications).

Measurable Elements of MMU.5

- 1. Medications are prepared and dispensed in clean and safe areas with appropriate medical technology, equipment, and supplies. (Also see PCI.7, ME 1)
- 2. Medication preparation and dispensing adhere to laws, regulations, and professional standards of practice.
- ☐ 3. Staff preparing sterile products are trained in the principles of medication preparation and aseptic techniques.

Standard MMU.5.1

Medication prescriptions or orders are reviewed for appropriateness. ®

Intent of MMU.5.1

Good medication management includes two reviews of each prescription or order:

- The appropriateness of the medication for the patient and his or her clinical needs performed at the time the medication is prescribed or ordered
- The verification at the time of administration that the medication is exactly as ordered or prescribed (see MMU.6.1)

The first review is conducted by a licensed pharmacist, technician, or trained professional. 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 changes; 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.

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 must still be performed by a trained individual. However, the review may be conducted in conjunction with the review prior to administration (verification) when the same individual will administer the medication.

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.

The appropriateness review is conducted by those individuals competent to do so by virtue of education and training, as specified by privileging or demonstrated competency in the review process. This individual may be the pharmacist during the normal operation hours of the pharmacy and may be a nurse on the clinical unit during the evenings. The nurse or other individual has documented training in conducting 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 nurse will write down and read back the order and then conduct an appropriateness review. Hospital policy may require a second review by a pharmacist the next day or review by a trained physician who did not prescribe the medication and has been trained to conduct the review, such as a medical resident in an academic medical center hospital or community teaching hospital.

There may be circumstances in which the formal review for appropriateness 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 software programs are used to cross-check drug/drug interactions and drug allergies, the software is current and updated according to recommendations of the software manufacturer.

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 prior to dispensing and administration and includes elements a) through g) in the intent. Thus, each prescription or order is evaluated for appropriateness.
3.	There is a process to contact the individual who prescribed or ordered the medication when questions arise.
4.	Individuals permitted to review orders or prescriptions are judged competent to do so and are provided resources to support the review process.
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 software, when used to cross-check drugs for drug/drug interactions and allergies, is current and updated according to the program manufacturer's recommendations.

Standard MMU.5.2

A system is used to dispense medications in the right dose to the right patient at the right time.

Intent of MMU.5.2

The hospital dispenses medications in the most ready-to-administer form possible to minimize opportunities for error during distribution and administration. 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, and the date of expiration. 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.

Measurable Elements of MMU.5.2

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- 2. After preparation, medications not immediately administered are labeled with the name of the medication, the dosage/concentration, the date prepared, the expiration date, and the patient's name.
- ☐ 3. Medications are dispensed in the most ready-to-administer form.
- **1** 4. The system supports accurate and timely dispensing.

Administration

Standard MMU.6

The hospital identifies those qualified individuals permitted to administer medications.

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. (*Also see* SQE.3 and SQE.10)

Measurable Elements of MMU.6

- ☐ 1. The hospital identifies those individuals, by job description or the privileging process, authorized to administer medications.
- 2. Only those permitted by the hospital and by relevant licensure, laws, and regulations administer medications.
- 3. There is a process to place limits, when appropriate, on the medication administration of individuals.

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

- a) medication with the prescription or order;
- b) time and frequency of administration with the prescription or order;
- c) dosage amount with the prescription or order;
- d) route of administration with the prescription or order; and
- e) identity of the patient (scored at IPSG.1, ME 3).

The hospital defines the verification process to be used in administering medications. When the medication is prepared and dispensed on the patient care unit, then 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. Medications are administered on a timely basis.
- 5. Medications are administered as prescribed and noted in the patient's record.

Standard MMU.6.2

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

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. Medications brought into the hospital by the patient or his or her family are known to the patient's physician and noted in the patient's record. The self-administration of medications—either those brought into the hospital or those prescribed or ordered within the hospital—is known to the patient's physician and noted in the patient's record. The hospital controls the availability and has a process for how medication samples are managed, used, and documented.

Measurable Elements of MMU.6.2

- 1. The hospital establishes and implements a process to govern patient self-administration of medications.
- 2. 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.

3. The hospital establishes and implements a process to govern the availability, management, use, and documentation of medication samples.

Monitoring

Standard MMU.7

Medication effects on patients are monitored. ®

Intent of MMU.7

Patients, their physicians, nurses, and other health care practitioners work together to monitor patients on medications. The purposes of monitoring are to evaluate the medication's effect on the patient's symptoms or illness, as well as blood count, renal function, liver function, and other monitoring with select medications, and to evaluate the patient for adverse effects. 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. (*Also see* AOP.2)
- 2. Medication adverse effects on patients are monitored and documented.
- 3. The hospital establishes and implements a process that identifies those adverse effects that are to be recorded in the patient's record and those that must be reported to the hospital. (Also see QPS.8)
- 4. Adverse effects are documented in the patient's record as identified.
- 5. Adverse effects are reported as identified by the process in the time frame required.

Standard MMU.7.1

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. (Also see QPS.8 and QPS.9)

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.

Reference

 Agency for Healthcare Research and Quality. Patient safety primers, Medication errors. Rockville, MD: Agency for Healthcare Research and Quality, 2012. Available at http://psnet.ahrq.gov/primer.aspx?primerID=23.

Patient and Family Education (PFE)

Changes to the PFE Chapter

Standard	Change	Explanation
PFE.2	Requirement change	Removes four MEs to streamline requirements
PFE.2.1	Requirement change	Revises intent and MEs to clarify requirements
PFE.3	Renumbered	Moves requirement from PFE.5 (4th edition)
PFE.4	Renumbered	Moves requirement from PFE.6 (4th edition)

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standard appeared in this chapter of the 4th edition standards but was deleted from this edition (listed with 4th edition numbers): PFE.3.

Standards, Intents, and Measurable Elements

Standard PFE.1

The hospital provides education that supports patient and family participation in care decisions and care processes.

Intent of PFE.1

Hospitals educate patients and families so that they have the knowledge and skills to participate in the patient care processes and care decisions. Each hospital builds education into care processes based on its mission, services provided, and patient population. Education is planned to ensure that every patient is offered the education he or she requires. 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.

Measurable Elements of PFE.1

- 1. The hospital plans education consistent with its mission, services, and patient population.
- 2. There is an established structure or mechanism for education throughout the hospital.
- □ 3. The education structure and resources are organized in an effective manner.

Standard PFE.2

Each patient's educational needs are assessed and recorded in his or her record.

Intent of PFE.2

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.

Education by hospital staff is provided to patients and families to support decisions in the care process. Education provided as part of the process of obtaining informed consent for treatment (**for example**, for surgery and anesthesia) is documented in the patient's record. In addition, when a patient or family directly participates in providing care (**for example**, changing dressings, feeding the patient, administering medications and treatments), they need to be educated.

Once the educational needs are identified, they are recorded in the patient's record. This helps all of the patient's caregivers participate in the education process. Each hospital decides the location and format for documenting educational assessment, planning, and delivery of information in the patient's record.

Measurable Elements of PFE.2

- ☐ 1. The educational needs of the patient and family are assessed.
- 2. Educational needs assessment findings are recorded in the patient's record.
- ☐ 3. There is uniform recording of patient education by all staff.

Standard PFE.2.1

The patient's and family's ability to learn and willingness to learn are assessed.

Intent of PFE.2.1

Knowledge and skill strengths and deficits are identified and used to plan the education. There are many patient variables that determine if the patient and family are willing and capable to learn. (Also see PFR.1.1) Thus, to plan the education, the hospital must assess

- the patient's and family's literacy, including health care literacy, educational level, and language;
- emotional barriers and motivations; and
- physical and cognitive limitations.

Measurable Elements of PFE.2.1

- ☐ 1. The patient's literacy, including health care literacy, educational level, and language, are assessed.
- 2. The patient's emotional barriers and motivations are assessed.
- 3. The patient's physical and cognitive limitations are assessed.
- 4. The assessment findings are used to plan the education.

Standard PFE.3

Education methods include 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 PFE.3

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 PFE.3

- ☐ 1. There is a process to verify that patients and families receive and understand the education provided.
- ☐ 2. Those who provide education encourage patients and their families to ask questions and to speak up as active participants.
- ☐ 3. 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.

Standard PFE.4

Health professionals caring for the patient collaborate to provide education.

Intent of PFE.4

When health care professionals 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, available adequate time, and ability to communicate effectively are important considerations in effective education. (Also see COP.2.1)

Measurable Elements of PFE.4

- ☐ 1. Patient and family education is provided collaboratively when indicated.
- ☐ 2. Those who provide education have the subject knowledge to do so.
- ☐ 3. Those who provide education have adequate time to do so.
- 4. Those who provide education have the communication skills to do so.

Section III: Health Care Organization Management Standards



Quality Improvement and Patient Safety (QPS)

Changes to the QPS Chapter

Change	Explanation				
New standard	Introduces a new standard to emphasize the responsibility of the individual with oversight of the quality and patient safety program for implementing and guiding the program; incorporates QPS.1.5 (4th edition); moves identification of priorities and measures to the "Governance, Leadership, and Direction" chapter				
New standard	Introduces a new standard to emphasize the need for the quality and patient safety program to support, coordinate, and integrate measurement activities throughout the hospital				
Renumbered	Moves requirement from MCI.21 (4th edition) for better alignment of all measurement activities*				
Renumbered; Requirement change	Moves and consolidates requirements from MCI.20, MCI.20.1, and MCI.20.2 (4th edition) for better alignment of all measurement activities*				
Renumbered; Requirement change	Moves standard from QPS.4 (4th edition) and incorporates requirements of QPS.4.2 (4th edition)				
New standard	Introduces a new standard to emphasize the need for the quality and patient safety program to analyze the impact of at least one hospitalwide priority improvement project per year on cost and efficiency				
Renumbered	Moves requirement from QPS.5 (4th edition) and changes text for clarification; removes example of data validation process from text and inserts references for multiple examples of data validation methods				
Renumbered; Requirement change	Moves standard from QPS.6 (4th edition) and adds additional events that require a root cause analysis and must be included in the operational definition of a sentinel event; revises ME 2 to require that hospitals complete a root cause analysis within a 45-day time frame from an event; eliminates ME 3 (4th edition)				
Renumbered	Moves standard from QPS.7 (4th edition)				
Renumbered	Moves standard from QPS.8 (4th edition)				
Renumbered; Requirement change	Moves standard from QPS.9 (4th edition) and incorporates portions of intent and MEs of QPS.10 (4th edition)				
	New standard Renumbered Renumbered; Requirement change Renumbered; Requirement change New standard Renumbered Renumbered Renumbered; Requirement change				

^{*}The "Management of Information" (MOI) chapter in this edition was named the "Management of Communication and Information" (MCI) chapter in the 4th edition standards.

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standard appeared in this chapter of the 4th edition standards but was deleted from this edition (listed with 4th edition numbers): QPS.2.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a Θ icon after the standard text.

Standards, Intents, and Measurable Elements

Note: In all QPS standards, *leaders* are individuals and *leadership* is the collective group. Accountabilities are described at the individual or collective level. (*Also see* the "Governance, Leadership, and Direction" [GLD] chapter for other related requirements.)

Management of Quality and Patient Safety Activities

The overall program for quality and patient safety in a hospital is approved by governance (see GLD.2), with the hospital's leadership defining the structure and allocating resources required to implement the program (see GLD.4). Leadership also identifies the hospital's overall priorities for measurement and improvement (see GLD.5), with the department/service leaders identifying the priorities for measurement and improvement within their department/service (see GLD.11 and GLD.11.1).

The standards in this QPS chapter identify the structure, leadership, and activities to support the data collection, data analysis, and quality improvement for the identified priorities—hospitalwide, as well as department- and service-specific. This includes the collection and analysis on, and the response to, hospitalwide sentinel events, adverse events, and near-miss events. The standards also describe the central role of coordinating all the quality improvement and patient safety initiatives in the hospital and providing guidance and direction for staff training and communication of quality and patient safety information. The standards do not identify an organizational structure, such as a department, as this is up to each hospital to determine.

Standard QPS.1

A qualified individual guides the implementation of the hospital's program for quality improvement and patient safety and manages the activities needed to carry out an effective program of continuous quality improvement and patient safety within the hospital.

Output

Description:

Intent of QPS.1

The continuous improvement in quality and patient safety in a hospital requires a well-implemented program. While governance approves the program and leadership provides resources to implement the program, it takes daily capable guidance and management to carry out the program and make continuous improvement part of the fabric of how the hospital meets its mission and strategic priorities. (Also see GLD.4)

One or more qualified individuals see that the program is put into operation. This takes knowledge and experience in the many facets of data collection, data validation, and data analysis, and in implementing sustainable improvements. The individual(s) with oversight for the quality program also selects quality program staff with those capabilities needed for the program. At times, some of the key quality individuals may be located within a department/service in the hospital. These individuals need to be supported with information and assistance. The quality program staff also understand how to take the hospitalwide priorities and the department/service—level priorities and turn them into a coordinated overall program. The quality program staff

coordinate and organize like measures throughout the organization and provide support with measurement activities related to hospital priorities.

Training and communication are also essential. The quality program staff help to support data collection throughout the hospital by assisting with data collection issues such as creating forms to collect data, identifying which data to collect, and how to validate data. Staff throughout the hospital may need assistance in data validation and analysis, implementing improvements, and evaluating if the improvements were sustained. The quality program staff are thus constantly involved in training and communicating quality and patient safety issues throughout the hospital. ^{1–5} (*Also see* GLD.9)

Measurable Elements of QPS.1

- 1. An individual(s) who is experienced in the methods and processes of improvement is selected to guide the implementation of the hospital's quality and patient safety program.
- ☐ 2. The individual(s) with oversight for the quality program selects and supports qualified staff for the program and supports those staff with quality and patient safety responsibilities throughout the hospital. (*Also see* SQE.1)
- ☐ 3. The quality program provides support and coordination to department/service leaders for like measures across the hospital and for the hospital's priorities for improvement. (Also see GLD.11)
- 4. The quality program implements a training program for all staff that is consistent with staff's roles in the quality improvement and patient safety program. (Also see SQE.14.1, ME 1 and SQE.16.1, ME 1)
- □ 5. The quality program is responsible for the regular communication of quality issues to all staff.

Measure Selection and Data Collection

Standard QPS.2

Quality and patient safety program staff support the measure selection process throughout the hospital and provide coordination and integration of measurement activities throughout the hospital.

Intent of QPS.2

Measure selection is a leadership responsibility. GLD.5 describes how the leadership of the hospital decides the priority areas to measure for the entire hospital, and GLD.11 and GLD.11.1 describe the measure selection process for each department/service. All departments and services—clinical and managerial—select measures related to their priorities. It can be anticipated that in large hospitals, there is some opportunity for similar measures to be selected in more than one department. **For example**, the pharmacy, infection control, and infectious disease departments/services may each set priorities related to reducing antibiotic use in the hospital. The quality and patient safety program described in these QPS standards plays an important role in helping these departments/services agree on a common measurement approach and facilitates the data collection of the measure(s) selected. The quality and patient safety program is also in the position to integrate all measurement activities in the hospital, including measurement of the safety culture and adverse event reporting systems. This integration of all the measurement systems will provide the opportunity for integrated solutions and improvements.^{3–6} (*Also see* GLD.4)

Measurable Elements of QPS.2

- ☐ 1. The quality and patient safety program supports the selection of measures throughout the hospital at the hospitalwide level and at the hospital department or service level.
- ☐ 2. The quality and patient safety program provides coordination and integration of measurement activities throughout the hospital.

3.	The quality and patient safety program provides for the integration of event reporting systems, safety
	culture measures, and others to facilitate integrated solutions and improvements.

4. The quality and patient safety program tracks the progress on the planned collection of measure data for the priorities selected.

Standard QPS.3

The quality and patient safety program uses current scientific and other information to support patient care, health professional education, clinical research, and management.

Intent of QPS.3

Health care practitioners, researchers, educators, and managers often need information to assist with their responsibilities. Such information may include scientific and management literature, clinical practice guidelines, research findings, and educational methodologies. The Internet, print materials in a library, online search sources, and personal materials are all valuable sources of current information. (Also see GLD.7)

Measurable Elements of QPS.3

- 1. Current scientific and other information supports patient care.
- ☐ 2. Current scientific and other information supports clinical education.
- □ 3. Current scientific and other information supports research.
- 4. Current professional and other information supports management.
- 5. Information is provided in a time frame that meets user expectations.

Analysis and Validation of Measurement Data

Standard QPS.4

The quality and patient safety program includes the aggregation and analysis of data to support patient care, hospital management, and the quality management program and participation in external databases.

Intent of QPS.4

The quality and patient safety program collects and analyzes aggregate data to support patient care and hospital management. Aggregate data provide a profile of the hospital over time and allow the comparison of the hospital's performance with other organizations, particularly on the hospitalwide measures selected by leadership. Thus, aggregate data are an important part of the hospital's performance improvement activities. In particular, aggregate data from risk management, utility system management, infection prevention and control, and utilization review can help the hospital understand its current performance and identify opportunities for improvement. External databases also are valuable in the ongoing monitoring of professional practice as described in SQE.11.

By participating in external databases, a hospital can compare itself to that of other similar hospitals locally, nationally, and internationally. Comparison is an effective tool for identifying opportunities for improvement and documenting the hospital's performance level. Health care networks and those purchasing or paying for health care often ask for such information. External databases vary widely from insurance databases to those maintained by professional societies. Hospitals may be required by laws or regulations to contribute to some external databases. In all cases, the security and confidentiality of data and information are maintained.

Measurable Elements of QPS.4

☐ 1. The quality and patient safety program has a process to aggregate data.

2.	Aggregate data and information support patient care, hospital management, professional practice review, and the overall quality and patient safety program.
3.	Aggregate data and information are provided to agencies outside the hospital when required by laws or regulations.
4.	There is a process to contribute to and learn from external databases for comparison purposes. (Also see PCI.6 and PCI.6.1)
5.	Security and confidentiality are maintained when contributing to or using external databases.

Standard QPS.4.1

Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the hospital.

Intent of QPS.4.1

To reach conclusions and to make decisions, data must be aggregated, analyzed, and transformed into useful information. Data analysis involves individuals who understand information management, have skills in data aggregation methods, and know how to use various statistical tools. Results of data analysis need to be reported to those individuals responsible for the process or outcome being measured and who can take action on the results. These individuals may be clinical, managerial, or a combination. Thus, data analysis provides continuous feedback of quality management information to help those individuals make decisions and continuously improve clinical and managerial processes.

Understanding statistical techniques is helpful in data analysis, particularly in interpreting variation and deciding where improvement needs to occur. Run charts, control charts, histograms, and Pareto charts are **examples** of statistical tools useful in understanding trends and variation in health care.

The quality program participates in the determination of how often data are aggregated and analyzed. The frequency of this process depends on the activity or area being measured and the frequency of the measurement. For example, clinical laboratory quality control data may be analyzed weekly to meet local regulations, and patient fall data may be analyzed monthly if falls are infrequent. Thus, aggregation of data at points in time enables the hospital to judge a particular process's stability or a particular outcome's predictability in relation to expectations.

The goal of data analysis is to be able to compare a hospital in four ways:

- 1) With itself over time, such as month to month, or one year to the next
- 2) With other similar organizations, such as through reference databases
- With standards, such as those set by accrediting and professional bodies or those set by laws or regulations
- 4) With recognized desirable practices identified in the literature as best or better practices or practice guidelines

These comparisons help the hospital understand the source and nature of undesirable change and help focus improvement efforts. (Also see GLD.5)

Measurable Elements of QPS.4.1

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	1.	Data are aggregated, analyzed, and transformed into useful information to identify opportunities for improvement.
	2.	Individuals with appropriate clinical or managerial experience, knowledge, and skills participate in the process.
	3.	Statistical tools and techniques are used in the analysis process when suitable.
	4.	The frequency of data analysis is appropriate to the process or outcome being studied.

- 5. Results of analysis are reported to those accountable for taking action. (Also see GLD.1.2, ME 2)

 Data analysis supports comparisons internally over time including comparisons with databases of
 - 6. Data analysis supports comparisons internally over time, including comparisons with databases of like organizations, with best practices, and with objective scientific professional sources.

Standard QPS.5

The data analysis process includes at least one determination per year of the impact of hospitalwide priority improvements on cost and efficiency.

Intent of QPS.5

The quality and patient safety program includes an analysis of the impact of priority improvements as supported by leadership (*see* GLD.5, ME 4). The quality and patient safety program staff develop tools to evaluate the use of resources for the existing process and then reevaluate the use of resources for the improved process. The resources may be human (**for example**, time devoted to each step in a process) or may involve the use of technology or other resources. The analysis will provide useful information on which improvements impact efficiency and therefore cost.^{4,7,8}

Measurable Elements of QPS.5

- ☐ 1. Data on the amount and type of resource use are collected on at least one hospitalwide priority improvement project per year before and following the improvement.
- ☐ 2. The quality and patient safety program staff work with other units such as human resources, information technology, and finance in deciding which data are to be collected.
- 3. The results of the analysis are used to refine the process and are reported through the quality coordination mechanism to leadership.

Standard QPS.6

Intent of QPS.6

A quality improvement program is only as valid as the data that are collected. If data are flawed, quality improvement efforts will be ineffective. The reliability and validity of measurements are thus at the core of all improvements. To ensure that good, useful data have been collected, an internal data validation process needs to be in place. Data validation is most important when

- a) a new measure is implemented (in particular, those clinical measures that are intended to help a hospital evaluate and improve an important clinical process or outcome);
- b) data will be made public on the hospital's website or in other ways;
- c) a change has been made to an existing measure, such as the data collection tools have changed or the data abstraction process or abstractor has changed;
- d) the data resulting from an existing measure have changed in an unexplainable way;
- e) the data source has changed, such as when part of the patient record has been turned into an electronic format and thus the data source is now both electronic and paper; or
- f) the subject of the data collection has changed, such as changes in average age of patients, comorbidities, research protocol alterations, new practice guidelines implemented, or new technologies and treatment methodologies introduced.

Data validation is an important tool for understanding the quality of the data and for establishing the level of confidence decision makers can have in the data. Data validation becomes one of the steps in the process of setting priorities for measurement, selecting what is to be measured, extracting or collecting the data, analyzing the data, and using the findings for improvement.^{8–12}

When a hospital publishes data on clinical outcomes, patient safety, or other areas, or in other ways makes data public, such as on the hospital's website, the hospital has an ethical obligation to provide the public with accurate information. Hospital leadership is accountable for ensuring that the data are valid. Reliability and validity of measurement and quality of data can be established through the hospital's internal data validation process or, alternatively, can be judged by an independent third party.

Measurable Elements of QPS.6

1.	Data validation is used by the quality program as a component of the improvement process selected by leadership.
2.	Data are validated when any of the conditions noted in a) through f) in the intent are met.
3.	An established methodology for data validation is used.
4.	Hospital leadership assumes accountability for the validity of the quality and outcome data made public. (Also see GLD.3.1, ME 3)

Standard QPS.7

The hospital uses a defined process for identifying and managing sentinel events. ®

Intent of QPS.7

A *sentinel event* is an unanticipated occurrence involving death or serious physical or psychological injury. Serious physical injury specifically includes loss of limb or function. Such events are called *sentinel* because they signal the need for immediate investigation and response. Each hospital establishes an operational definition of a sentinel event that includes at least

- a) an unanticipated death, including, but not limited to,
 - death that is unrelated to the natural course of the patient's illness or underlying condition (**for example**, death from a postoperative infection or a hospital-acquired pulmonary embolism);
 - o death of a full-term infant; and
 - o suicide;
- b) major permanent loss of function unrelated to the patient's natural course of illness or underlying condition;
- c) wrong-site, wrong-procedure, wrong-patient surgery;
- transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;
- e) infant abduction or an infant sent home with the wrong parents; and
- f) rape, workplace violence such as assault (leading to death or permanent loss of function); or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on hospital property. (Also see SQE.8.2)

The hospital's definition of a sentinel event includes a) through f) above and may include other events as required by laws or regulations or viewed by the hospital as appropriate to add to its list of sentinel events. All events that meet the definition of sentinel event must be assessed by performing a credible root cause analysis. Accurate details of the event are essential to a credible root cause analysis, thus the root cause analysis needs to be performed as soon after the event as possible. The analysis and action plan is completed within 45 days of the event or becoming aware of the event. The goal of performing a root cause analysis is for the hospital to better understand the origins of the event. When the root cause analysis reveals that systems improvements or other actions can prevent or reduce the risk of such sentinel events recurring, the hospital redesigns the processes and takes whatever other actions are appropriate to do so.

It is important to note that the terms *sentinel event* and *medical error* are not synonymous. Not all errors result in a sentinel event, nor does a sentinel event occur only as a result of an error. Identifying an incident as a sentinel event is not an indicator of legal liability. (*Also see* GLD.4.1, ME 2)

Measurable Elements of QPS.7

- ☐ 1. Hospital leadership has established a definition of a sentinel event that at least includes a) through f) found in the intent.
 - 2. The hospital completes a root cause analysis of all sentinel events in a time period specified by hospital leadership that does not exceed 45 days from the date of the event or when made aware of the event.
 - 1 3. Hospital leadership takes action on the results of the root cause analysis.

Standard QPS.8

Data are always analyzed when undesirable trends and variation are evident from the data. ®

Intent of QPS.8

When the hospital detects or suspects undesirable change from what is expected, it initiates intense analysis to determine where best to focus improvement (also see MMU.7.1). In particular, intense analysis is initiated when levels, patterns, or trends vary significantly and undesirably from

- what was expected;
- that of other organizations; or
- recognized standards.

An analysis is conducted for the following:

- a) All confirmed transfusion reactions, if applicable to the hospital
- b) All serious adverse drug events, if applicable and as defined by the hospital
- c) All significant medication errors, if applicable and as defined by the hospital
- d) All major discrepancies between preoperative and postoperative diagnoses
- e) Adverse events or patterns of adverse events during moderate or deep sedation and anesthesia use
- f) Other adverse events; for example, health care—associated infections and infectious disease outbreaks

Measurable Elements of QPS.8

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	_	2.	All confirmed	transfusion	reactions.	if ap	plicable to	o the hos	pital.	are analy	zed.	(Also see	COP	.3	.3	1
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- All serious adverse drug events, if applicable and as defined by the hospital, are analyzed. (Also see MMU.7)
- 4. All significant medication errors, if applicable and as defined by the hospital, are analyzed. (Also see MMU.7.1)
- 5. All major discrepancies between preoperative and postoperative diagnoses are analyzed. (Also see ASC.7.2)
- ☐ 6. Adverse events or patterns of adverse events during moderate or deep sedation and anesthesia use are analyzed. (Also see ASC.3.2 and ASC.5)
- ☐ 7. Other adverse events defined by the hospital are analyzed.

Standard QPS.9

The organization uses a defined process for the identification and analysis of near-miss events.

Intent of QPS.9

In an attempt to proactively learn where systems may be vulnerable to actual adverse event occurrence, the hospital collects data and information on those events identified as a *near miss* and evaluates those events in an effort to prevent their actual occurrence. First, the hospital establishes a definition of a near miss and what types of events are to be reported. Second, a reporting mechanism is put into place, and finally there is a process to

aggregate and to analyze the data to learn where proactive process changes will reduce or eliminate the related event or near miss. (Also see MMU.7.1)

Measurable Elements of QPS.9

- ☐ 1. The hospital establishes a definition of a near miss.
- 2. The hospital defines the type of events to be reported.
- ☐ 3. The hospital establishes the process for the reporting of near misses.
- 4. The data are analyzed and actions taken to reduce near-miss events.

Gaining and Sustaining Improvement

Standard QPS.10

Improvement in quality and safety is achieved and sustained.

Intent of QPS.10

The information from data analysis is used to identify potential improvements or to reduce (or prevent) adverse events. Routine measurement data, as well as data from intensive assessments, contribute to this understanding of where improvement should be planned and what priority should be given to the improvement. In particular, improvements are planned for the priority data collection areas identified by hospital leadership.

After an improvement(s) is planned, data are collected during a test period to demonstrate that the planned change was actually an improvement. To ensure that the improvement is sustained, measurement data are then collected for ongoing analysis. Effective changes are incorporated into standard operating procedure, and any necessary staff education is carried out. The hospital documents those improvements achieved and sustained as part of its quality management and improvement program. (Also see GLD.11, ME 4)

Measurable Elements of QPS.10

- 1. Improvements in quality and patient safety are planned, tested, and implemented.
- Data are available to demonstrate that improvements are effective and sustained. (Also see GLD.11, ME
 3)
- □ 3. Policy changes necessary to plan, to carry out, and to sustain the improvement are made.
- 4. Successful improvements are documented.

Standard QPS.11

An ongoing program of risk management is used to identify and to proactively reduce unanticipated adverse events and other safety risks to patients and staff. \bullet

Intent of QPS.11

Hospitals need to adopt a proactive approach to risk management. One such way is a formalized risk management program whose essential components include

- a) risk identification;
- b) risk prioritization;
- c) risk reporting;
- d) risk management;
- e) investigation of adverse events; and
- f) management of related claims.

An important element of risk management is risk analysis, such as a process to evaluate near misses and other high-risk processes for which a failure would result in a sentinel event. One tool that provides such a proactive analysis of the consequences of an event that could occur in a critical, high-risk process is failure mode and effects analysis. The hospital can also identify and use similar tools to identify and to reduce risks, such as a hazard vulnerability analysis.

To use this or similar tools effectively, the hospital's leaders need to adopt and to learn the approach, to agree on a list of high-risk processes in terms of patient and staff safety, and then to use the tool on a priority risk process. Following analysis of the results, the hospital's leaders take action to redesign the process or similar actions to reduce the risk in the process. This risk-reduction process is carried out at least once per year and documented.

Measurable Elements of QPS.11

- 1. The hospital's risk management framework includes a) through f) in the intent.
- 2. At least annually, a proactive risk-reduction exercise is conducted on one of the priority risk processes.
- ☐ 3. High-risk processes are redesigned based on the analysis of the test results.

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Prevention and Control of Infections (PCI)

Changes to the PCI Chapter

Standard	Change	Explanation
PCI.2	Requirement change	Revises MEs to consolidate and clarify requirements
PCI.3	Requirement change	Adds examples of information sources to intent; consolidates MEs from 4th edition and adds two new MEs to address reporting to and taking action on reports from public health agencies
PCI.4	Requirement change	Adds text to intent and an ME to clarify that the infection prevention and control program is staffed according to hospital size, level of risk, and the program's complexity and scope
PCI.5	Requirement change	Adds text to intent and MEs for clarity and emphasizes that program strategies should cross all levels of the hospital; removes MEs to streamline requirements
PCI.6 and PCI.6.1	Requirement change	Adds new content to intent to emphasize the need for hospitals to track infection risks and trends in an effort to reduce risks within the hospital; revises and adds MEs to clarify requirements
PCI.7.1	Requirement change	Revises MEs to consolidate and clarify requirements; removes one ME
PCI.7.1.1	Requirement change	Adds text to and revises standard, intent, and MEs to clarify requirements
PCI.7.3	Requirement change	Adds text to standard and intent and revises MEs to clarify requirements for safe handling and disposal of sharps and needles
PCI.7.4	Requirement change	Revises standard, intent, and MEs to increase the emphasis on reducing the risk of infections associated with the operations of food services; incorporates requirements of COP.4.1 (4th edition)
PCI.7.5	Requirement change	Rewords standard, intent, and MEs to emphasize the importance of mechanical and engineering controls in minimizing infection risk
PCI.8 and PCI.8.1	Requirement change; New standard	Adds new standard and rewords intent and MEs to better delineate the hospital's requirements for providing barrier precautions and isolation procedures to prevent transmission of infectious diseases
PCI.9	Requirement change	Rewords intent and MEs for clarity; eliminates ME 5 (4th edition)

Standard	Change	Explanation
PCI.10	Requirement change	Streamlines and combines PCI.10–PCI.10.6 (4th edition) into one standard for clarity and to link requirements to GLD.11, which requires department/service leaders to participate in selecting measures for department/service–specific priorities for the infection prevention and control program
PCI.11	Requirement change	Revises MEs to clarify requirements

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes to This Chapter" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

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, or certification.

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 professionals, 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 employees. Thus, the oversight of the infection prevention and control program corresponds to the hospital's size, complexity of activities, and level of risks, as well as the program's scope. One or more individuals, acting on a full-time or part-time basis, provide that oversight as part of their assigned responsibilities or job descriptions. (*Also see* SQE.1.1) Their qualification(s) depend on the activities they will carry out and may be met through

- education;
- training;
- experience; and
- certification or licensure. (Also see GLD.9)

Measurable Elements of PCI.1

- ☐ 1. One or more individuals oversee the infection prevention and control program.
- ☐ 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.

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). 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. Responsibilities 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.
- 2. Coordination of infection prevention and control activities involves physicians and nurses, and others based on the size and complexity of the hospital.
- ☐ 3. Coordination of infection prevention and control activities involves infection prevention and control professionals.

Standard PCI.3

The infection prevention and control program is based on current scientific knowledge, accepted practice guidelines, applicable laws and regulations, and standards for sanitation and cleanliness.

Intent of PCI.3

Information is essential to an infection prevention and control program. Current scientific information is required to understand and to implement effective surveillance and control activities and can come from many national or international sources; **for example**, the United States Centers for Disease Control and Prevention (US CDC), the World Health Organization (WHO), regional public health protection agencies, and other similar organizations can be a significant source of evidence-based practices and guidelines.^{1–7} In addition, publications and professional organizations address standards related to environmental sanitation and cleanliness in hospitals. Practice guidelines provide information on preventive practices and infections associated with clinical and support services. Applicable laws and regulations define elements of the basic program, the response to infectious disease outbreaks, and any reporting requirements.

Measurable Elements of PCI.3

- ☐ 1. The infection prevention and control program is based on current scientific knowledge, accepted practice guidelines, and local laws and regulations.
- ☐ 2. The infection prevention and control program is based on standards from national or local agencies for sanitation and cleanliness.
- 3. Infection prevention and control program results are reported to public health agencies as required.

4. The hospital takes appropriate action on reports from relevant public health agencies.

Standard PCI.4

Hospital leadership provides resources to support the infection prevention and control program.

Intent of PCI.4

The infection prevention and control program requires staff to meet the program goals and the needs of the hospital. 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 level is approved by the hospital's leadership. 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 rubs for hand hygiene. Hospital leadership ensures that the program has adequate resources to effectively carry out the program.

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.4

- 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.
- Hospital leadership allocates and approves staffing and resources required for the infection prevention and control program.
- 3. Information management systems support the infection prevention and control program.

Standard PCI.5

Intent of PCI.5

For an infection prevention and control program to be effective, it must be comprehensive, encompassing both patient care and employee health. The program identifies and addresses the infection issues that are epidemiologically important to the hospital. 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, and oversight for improving the safe use of antimicrobials. The periodic assessment of risk and setting of risk-reduction goals guide the program. (*Also see* AOP.5.3)

Measurable Elements of PCI.5

- 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 health care workers. (Also see SQE.8.2)
- 3. The program incorporates a range of strategies that includes systematic and proactive surveillance activities to determine usual (endemic) rates of infection.
- 4. The program includes systems to investigate outbreaks of infectious diseases.
- ☐ 5. Risk-reduction goals and measurable objectives are established and reviewed.

Standard PCI.5.1

All patient, staff, and visitor areas of the hospital are included in the infection prevention and control program.

Intent of PCI.5.1

Infections can enter the hospital via patients, families, staff, volunteers, visitors, and other individuals, such as trade representatives. Thus, all areas of the hospital where these individuals are found must be included in the program of infection surveillance, prevention, and control.

Measurable Elements of PCI.5.1

- 1. All patient care areas of the hospital are included in the infection prevention and control program.
- ☐ 2. All staff areas of the hospital are included in the infection prevention and control program. (Also see SQE.8.2)
- 3. All visitor areas of the hospital are included in the infection prevention and control program.

Standard PCI.6

Standard PCI.6.1

The hospital tracks infection risks, infection rates, and trends in health care–associated infections to reduce the risks of those infections.

Intent of PCI.6 and PCI.6.1

Each hospital must identify those epidemiologically important infections, infection sites, and associated devices, procedures, and practices that will provide the focus of efforts to prevent and to reduce the risk and incidence of health care—associated infections. A risk-based approach helps hospitals identify those practices and infections on which they should focus their programs. A risk-based approach uses surveillance as an important component for gathering and analyzing the data that guide the risk assessment.

Hospitals collect and evaluate data on the following relevant infections and sites:

- a) Respiratory tract—such as the procedures and medical technology associated with intubation, mechanical ventilatory support, tracheostomy, and so on
- b) Urinary tract—such as the invasive procedures and medical technology 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
- f) Emerging or reemerging infections with the community

In addition, applying the scientific knowledge related to the control of infections through such strategies as the use of clinical practice guidelines, 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. (Also see GLD.11.2)

The infection prevention and control process is designed to lower the risk of infection for patients, staff, and others. To reach this goal, the hospital must proactively identify and track risks, rates, and trends in health care—associated infections. The hospital uses measurement information to improve infection prevention and control activities and to reduce health care—associated infection rates to the lowest possible levels. A hospital can

best use measurement data and information by understanding rates and trends in other similar hospitals and contributing data to infection-related databases. (Also see QPS.4, ME 4 and GLD.5)

Measurable Elements of PCI.6

- 1. The hospital has established the focus of the program through the collection of data related to a) through f) in the intent.
- 2. The data collected in a) through f) are analyzed to identify priorities for reducing rates of infection.
- 3. Infection control strategies are implemented to reduce the rates of infection for the identified priorities.

Measurable Elements of PCI.6.1

- ☐ 1. Health care—associated infection risks, rates, and trends are tracked.
- 2. Processes are redesigned based on risk, rate, and trend data and information.
 - 3. The hospital assesses the infection control risks at least annually and takes action to focus or refocus the infection prevention and control program.

Standard PCI.7

Intent of PCI.7

Hospitals assess and care for patients using many simple and complex processes, each associated with a level of infection risk to patients and staff. It is important for a hospital to measure and review those processes and to implement needed policies, procedures, education, and evidence-based activities designed to reduce the risk of infection. (Also see ACC.6)

Measurable Elements of PCI.7

- 1. The hospital has identified those processes associated with infection risk. (Also see MMU.5, ME 1)
- 2. The hospital has implemented strategies, education, and evidence-based activities to reduce infection risk in those processes.
- 3. The hospital identifies which risks require policies and/or procedures, staff education, practice changes, and other activities to support risk reduction.

Standard PCI.7.1

The hospital reduces the risk of infections by ensuring adequate medical technology cleaning and sterilization and the proper management of laundry and linen.

Intent of PCI.7.1

Infection risk is minimized with proper cleaning, disinfection, and sterilization processes, such as the cleaning and disinfection of endoscopes and the sterilization of surgical supplies and other invasive or noninvasive medical technology for patient care.⁴ Cleaning, disinfection, and sterilization can take place in a centralized sterilization area or, with proper oversight, in other areas of the hospital, such as an endoscope clinic. Cleaning, disinfection, and sterilization methods maintain the same standards wherever they are performed in the hospital. (Also see ACC.6) Also, the proper management of laundry and linen can result in reduced contamination of clean linen and reduced infection risk to staff from soiled laundry and linen.⁶

Measurable Elements of PCI.7.1

- ☐ 1. Methods for medical technology cleaning, disinfection, and sterilization address the principles of infection prevention and control.
 - Methods for medical technology cleaning, disinfection, and sterilization are coordinated and uniformly applied throughout the hospital.
- 3. The principles of infection prevention and control are applied to laundry and linen management, including transportation, cleaning, and storage.

Standard PCI.7.1.1

The hospital identifies and implements a process for managing expired supplies and the reuse of single-use devices when laws and regulations permit. ©

Intent of PCI.7.1.1

Most medical materials (IV fluids, catheters, sutures, and the like) 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 handling of expired supplies.

In addition, certain single-use devices may be reused under specific circumstances.⁴ There are two risks associated with the reuse of single-use devices: There is 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. When single-use devices are reused, there is a hospital policy that guides such reuse. The policy is consistent with national laws and regulations and professional standards and includes identification of

- a) devices and materials that may be reused;
- b) the maximum number of reuses specific for each device and material that is reused;
- c) the types of wear and cracking, among others, that indicate the device cannot be reused;
- d) the cleaning process for each device that starts immediately after use and follows a clear protocol;
- e) identification of patients on whom reusable medical devices have been used; and
- f) a proactive evaluation of the safety of reusing single-use items. The hospital collects infection prevention and control data related to reused devices and materials to identify risks and implements actions to reduce risks and improve processes.

Measurable Elements of PCI.7.1.1

- ☐ 1. The hospital implements a process consistent with national laws and regulations and professional standards that identifies the process for managing expired supplies. (Also see ACC.6)
- ☐ 2. When single-use devices and materials are reused, the hospital implements a process that addresses items a) through f) in the intent.
- 3. Data are used to identify risks, and actions are implemented to reduce risk and improve processes.

Standard PCI.7.2

The hospital reduces the risk of infections through proper disposal of waste.

Intent of PCI.7.2

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.⁶ (Also see ACC.6 and FMS.5.1) 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 of waste from the mortuary and postmortem areas, when present. (Also see AOP.5.3.1)

Measurable Elements of PCI.7.2

- ☐ 1. Disposal of infectious waste and body fluids is managed to minimize infection transmission risk.
- 2. The handling and disposal of blood and blood components are managed to minimize infection transmission risk.
- 3. Operation of the mortuary and postmortem area is managed to minimize infection transmission risk.

Standard PCI.7.3

Intent of PCI.7.3

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 challenge. Work practices influence the risk of injury and potential exposure to disease. Identifying and implementing evidence-based practices to reduce the risk of injury from sharps ensures that exposure to such injuries is minimal. Hospitals need to provide staff with education related to safe handling and management of sharps and needles.

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

Disposal of discarded needles, scalpels, and other sharps, when not done properly, can pose a health risk to the general public and to those who work in waste management. Disposing of sharps containers in the ocean, **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. (Also see ACC.6)

Measurable Elements of PCI.7.3

- 1. The hospital identifies and implements practices to reduce the risk of injury and infection from the handling and management of sharps and needles.
- 2. Sharps and needles are collected in dedicated, closable, puncture-proof, leakproof containers that are not reused.
- 3. 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.

Standard PCI.7.4

The hospital reduces the risk of infections associated with the operations of food services.

Intent of PCI.7.4

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 and prepared at temperatures that prevent the risk of bacterial growth.

Cross contamination, particularly from raw foods to cooked foods, is another source of food infections. 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.

Measurable Elements of PCI.7.4

- 1. The hospital stores food and nutrition products using sanitation, temperature, light, moisture, ventilation, and security in a manner that reduces the risk of infection.
- ☐ 2. The hospital prepares food and nutrition products using proper sanitation and temperature.
- ☐ 3. Kitchen sanitation measures are implemented to prevent the risk of cross contamination.

Standard PCI.7.5

The hospital reduces the risk of infection in the facility associated with mechanical and engineering controls and during demolition, construction, and renovation.

Intent of PCI.7.5

Engineering controls, such as positive 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 the important role environmental standards and controls contribute to good sanitation and the reduction of infection risks in the hospital.

Demolition, construction, or renovation 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. (*Also see* FMS.4, ME 3)

Measurable Elements of PCI.7.5

- ☐ 1. Engineering controls are implemented to minimize infection risk in the hospital.
- 2. 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, or renovation take place.
- ☐ 3. The risks and impact of the demolition, renovation, or construction on air quality and infection prevention and control activities are assessed and managed.

Standard PCI.8

The hospital provides barrier precautions and isolation procedures that protect patients, visitors, and staff from communicable diseases and protects immunosuppressed patients from acquiring infections to which they are uniquely prone.

Output

Description:

Standard PCI.8.1

Intent of PCI.8 and PCI.8.1

The hospital develops policies and procedures that establish the isolation and barrier procedures for the hospital. These are based on the method of disease transmission and address individual patients who may be infectious or

immunosuppressed. The isolation procedures also address staff and visitor protection and the patient environment. (Also see COP.3)

Airborne 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 recirculate the air through a high-efficiency particulate air (HEPA) filtration system at the rate of at least 12 air changes per hour.²

The hospital should have a program that addresses how to manage patients with airborne infections for short periods of time when negative-pressure rooms or HEPA filtration systems are not available, as well as when there is a large influx of patients with contagious infections.

Proper cleaning of the room during the patient's stay in the hospital and terminal cleaning of the room after the patient is discharged are performed according to infection control guidelines.

Measurable Elements of PCI.8

- 1. Patients with known or suspected contagious diseases are isolated in accordance with recommended guidelines. (*Also see* ACC.6)
- 2. Patients with communicable diseases are separated from patients and staff who are at greater risk due to immunosuppression or other reasons.
- 3. Negative-pressure rooms are monitored routinely and available for infectious patients who require isolation for airborne infections; when negative-pressure rooms are not immediately available, rooms with HEPA filtration systems with a minimum of 12 air changes per hour may be used.
- 4. Cleaning of infectious rooms during the patient's hospitalization and after discharge follow infection control guidelines.

Measurable Elements of PCI.8.1

- 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.9

Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required. ©

Intent of PCI.9

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. 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. Soap, disinfectants, and towels or other means of drying are located in those areas where hand-washing and hand-disinfecting procedures are required. Staff are educated in proper hand-washing, hand-disinfection, and surface-disinfection procedures as well as proper use of personal protective equipment. (Also see IPSG.5 and ACC.6)

Measurable Elements of PCI.9

- 1. The hospital identifies situations in which personal protective equipment is required and ensures that it is available at any site of care at which it could be needed.
- 2. Personal protective equipment is correctly used in those identified situations.
- ☐ 3. Surface disinfecting procedures are implemented for areas and situations in the hospital identified as at risk for infection transmission.
- 4. Soap, disinfectants, and towels or other means of drying are located in areas where hand-washing and hand-disinfecting procedures are required.

Standard PCI.10

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.10

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.

Measurable Elements of PCI.10

- 1. Infection prevention and control activities are integrated into the hospital's quality improvement and patient safety program. (*Also see* GLD.4 and GLD.11)
- 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.
- 4. Monitoring data are documented and reports of data analysis and recommendations are provided to leadership on a quarterly basis.

Standard PCI.11

Intent of PCI.11

For a hospital to have an effective infection prevention and control program, it must educate staff members about the program when they begin work in the hospital and regularly thereafter. The education program includes professional staff, clinical and nonclinical support staff, patients and families, and even including 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. The education also includes communicating the findings and trends from the measurement activities. (Also see SQE.7)

Measurable Elements of PCI.11

- ☐ 1. The hospital provides education about infection prevention and control to all staff and other professionals.
- ☐ 2. The hospital provides education about infection prevention and control to patients and families.
- 3. All staff are educated on the policies, procedures, and practices of the infection prevention and control program.
- 4. Periodic staff education is provided in response to significant trends in infection data.
- 5. Findings and trends from the measurement activities are communicated throughout the hospital and included as part of periodic education.

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Governance, Leadership, and Direction (GLD)

Changes to the GLD Chapter

Note: The chapter overview provides definitions for the levels of leadership referred to in the standards.

Standard	Change	Explanation
GLD.1	Requirement change	Rewords standard, intent, and MEs for greater clarity of requirements; adds ME 5 to emphasize the need to describe in documentation when and how governance and senior management authority can be delegated
GLD.1.1	Renumbered; Requirement change	Combines GLD.1.1–GLD.1.4 (4th edition) into a single standard; rewords and consolidates MEs to clarify requirements
GLD.1.2	Renumbered; Requirement change	Moves standard from GLD.1.5 (4th edition); revises intent and MEs to clarify requirements; adds text to ME 2 to require that those responsible for governance receive and act on reports of the quality and patient safety program at least quarterly and that the reports include adverse and sentinel events
GLD.2	No significant change	Changes the term <i>senior manager or director</i> (4th edition) to <i>chief executive(s)</i> in standard, intent, and MEs for clarity (this change is made throughout the chapter)
GLD.3	Requirement change	Changes the term <i>organization's leaders</i> to <i>hospital leadership</i> , which is used consistently within the chapter in standards referring to this level of leadership within the hospital; expands ME 1 to require chief executive(s) and hospital leadership to be identified by title, name, and collective accountabilities in hospital documents
GLD.3.1	Requirement change	Adds requirements of MCI.1 (4th edition) and GLD.3.2 (4th edition) to this standard; adds ME 3 to emphasize the need for hospital leadership to provide data on the quality of services to stakeholders
GLD.3.2	Renumbered; Requirement change	Moves and combines MCI.4 and MCI.5 (4th edition) here to better align hospital leadership requirements; revises standard, intent, and MEs to clarify expectations
GLD.3.3	Renumbered	Moves standard from GLD.3.5 (4th edition); rewords standard, intent, and MEs for clarity
GLD.4	Renumbered; Requirement change	Moves, combines, and streamlines QPS.1, QPS.1.1, and QPS.1.3 (4th edition) here to align with other hospital leadership requirements; revises standard, intent, and MEs to clarify expectations

Standard	Change	Explanation
GLD.4.1	Renumbered; Requirement change	Moves requirements from QPS.1, ME 4 (4th edition) and QPS.1.4 (4th edition) here to better align hospital leadership requirements; rewords standard, intent, and MEs for clarity; adds language requiring quarterly reports to governance on the quality and patient safety program; adds ME 2 to emphasize the need for hospital leadership to report to governance at least once every six months on sentinel events and the hospital's response to such events
GLD.5	Renumbered; Requirement change	Moves requirements from QPS.1.2 and QPS.3 (4th edition) here to better align hospital leadership requirements; rewords standard, intent, and MEs to clarify expectations
GLD.6	Renumbered; Requirement change	Moves requirements of GLD.3.3 (4th edition) here for better chapter flow; rewords standard, intent, and MEs for clarity; adds ME 3 to require credential review for health professional staff contracts
GLD.6.1	Renumbered; Requirement change	Moves requirements of GLD.3.3.1 (4th edition) here for better chapter flow; revises MEs to add and clarify expectations
GLD.6.2	Renumbered	Moves requirements of GLD.3.3.2 (4th edition) here for better chapter flow
GLD.7	Renumbered	Moves and expands on requirements of GLD.3.2.1 (4th edition); revises standard, intent, and MEs to clarify expectations; adds requirements regarding hospital leadership decisions related to staffing
GLD.7.1	New standard	Introduces a new standard to emphasize the need to protect patients and staff from contaminated, fake, and diverted drugs, medical technology, and supplies
GLD.8	Renumbered; Requirement change	Moves requirements of GLD.4 (4th edition) here for better chapter flow; rewords standard, intent, and MEs minimally for clarity; adds culture of safety to ME 3
GLD.9	Renumbered; Requirement change	Consolidates and condenses requirements of GLD.5 and GLD.5.2–GLD.5.4 (4th edition) into a single standard
GLD.10	Renumbered	Moves and consolidates requirements of GLD.5.1 and GLD.5.1.1 (4th edition) into a single standard
GLD.11	Renumbered; Requirement change	Moves and incorporates requirements from QPS.3.1, QPS.3.2, and QPS.3.3 (4th edition); rewords standard, intent, and MEs extensively, emphasizing the department/service leader's role in participating in hospitalwide improvement priorities and monitoring and improving patient care specific to the department/service
GLD.11.1	New standard	Adds a new standard that expands on GLD.11 in the 5th edition to emphasize the need for department/service quality improvement activities to be used in the ongoing professional practice reviews of physicians and the annual performance evaluations of nursing and other health professional staff
GLD.11.2	Renumbered	Moves requirements from QPS.2.1 (4th edition); revises standard, intent, and MEs to clarify expectations

Standard	Change	Explanation
GLD.12– 12.2	Renumbered; Requirement change	Moves GLD.6–GLD.6.2 (4th edition) here and rewords standards and intent for clarity; rewords and reduces number of MEs
GLD.13 and GLD.13.1	New standards	Adds new requirements for hospital leadership to create, implement, support, monitor, and take action to improve a culture of safety
GLD.14	Renumbered	Moves requirements from SQE.8.3 (4th edition) to this chapter to better align with hospital leadership requirements; adds text to intent and MEs for clarity
GLD.15–19	Requirement change; Renumbered	Adds standards to this chapter that are applicable to hospitals that conduct human subjects research but do not meet the eligibility criteria for Academic Medical Center Hospital accreditation; renumbers some standards from the 4th edition with text changes to improve clarity: GLD.16 (previously PFR.7); GLD.17 (previously PFR.7.1); GLD.18 (previously PFR.8); GLD.19 (previously PFR.9)

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): GLD.3.4, GLD.5.5.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Overview

Note: In all GLD standards, the term *leaders* is used to indicate that one or more individuals are accountable for the expectation(s) found in the standard. *Leadership* is used to indicate that a group of leaders is collectively accountable for the expectation(s) found in the standard.^{1–3}

Standards in this chapter are grouped using the following leadership hierarchy (and illustrated in the figure below):

Level I: Governance

Governance may consist of many configurations. For example, governance may be a group of individuals (such as a community board), one or more individual owners, or in the case of public hospitals, the Ministry of Health. Any individual, entity, or group responsible for the requirements found in GLD.1.1 is considered the governance of the hospital.

Level II: Chief Executive

The most senior hospital executive, commonly termed the *chief executive*, is a position occupied by one or more individuals selected by governance to manage the organization on a day-to-day basis. This position is most

commonly occupied by a physician, an administrator, or both working together. In academic medical centers, the dean of the medical school may be at this executive level in the hospital.

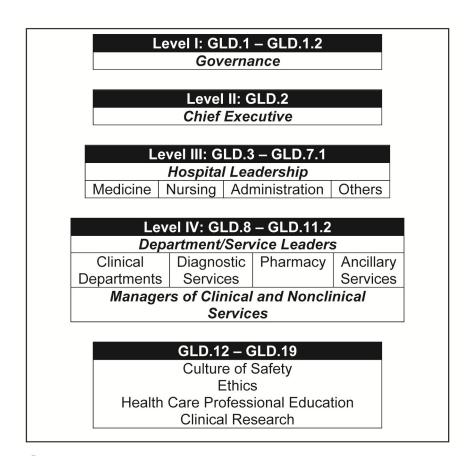
Level III: Hospital Leadership

The standards assign to *hospital leadership* a variety of responsibilities intended to collaboratively guide the hospital in meeting its mission. Most frequently, hospital leadership consists of a chief medical officer representing the medical staff of the hospital, a chief nursing officer representing all levels of nursing in the hospital, senior administrators, and any other individuals the hospital selects, such as a chief quality officer or vice president of human resources. In larger hospitals with different organizational structures, such as divisions, hospital leadership may include the leaders of these divisions. Each hospital identifies hospital leadership, and standards GLD.3 through GLD.7.1 describe the accountabilities of this group. GLD.8 describes the responsibilities of clinical staff, however they are formally or informally organized. In academic medical centers, the leader of medical education and leader of clinical research may be a part of hospital leadership.

Level IV: Department/Service Leaders

For effective and efficient daily delivery of clinical services and management of the organization, hospitals are most frequently divided into cohesive subgroups such as departments, services, or units, each under the direction of a *department/service leader(s)*. Standards GLD.9 through GLD.11.2 describe the expectations of these department/service leaders. Typically, the subgroups consist of clinical departments such as medicine, surgery, obstetrics, pediatrics, and others; one or more nursing subgroups; diagnostic services or departments such as radiology and clinical laboratory; pharmacy services, both centralized and distributed throughout the hospital; and ancillary services such as transportation, social work, finance, purchasing, facility management, and human resources, among others. Most larger hospitals also have managers within these subgroups. **For example**, nursing may have a manager of the operating theatres and one for outpatient services, the department of medicine may have managers of each patient clinical unit, and the hospital business office may have managers for the different business functions such as bed control, billing, and purchasing, among others.

Finally, there are requirements in the GLD chapter that touch on all of the levels described above. These requirements are found in GLD.12 through GLD.19 and include the culture of safety, ethics, and health professional education and research when present.



Standards, Intents, and Measurable Elements

Governance of the Hospital

Standard GLD.1

Governance structure and authority are described in bylaws, policies and procedures, or similar documents. (9)

Intent of GLD.1

There is an entity (**for example**, a ministry of health), an owner(s), or a group of identified individuals (**for example**, a board or governing body) responsible for overseeing the hospital's operation and accountable for providing high-quality health care services to its community or to the population that seeks care. This entity's structure, responsibilities, and accountabilities are described in a document(s) that identifies how they are to be carried out. Also described is how the governing entity will be evaluated against specific criteria. **For example**, the criteria can relate to the specific responsibilities and accountabilities that are described in the documents required in ME 2 and how effectively they have been carried out, and/or to the criteria for public governance or criteria developed and adopted by the governing entity. The hospital's governance structure is represented or displayed in an organizational chart or other document that shows lines of authority and accountability. The individuals represented on the chart are identified by title or name.

Measurable Elements of GLD.1

- 1. The hospital's governance structure is described in a written document(s), and those responsible for governance of the hospital are identified by name and governance function.
- 2. Governance responsibilities and accountabilities are described in the document(s).
- ☐ 3. The document(s) describes how the governing entity will be evaluated and the criteria approved for the evaluation process.
- 4. There is an annual evaluation conducted of the governing entity, and the results are documented.
- ☐ 5. The document(s) describes when and how governance and senior management authority can be delegated.

Standard GLD.1.1

Intent of GLD.1.1

The governing entity's responsibilities and accountabilities are described in a document(s) that identifies how they are to be carried out. The governing entity has important responsibilities that must be carried out for the hospital to have clear leadership, to operate efficiently, and to provide high-quality health care services. These responsibilities are primarily at the approval level and include

- approving and periodically reviewing the hospital's mission and ensuring that the public is aware of the hospital's mission;
- approving the hospital's various strategic and operational plans and the policies and procedures needed to operate the hospital on a daily basis;
- approving the hospital's participation in health care professional education and in research and the oversight of the quality of such programs; (Also see GLD.14 and GLD.15)
- approving or providing a capital and operating budget(s) and other resources required to operate the hospital and to meet the hospital's mission and strategic plan; and
- appointing or approving the hospital's chief executive(s), and providing for an annual evaluation of the individual's(s') performance using an established criteria and process.

Measurable Elements of GLD.1.1

- ☐ 1. Those responsible for governance approve, periodically review, and make public the hospital's mission statement.
- 2. Those responsible for governance approve the hospital's strategic plans, operational plans, policies, and procedures.
- 3. Those responsible for governance approve the hospital's capital and operating budget(s) and allocate other resources required to meet the hospital's mission. (*Also see* COP.8)
- 4. Those responsible for governance approve the hospital's participation in health care professional education and in research and in the oversight of the quality of such programs.
- 5. Those responsible for governance appoint, and annually evaluate, the hospital's chief executive(s) using established criteria and process.

Standard GLD.1.2

Those responsible for governance approve the hospital's program for quality and patient safety and regularly receive and act on reports of the quality and patient safety program.

Intent of GLD.1.2

The governance structure approves or provides for all of the hospital's programs and policies and allocates resources to meet the hospital's mission. One important accountability is to carry out all responsibilities in a manner that supports the continual improvement in quality and patient safety. This important investment in quality needs to be planned, provided adequate resources, and monitored for progress. Thus, governance approves the quality program on an annual basis, and on a regular basis receives quality reports. The reports can be global in nature or focus on a particular clinical service, a patient group, or some operational aspect. Thus, over a period of time, all aspects of the quality program, including adverse events and sentinel events, are presented to governance for their information and discussion. When the discussion results in actions, such as allocation of additional resources, those actions are recorded in minutes and are reexamined at a future meeting(s).

Measurable Elements of GLD.1.2

- ☐ 1. Those responsible for governance annually approve the hospital's program for quality and patient safety.
- ☐ 2. Those responsible for governance at least quarterly receive and act on reports of the quality and patient safety program, including reports of adverse and sentinel events. (*Also see* QPS.4.1, ME 5)
- ☐ 3. Minutes reflect actions taken and any follow-up on those actions.

Chief Executive(s) Accountabilities

Standard GLD.2

Intent of GLD.2

Effective leadership is essential for a hospital to be able to operate efficiently and to fulfill its mission. Leadership is what individuals provide together and individually to the hospital and can be carried out by any number of individuals.

The chief executive(s) is responsible for the hospital's overall, day-to-day operations. This includes the procurement and inventory of essential supplies, maintenance of the physical facility, financial management, quality management, and other responsibilities. The education and experience of the individual(s) matches the requirements in the position description. The chief executive(s) cooperates with hospital leadership to define the hospital's mission and to plan the policies, procedures, and clinical services related to that mission. Once approved by the governing body, the chief executive(s) is responsible for implementing all policies and ensuring that all policies are complied with by the hospital's staff. (Also see the QPS chapter)

The chief executive(s) is responsible for the hospital's

- compliance with applicable laws and regulations;
- response to any reports from inspecting and regulatory agencies; and
- processes to manage and to control human, financial, and other resources.

Measurable Elements of GLD.2

- ☐ 1. The education and experience of the chief executive(s) match the requirements in the position description.
- ☐ 2. The chief executive(s) manages the hospital's day-to-day operations, including those responsibilities described in the position description.
- □ 3. The chief executive(s) recommends policies, strategic plans, and budgets to the governing body.

4. The chief executive(s) ensures compliance with approved policies.
 5. The chief executive(s) ensures compliance with applicable laws and regulations.
 6. The chief executive(s) responds to any reports from inspecting and regulatory agencies.

Hospital Leadership Accountabilities

Standard GLD.3

Hospital leadership is identified and is collectively responsible for defining the hospital's mission and creating the programs and policies needed to fulfill the mission.

Intent of GLD.3

Hospital leadership comes from many sources. The governing body names the chief executive(s). The chief executive(s) may name others to hospital leadership. Hospital leadership may have formal titles, such as Medical Director or Director of Nursing, may be leaders of clinical or nonclinical departments or services, or may be informally recognized for their seniority, stature, or contribution to the hospital. It is important that hospital leadership is recognized and brought into the process of defining the hospital's mission. Based on that mission, hospital leadership works collectively and collaboratively to develop the programs, policies, and services needed to fulfill the mission. When the mission and policy framework are set by owners or agencies outside the hospital, hospital leadership works collaboratively to carry out the mission and policies.

Measurable Elements of GLD.3

- 1. The chief executive(s) and hospital leadership are identified by title and name, and their collective accountabilities are described in written documents.
- 2. Hospital leadership is responsible for defining the hospital's mission.
- 3. Hospital leadership is responsible for creating the policies and procedures necessary to carry out the mission.
- 4. Hospital leadership ensures that policies and procedures are followed.

Standard GLD.3.1

Intent of GLD.3.1

Patient care services are planned and designed to respond to the needs of the patient population. The care and services to be provided are documented and are consistent with the hospital's mission. Hospital leadership determines with the leaders of the various clinical departments and services in the hospital the diagnostic, therapeutic, rehabilitative, and other services that are essential to the patient population. Hospital leadership also plans with the department/service leaders the scope and intensity of the various services to be provided by the hospital directly or indirectly. When applicable to the mission, hospital leadership plans and participates with the community, local hospitals, and others in meeting community health care needs. The services planned reflect the strategic direction of the hospital and the perspective of the patients cared for by the hospital.

Planning patient care services also involves hospital leadership defining its communities and patient populations, identifying community needs for services, and planning ongoing communication with those key community stakeholder groups. The communications may be directly to individuals or through public media and through agencies within the community or third parties. The types of information communicated include

- information on services, hours of operation, and the process to obtain care; and
- information on the quality of services, which is provided to the public and to referral sources.

Measurable Elements of GLD.3.1

- ☐ 1. Hospital leadership determines and plans with department/service leaders the type of care and services to be provided by the hospital that are consistent with the hospital's mission and needs of the patients served by the hospital. (*Also see* ACC.1, ME 1)
- ☐ 2. Hospital leadership communicates with key stakeholders in its community to facilitate access to care and access to information about its patient care services.
- ☐ 3. Hospital leadership provides data and information on the quality of its services to stakeholders. (*Also see* QPS.6, ME 4)
- 4. Hospital leadership describes and documents the care and services to be provided.

Standard GLD.3.2

Intent of GLD.3.2

Effective communication within a hospital is the responsibility of hospital leadership. Thus, hospital leadership understands the dynamics of communication between professional groups; between structural units, such as departments; between professional and nonprofessional groups; between health professionals and management; between health professionals and families; and between health professionals and outside organizations, **for example**. Hospital leadership not only sets the parameters of effective communication but also serves as role models with the effective communication of the hospital's mission, strategies, plans, and other relevant information. Hospital leadership pays attention to the accuracy and timeliness of information shared and communicated throughout the hospital.

To coordinate and to integrate patient care, hospital leadership develops a culture that emphasizes cooperation and communication. Formal (**for example**, standing committees, joint teams) and informal (**for example**, newsletters and posters) methods for promoting communication among services and individual staff members are used. Coordination of clinical services comes from an understanding of each department's mission and services and collaboration in developing common policies and procedures.

Measurable Elements of GLD.3.2

- ☐ 1. Hospital leadership ensures that processes are in place for communicating relevant information throughout the hospital in a timely manner.
- 2. Hospital leadership ensures effective communication among clinical and nonclinical departments, services, and individual staff members.
- 3. Hospital leadership communicates the hospital's vision, mission, goals, policies, and plans to staff.

Standard GLD.3.3

Hospital leadership ensures that there are uniform programs for the recruitment, retention, development, and continuing education of all staff.

Intent of GLD.3.3

A hospital's ability to care for patients is directly related to its ability to attract and to retain qualified, competent staff. Hospital leadership recognizes that staff retention, rather than recruitment, provides greater long-term benefit. Retention is increased when hospital leadership supports staff advancement through continuing education. Thus, hospital leadership plans and implements a uniform program and processes related to

recruitment, retention, development, and continuing education for each category of staff. The hospital's recruitment program considers published guidelines, such as those from the World Health Organization, International Council of Nurses, and World Medical Association.

Measurable Elements of GLD.3.3

- ☐ 1. The hospital develops and implements a process for staff recruitment. (Also see SQE.2, ME 1)
- 2. The hospital develops and implements a process for staff retention.
- 3. The hospital develops and implements a process for staff personal development and continuing education. (Also see SQE.8)
- 4. The planning is collaborative and includes all departments and services in the hospital.

Hospital Leadership for Quality and Patient Safety

Standard GLD.4

Hospital leadership plans, develops, and implements a quality improvement and patient safety program.

Standard GLD.4.1

Hospital leadership communicates quality improvement and patient safety information to governance and hospital staff on a regular basis.

Intent of GLD.4 and GLD.4.1

If a hospital is to successfully initiate and to maintain improvement and reduce risks to patients and staff, leadership and planning are essential. Leadership and planning begins with the governing body of the hospital, along with those who manage and lead the clinical and managerial activities of the hospital on a daily basis. Collectively, these persons represent the leaders of the departments and services of the hospital. Hospital leadership is responsible for establishing and providing ongoing support for an organizational commitment to quality. Hospital leadership develops the quality and patient safety program for governance approval, and through its vision and support, shapes the quality culture of the hospital. (Also see QPS.1)

Hospital leadership selects the approach to be used by the hospital to measure, assess, and improve quality and patient safety. Also, hospital leadership determines how the program will be directed and managed on a daily basis, such as a quality department, and ensures that the program has adequate resources to be effective.

Hospital leadership also implements a structure and process for the overall monitoring and coordination of the program throughout the hospital. These actions ensure coordination among all the department and services in measurement and improvement efforts. Coordination can be achieved through a quality management council/committee, or some other structure. Coordination encourages a systemwide approach to quality monitoring and improvement activities while reducing duplication of effort; for example, two departments independently measuring similar processes or outcomes. (Also see QPS.2 and PCI.10, ME 1)

Hospital leadership is also responsible for seeing that at least quarterly quality reports are prepared for governance review and discussion and for seeing that the actions of governance related to the quality program reports are carried out. In addition to the quarterly quality reports, at least once every six months, the quality report to governance includes

- the number and type of sentinel events and associated root causes;
- whether the patients and families were informed of the event;
- actions taken to improve safety in response to events; and
- if the improvements were sustained.

Regular communication of information about the quality improvement and patient safety program to staff is essential. This flow of quality communications is through effective channels, such as newsletters, storyboards, staff meetings, and human resources processes. The information can be about new or recently completed improvement projects, progress in meeting the International Patient Safety Goals, the results of the analysis of sentinel and other adverse events, or recent research or benchmark programs, among others.

Measurable Elements of GLD.4

- ☐ 1. Hospital leadership participates in developing and implementing a hospitalwide quality improvement and patient safety program.
- 2. Hospital leadership selects and implements a hospitalwide process to measure, assess data, plan change, and sustain improvements in quality and patient safety, and provides for staff education on this quality improvement process.
- 3. Hospital leadership determines how the program will be directed and managed on a daily basis and ensures that the program has adequate technology and other resources to be effective.
- 4. Hospital leadership implements a structure and process for the overall monitoring and coordination of the quality improvement and patient safety program.

Measurable Elements of GLD.4.1

- ☐ 1. Hospital leadership reports on the quality and patient safety program quarterly to governance.
- 2. Hospital leadership reports to governance include, at least once every six months, the number and type of sentinel events and root causes, whether the patients and families were informed of the sentinel event, actions taken to improve safety in response to sentinel events, and if the improvements were sustained. (Also see QPS.7)
- ☐ 3. Information on the quality improvement and patient safety program is regularly communicated to staff, including progress on meeting the International Patient Safety Goals.

Standard GLD.5

Hospital leadership prioritizes which hospitalwide processes will be measured, which hospitalwide improvement and patient safety activities will be implemented, and how success of these hospitalwide efforts will be measured.

Intent of GLD.5

Due to staff and resource limitations, not every process within a hospital can be measured and improved at the same time. Thus, a primary responsibility of hospital leadership is to set hospitalwide measurement and improvement priorities. These are measurement and improvement efforts that impact or reflect activities in multiple departments and services. Hospital leadership provides focus for the hospital's quality measurement and improvement activities, including measurement and activities regarding the hospital's full compliance with the International Patient Safety Goals. Priorities may focus on the achievement of strategic objectives; for example, to become the leading regional referral center for cancer patients. Similarly, hospital leadership may give priority to projects that increase efficiency, reduce readmission rates, eliminate patient flow problems in the emergency department, or create a monitoring process for the quality of services provided by contractors. Hospital leadership considers priorities at a system level to spread the impact of improvements broadly throughout the hospital; for example, improving the hospital's medication management system. The priority-setting process includes the consideration of available data on which systems and processes demonstrate the most variation in implementation and outcomes. Hospital leadership ensures that, when present, clinical research and medical education programs are represented among the priorities.

Hospital leadership also assesses the impact of improvements. Measuring improvement in efficiency of a complex clinical process, and/or identifying reductions in cost and resource use following improvement in a process, are **examples**. Measuring the impact of an improvement supports an understanding of the relative costs for investing in quality and the human, financial, and other returns on that investment. Hospital leadership

supports the creation of simple tools to quantify resource use of the old process and for assessing a new process. Understanding both the impact of an improvement on patient outcome and the relative cost and resulting process efficiency contributes to improved priority setting in the future, both at an organizational level and at a departmental/service level. When this information is combined hospitalwide, hospital leadership can better understand how to allocate available quality and patient safety resources. (*Also see* QPS.2, QPS.4.1, PCI.6, PCI.6.1, and GLD.11)

Measurable Elements of GLD.5

- ☐ 1. Hospital leadership uses available data to set collective priorities for hospitalwide measurement and improvement activities and consider potential system improvements.
- 2. Hospital leadership ensures that, when present, clinical research and health professional education programs are represented in the priorities.
- ☐ 3. Hospital leadership priorities include full compliance with the International Patient Safety Goals.
- 4. Hospital leadership assesses the impact of hospitalwide and departmental/service improvements on efficiency and resource use. (Also see QPS.5)

Hospital Leadership for Contracts

Standard GLD.6

Intent of GLD.6

Hospitals frequently have the option to either provide clinical and management services directly or to arrange for such services through referral, consultation, contractual arrangements, or other agreements. Such services may range from radiology and diagnostic imaging services to financial accounting services and services provided for housekeeping, food, or linens. Hospital leadership describes, in writing, the nature and scope of services provided through contractual agreements.

When contracts relate to health professional staffing—for example, a contract for critical care nurses—the contracts stipulate that the professional staff provided meet the hospital's requirement for similar staff. For example, the critical care nurses meet the requirement of SQE.13, ME 6. In all cases, hospital leadership is accountable for such contracts or other arrangements to ensure that the services meet patient needs and are included as part of the hospital's quality management and improvement activities. Department/service leaders participate in the review and selection of all clinical and nonclinical contracts and are accountable for monitoring those contracts. (Also see ASC.1 and MOI.6)

Measurable Elements of GLD.6

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_	١.	Hospital leadership	D 18	accountable for	contracts to meet	patient and	management need	IS.

- ☐ 2. The hospital has a written description of the nature and scope of those services to be provided through contractual agreements.
- ☐ 3. Health professional staff contracts require credential review comparable to the hospital's review process.
- 4. Department/service leaders share accountability for the review, selection, and monitoring of clinical and nonclinical contracts. (*Also see* AOP.5.1, ME 5 and AOP.6.1, ME 5)
- 5. When contracts are renegotiated or terminated, the hospital maintains the continuity of patient services.

Standard GLD.6.1

Hospital leadership ensures that contracts and other arrangements are included as part of the hospital's quality improvement and patient safety program.

Intent of GLD.6.1

The quality and safety of patient care require evaluation of all services provided by the hospital or provided through contracts. Thus, the hospital needs to receive, to analyze, and to take action on quality information from outside sources. The contract with the outside source of service includes quality and patient safety expectations and the data that are to be provided to the hospital, their frequency, and their format. Department/service leaders receive and act on quality reports from contracting agencies that relate to the scope of services provided within their department/service and ensure that the reports are integrated into the hospital's quality measurement process. (Also see AOP.5.10.1, ASC.1, and MOI.6)

Measurable Elements of GLD.6.1

1.	All contracts stipulate the quality data that are to be reported to the hospital, the reporting frequency
	and mechanism, and how the hospital will respond when quality requirements or expectations are not
	met.

	2. Ç	uality of	data rej	orted	under	contracts	are integrat	ed into	the ho	spital's	quality	y monitorin	g program.
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3.	The relevant clinical and managerial leaders participate with the quality improvement program in the
	analysis of quality and safety information from outside contracts.

Standard GLD.6.2

Intent of GLD.6.2

Clinical leaders may recommend contracts with or arrange services from physicians, dentists, and other independent practitioners outside the hospital or arrange for them to come into the hospital to provide services. In some cases, these individuals may even be located outside the region or country of the hospital. The services provided may include telemedicine or teleradiology. If the services provided determine the care choice or course of care for the patient, the practitioner must proceed through the credentialing and privileging processes of the hospital.

Measurable Elements of GLD.6.2

_	1.	outside the hospital.
	2.	All diagnostic, consultative, and treatment services provided by independent practitioners outside

1 Hospital leadership determines these corriges that will be provided by independent practitioners

Ц	2.	All diagnostic, consultative, and treatment services provided by independent practitioners outside the
		hospital, such as telemedicine, teleradiology, and interpretations of other diagnostics, such as
		electrocardiogram (ECG), electroencephalogram (EEG), and electromyogram (EMG), and the like, are
		privileged by the hospital to provide such services.

3.	Independent practitioners who provide patient care services on the premises of the hospital but are not
	employees or members of the clinical staff are credentialed and privileged as required in SQE.9 through
	SQE.12.

4.	The quality of services by independent practitioners outside the hospital is monitored as a component
	of the hospital's quality improvement program.

Hospital Leadership for Resource Decisions

Standard GLD.7

Hospital leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.

Intent of GLD.7

Hospital leadership improves decision making when they have data upon which to base those decisions. For example, when the hospital needs to replace or add infusion pumps, information on maintenance requirements, staff training or retraining requirements, information on previous failure rates and patient safety incidents, preferences of staff, alarm issues, and others, will result in decisions based more on quality and patient safety than on cost alone. Similarly, when making decisions regarding the reduction or reassignment of nursing staff, consideration of the implications for patient care quality and patient safety need to be brought forward to inform the decision. (Also see SQE.6) Hospital leadership develops a process to gather data and information for key purchase or resource decisions to ensure that they include a safety and quality due-diligence component.

One component of data gathering related to resource decisions is to understand the required or recommended medical technology, supplies, and medications necessary to provide a service. Recommendations on medical technology, supplies, and medication can come from a government agency, national or international professional organizations, or other authoritative sources. (Also see QPS.3)

When resource decisions are made by a third party—for example, a ministry of health—hospital leadership provides data and information to the third party on their experiences and preferences to better inform future resource choices.

When a hospital uses what is identified as "experimental" medical technology and/or pharmaceutical agents in patient care procedures (that is, medical technology or agents identified as "experimental" either nationally or internationally), there is a process to review and to approve such use. It is essential that such approval occur prior to use in patient care. A determination is made if special patient consent is necessary. (*Also see* COP.8 and SQE.11)

Measurable Elements of GLD.7

- 1. Hospital leadership seeks data to inform decisions related to the purchase and use of new technologies.
- 2. Hospital leadership uses data and information on the quality and safety implications of medical technology choices.
- 3. Hospital leadership uses data and information on the quality and safety implications of staffing choices.
- 4. Hospital leadership monitors the results of its decisions and uses the data to evaluate and improve the quality of its resource purchasing and allocation decisions.
- 5. The hospital uses the recommendations of professional organizations and other authoritative sources in making resource decisions.

Standard GLD.7.1

Hospital leadership seeks and uses data and information on the safety of the supply chain for drugs, medical technology, and supplies to protect patients and staff from contaminated, fake, and diverted products.

Intent of GLD.7.1

Supply chain management (**for example**, how supplies move from the manufacturer to distributors and eventually to the hospital; *see* Glossary) is an important component of ensuring not only the timely availability of

necessary supplies, but in preventing drugs, medical technology, and supplies that are contaminated, fake, or from diverted sources from reaching the hospital's patients. This well-documented global problem begins with understanding the reputation, credibility, and ethical operation of each component of the hospital's supply chain. Although this information may not be complete and may be difficult to piece together, the hospital can, at minimum, decide where the most significant risks reside and make better-informed choices. Product tracking through bar coding and other means can help management and staff understand the supply chain and prevent diversion. Although there is no single global standard for supply chains, or even national standards in many countries, it is the responsibility of hospital leadership to be informed on the issues and implement available strategies to protect the integrity of their most important supply chains. When hospital supplies are purchased, stored, and distributed by a governmental authority, the hospital participates in programs to detect and report suspected contaminated and fake supplies and take measures to prevent potential patient harm. While such a public hospital may not know the integrity of each supplier in the chain, it can become aware of how supplies are purchased and managed by the governmental or nongovernmental agency.

Measurable Elements of GLD.7.1

- ☐ 1. Hospital leadership identifies the supply chain of critical supplies and medical technology.
- 2. Hospital leadership evaluates the integrity of each supplier in that chain.
- 3. Hospital leadership makes resource decisions based on their understanding of the risks in the supply chain.
- 4. Hospital leadership tracks critical supplies to prevent diversion or substitution.

Clinical Staff Organization and Accountabilities

Standard GLD.8

Medical, nursing, and other leaders of departments and clinical services plan and implement a professional staff structure to support their responsibilities and authority.

Intent of GLD.8

Medical, nursing, and other leaders of departments and clinical services have special responsibilities to patients and to the hospital. These department/service leaders

- support good communication between professionals;
- jointly plan and develop policies; clinical guidelines; and related protocols, pathways, and other documents that guide the delivery of clinical services;
- provide for the ethical practice of their professions; and
- oversee the quality of patient care. (Also see GLD.11.2 and GLD.12.1)

The department/service leaders of the medical and nursing staff create a suitable professional staff structure(s) to carry out these responsibilities. The structure(s) and the associated processes or committees used to carry out these responsibilities can be through a single professional staff composed of physicians, nurses, and other health professionals or separate medical and nursing staff structures, **for example**. The structure chosen can be highly organized with committees, bylaws, and rules and regulations or can be informally organized. In general, the structure(s) chosen

- includes all the relevant clinical staff;
- is consistent with the hospital's ownership, mission, and structure;
- is appropriate for the hospital's complexity and size of the professional staff; and
- is effective in carrying out the responsibilities listed above. (Also see SQE.1)

Measurable Elements of GLD.8

- 1. There is a professional staff structure(s) used by medical, nursing, and other department/service leaders to carry out their responsibilities and authority.
- ☐ 2. The structure(s) is appropriate to the hospital's size and complexity.
- ☐ 3. The organizational structure(s) and processes support a culture of safety and professional communication.
- 4. The organizational structure(s) and processes support clinical planning and policy development.
- □ 5. The organizational structure(s) and processes support oversight of professional ethical issues.
- ☐ 6. The organizational structure(s) and processes support oversight of the quality of clinical services.

Direction of Hospital Departments and Services

Standard GLD.9

One or more qualified individuals provide direction for each department or service in the hospital. ®

Intent of GLD.9

The clinical care, patient outcomes, and overall management of a hospital are only as good as the clinical and managerial activities of each individual department or service. Good departmental or service performance requires clear leadership from a qualified individual. In larger departments or services, there may be multiple leaders. In such a case, the responsibilities of each role are defined in writing.

Each department/service leader communicates his or her human resources and other resource requirements to hospital leadership. This helps ensure that adequate staff, space, medical technology, equipment, and other resources are available to meet patients' needs at all times. Although the department/service leaders make recommendations regarding human and other resource needs, those needs sometimes change or are not fully met. Thus, department/service leaders have a process to respond to resource shortages to ensure safe and effective care for all patients.

Department/service leaders consider the services provided and planned by the department or service and the education, skills, knowledge, and experience needed by the department's professional staff to provide those services. Department/service leaders develop criteria reflecting this consideration and then select staff. Department/service leaders may also work with human resources or other departments in the selection process based on their recommendations.

Department/service leaders ensure that all staff in the department or service understand their responsibilities and establish the orientation and training for new employees. The orientation includes the hospital's mission, the department's or service's mission, the scope of services provided, and the policies and procedures related to providing services. **For example**, all staff understand the infection prevention and control procedures within the hospital and within the department or service. When new or revised policies or procedures are implemented, staff are trained. (*Also see* ACC.3, ME 1; AOP.5.1; AOP.6.1; AOP.5.11, ME 1; ASC.2; MMU.1; QPS.1; and PCI.1)

Measurable Elements of GLD.9

- 1. Each department or service in the hospital is directed by an individual with the training, education, and experience comparable to the services provided. (*Also see* AOP.5.11, ME 1 and COP.8.1)
- ☐ 2. Department/service leaders recommend space, medical technology, equipment, staffing, and other resources needed by the department or service and have a process in place to respond to shortages. (Also see AOP.6.2, ME 5; COP.3.2; COP.8; and SQE.6)

3.	Department/service leaders recommend criteria for selecting the department's or service's professiona staff and choose or recommend individuals who meet those criteria. (Also see COP.8.2)
4.	Department/service leaders provide orientation and training for all staff of the duties and responsibilities for the department or service to which they are assigned. (<i>Also see</i> AOP.5.3, ME 4; AOP.6.3 ME 4; and SOE.7)

Standard GLD.10

Intent of GLD.10

The department/service leaders collaborate to determine the uniform format and content of the department-specific planning documents. In general, the documents prepared by each clinical department define its goals, as well as identify current and planned services. Department policies and procedures reflect the department's goals and services as well as the knowledge, skills, and availability of staff required to assess and to meet patient care needs. (*Also see* ACC.3, ME 1)

Clinical services provided to patients are coordinated and integrated within each department or service. For **example**, there is integration of medical and nursing services. Also, each department or service coordinates and integrates its services with other departments and services. Unnecessary duplication of services is avoided or eliminated to conserve resources.

Measurable Elements of GLD.10

_	_	
		documents.
	1.	Department/service leaders have selected and use a uniform format and content for planning

2.	The departmental or service documents describe the current and planned services provided by each
	department or service.

	The department				

- 4. The departmental or service documents address the staff knowledge and skills needed to assess and to meet patient needs.
- ☐ 5. There is coordination and/or integration of services within and with other departments and services.

Standard GLD.11

Department/service leaders improve quality and patient safety by participating in hospitalwide improvement priorities and in monitoring and improving patient care specific to the department/service.

Intent of GLD.11

Department/service leaders engage their staff in improvement activities that reflect the hospitalwide priorities (see GLD.5) and address the clinical or nonclinical activities specific to the department or service. For example, a clinical department or service would participate in the hospitalwide effort to improve handover communications and also may monitor and reduce variation in an internal process such as the ordering of diagnostic tests for patients with the same condition. Similarly, a managerial department may be involved in automation projects to improve handover communications and also may monitor and improve the accuracy of patient bills.

Department/service leaders of clinical departments or services also consider the Joint Commission International Library of Measures as applicable to the services provided by the department or service.

Thus, the leaders of the department or service implement the selection and monitoring of measures specific to the department or service that include the following:

- Those hospitalwide measurement and improvement priorities set by hospital leadership that relate to their specific department or service
- The measures associated with specific department/service priorities to reduce variation, improve the safety of high-risk procedures/treatments, improve patient satisfaction, or improve efficiency

Selection of measures should be based on those activities and processes that need improvement in the department or service. For each measure, a target should be set. It is expected that initial measurement will not reach the target; however, once strategies for improvement are implemented, department/service leaders should expect to see improvement toward the target. When the target has been met and sustained for at least four measurement periods, a new measure is selected.

The leader of the clinical department or service is responsible for ensuring that the measurement activities provide the opportunity for the evaluation of staff as well as the processes of care. Thus, measurement includes, over time, all of the services provided. The resulting data and information are important to the department's or service's improvement efforts but are also important to the hospital's quality improvement and patient safety program. (Also see QPS.1, ME 3; QPS.2; and PCI.10, ME 1)

Note: Some departments, such as infection control, facility management, radiology, and the clinical laboratory, have ongoing quality monitoring or control programs that are included in the measurement priorities and are described in the standards related to those services. (*Also see* AOP.5.9, AOP.6.7, PCI.10, and FMS.10)

Measurable Elements of GLD.11

- 1. Department/service leaders implement hospitalwide quality measures that relate to the services provided by their department or service, including any contracted services for which they are responsible.
- 2. Department/service leaders implement quality measures to reduce variation and improve processes within the department or service, including implementation of measures found in the Joint Commission International Library of Measures.
- ☐ 3. Department/service leaders select measures based on the need for improvement, and once improvement has been sustained, select a new measure. (Also see QPS.10, ME 2)
- 4. Department and service quality measurement and improvement activities are integrated into and supported by the quality management and coordination structure of the organization. (Also see QPS.10)

Standard GLD.11.1

Department/service leaders of clinical departments or services select and implement quality and patient safety measures specific to the scope of services provided by the department or service and useful in the evaluation of the physicians, nurses, and other professional staff participating in the clinical care processes.

Intent of GLD.11.1

The leader of a clinical department or service is responsible for ensuring that the measurement activities provide the opportunity for the evaluation of staff as well as the processes of care. For example, the department/service leader will be involved in the appointment, privilege delineation, ongoing monitoring and evaluation, and reappointment of the physicians within the department or service. To ensure that the department/service leader has objective information to support these activities, quality measurement includes, over time, all of the services provided by the department or service and includes the clinical privileges of all the physicians. The "Clinical Results" section of the intent of SQE.11 provides additional information on the ongoing physician evaluation process. In some cases the measures will be linked to the clinical practice guidelines implemented in the department or service (also see GLD.11.2). When possible, the measures will be taken from the Joint Commission International Library of Measures to permit the use of standardized measures within the department or service and to permit comparisons with other organizations.

Similarly, data are needed to support the evaluation of the nurses and other health professional staff in the department. Although these individuals have job descriptions rather than clinical privileges, the department/service leader is still accountable for evaluating their work. Standard SQE.3 describes the evaluation process for these individuals, and the measurement activities described in this standard will support an objective evaluation process. In many cases, the clinical practice guidelines implemented in the department or service will have associated pathways and protocols that will support the collection of measurement data for nursing staff and other health professionals. (Also see QPS.2 and SQE.10)

Measurable Elements of GLD.11.1

- 1. Department/service leaders implement measures that will be useful in the ongoing professional practice review of the department's or service's physicians. (Also see SQE.11)
- ☐ 2. Department/service leaders implement measures that will be useful in the performance evaluation of nursing staff. (*Also see* SQE.14.1, ME 2)
- ☐ 3. Department/service leaders implement measures that will be useful in the performance evaluation of other health professional staff. (Also see SQE.16.1, ME 2)

Standard GLD.11.2

Department/service leaders select and implement clinical practice guidelines, and related clinical pathways, and/or clinical protocols, to guide clinical care.

Output

Department/service leaders select and implement clinical practice guidelines, and related clinical pathways, and/or clinical protocols, to guide clinical care.

Intent of GLD.11.2

The goals of hospitals include

- standardizing clinical care processes;
- reducing risks within care processes, particularly those associated with critical decision steps;
- providing clinical care in a timely, effective manner using available resources efficiently; and
- consistently delivering high-quality care using evidence-based practices.

Hospitals use a variety of tools to reach these and other goals. **For example**, health care practitioners seek to develop clinical care processes and make clinical care decisions based on the best available scientific evidence. Clinical practice guidelines are useful tools in this effort to understand and to apply the best science to a particular diagnosis or condition. (*Also see* PCI.6.1) The hospital uses only those clinical practice guidelines that have been reviewed and endorsed by relevant authoritative sources; **for example**, a national professional association or council, or international organization that catalogues approved guidelines. If the clinical practice guideline was developed by the hospital, it would be submitted to an authoritative source for endorsement.

Frequently, the effective implementation of a clinical practice guideline will require clinical care pathways and clinical protocols to be adapted or developed. Pathways and protocols are useful tools in this effort to ensure effective sequencing, integration, and coordination of care and efficient use of available resources.

Clinical practice guidelines and any related clinical care pathways and clinical protocols relevant to the hospital's patient population and mission are

- a) selected from among those applicable to the services and patients of the hospital (mandatory national guidelines are included in this process, if present);
- b) evaluated for their relevance to identified patient populations;
- c) adapted when needed to the technology, drugs, and other resources of the hospital or to accepted national professional norms;
- d) assessed for their scientific evidence and endorsement by an authoritative source;
- e) formally approved or adopted by the hospital;
- f) implemented and measured for consistent use and effectiveness;
- g) supported by staff trained to apply the guidelines or pathways; and
- h) periodically updated based on changes in the evidence and evaluation of processes and outcomes.

As many guidelines, and related protocols and pathways, impact multiple clinical departments or services, the leaders are collectively expected to accomplish the following on an annual basis:

- Department/service leaders collectively determine at least five hospitalwide priority areas on which to
 focus—for example, a patient diagnosis such as stroke, or a procedure such as transplantation, or a
 population such as geriatric, or a disease such as diabetes, among others—for which guidelines would
 impact the quality and safety of patient care and reduce unwanted variation in outcomes. (Also see
 GLD.11.1)
- Complete the process described in a) through h) for the guideline related to the identified priority focus
 areas.

This collective selection process does not prohibit an individual department or service from selecting additional guidelines, and any associated protocols or pathways more specific to the services provided in that department or service. (Also see IPSG.5; COP.8.6; COP.9.3, ME 1; GLD.8; and SQE.11)

Measurable Elements of GLD.11.2

- 1. On an annual basis, department/service leaders collectively determine at least five hospitalwide priority areas on which to focus the use of clinical practice guidelines.
- ☐ 2. Department/service leaders follow the process described in a) through h) of the intent in selecting and implementing clinical practice guidelines.
- ☐ 3. Department/service leaders implement clinical guidelines and any associated clinical pathways or clinical protocols for each identified priority area as relevant to the department/service.
- 4. Department/service leaders demonstrate how the use of clinical practice guidelines, clinical pathways, and/or clinical protocols has reduced variation in processes and outcomes.

Organizational and Clinical Ethics

Standard GLD.12

The hospital's framework for ethical management addresses operational and business issues, including marketing, admissions, transfer, discharge, and disclosure of ownership and any business and professional conflicts that may not be in patients' best interests.

Standard GLD.12.1

Hospital leadership establishes a framework for ethical management that promotes a culture of ethical practices and decision making to ensure that patient care is provided within business, financial, ethical, and legal norms and protects patients and their rights.

Output

Description:

Standard GLD.12.2

The hospital's framework for ethical management addresses ethical issues and decision making in clinical care. (9)

Intent of GLD.12 Through GLD.12.2

Hospitals face many challenges in providing safe, high-quality health care. With advances in medical technology, financial constraints, and increasing expectations, ethical dilemmas and controversies are much more common. Hospital leadership has a professional and legal responsibility to create and promote an environment and culture that operate within an ethical framework. The ethical framework must apply to both the hospital's business and clinical activities alike. Hospital leadership must demonstrate ethical behaviors and develop guidelines for organizational performance and conduct. Hospital leadership's actions and the hospital's guidelines for ethical behavior must be congruent with the hospital's vision, mission, and value statements; personnel policies; annual reports; and other documents.

The framework supports the hospital's health care providers, other staff, and patients and family when confronted by ethical dilemmas in patient care, such as interprofessional disagreements and disagreements between patients and their health care practitioners regarding care decisions. Such support is readily available and includes ethics resources and training for health care providers and other staff. In addition, national and international norms related to human rights and professional ethics must be taken into consideration when creating an ethical framework and guiding documents.

The hospital operates within this framework to

- disclose ownership and any conflicts of interest;
- honestly portray its services to patients;
- protect confidentiality of patient information;
- provide clear admission, transfer, and discharge policies;
- bill accurately for its services and ensure that financial incentives and payment arrangements do not compromise patient care;
- encourage transparency in reporting organizational and clinical performance measures;
- establish a mechanism by which health care providers and other staff may report clinical errors and raise ethical concerns with impunity, including disruptive staff behavior related to clinical and/or operational
- support an environment that allows free discussion of ethical concerns without fear of retribution;
- provide an effective and timely resolution to ethical conflicts that arise;
- ensure nondiscrimination in employment practices (see Glossary) and provision of patient care in the context of the cultural and regulatory norms of the country; and
- reduce disparities in health care access and clinical outcomes. (Also see COP.1, PFR.1.1, and GLD.8)

Measurable Flements of GLD 12

	1.	Hospital leadership establishes a framework for the hospital's ethical management that promotes a culture of ethical practices and decision making to ensure the protection of patients and their rights.
	2.	The ethical framework ensures that patient care is provided within business, financial, ethical, and legal norms.
	3.	The hospital ensures nondiscrimination in employment practices and provision of patient care in the context of the cultural and regulatory norms of the country.
	4.	Hospital leadership examines national and international ethical norms for incorporation when developing the hospital's framework for ethical conduct.
_		urable Elements of GLD.12.1 The hospital discloses its ownership and any conflicts of interest. (Also see AOP.5, ME 5 and AOP.6.

┙	1.	The hospital	discloses its	ownership and	d any conflicts	of interest.	(Also see AOP.5,	, ME 5 and A0	ЭР.6,
		ME 5)							

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3.	The hospital accurately bills for services and ensures that financial incentives and payment
	arrangements do not compromise patient care.

Measurable Elements of GLD.12.2

- The hospital's framework for ethical management establishes a mechanism by which health care providers and other staff may raise ethical concerns without fear of retribution.
- Support for identifying and addressing ethical concerns is readily available and includes ethics resources and training for health care providers and other staff.
- □ 3. The hospital provides an effective and timely resolution to ethical conflicts that arise.

Standard GLD.13

Standard GLD.13.1

Hospital leadership implements, monitors, and takes action to improve the program for a culture of safety throughout the hospital.

Intent of GLD.13 and GLD.13.1

A culture of safety has been defined as follows: "The safety culture of [a hospital] is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, [a hospital's] health and safety management. [Hospitals] with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures."

Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the hospital. Hospital leadership demonstrates their commitment to a culture of safety and set expectations for those who work in the hospital. Behaviors that are not consistent with a safe culture or that intimidate others and affect morale or staff turnover can be harmful to patient care. Key features of a program for a culture of safety include

- acknowledgment of the high-risk nature of a hospital's activities and the determination to achieve consistently safe operations;
- an environment in which individuals are able to report errors or near misses without fear of reprimand or punishment;
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems; and
- organizational commitment of resources, such as staff time, education, a safe method for reporting issues, and the like, to address safety concerns.^{2,8–16}

Health care continues to have a culture of individual blame, which impairs the advancement of a safety culture. There are instances in which individuals should not be blamed for an error; **for example**, when there is poor communication between patient and staff, when there is a need for rapid decision making, or when there are human factor design flaws in a treatment process. However, certain errors are the result of reckless behavior and do require accountability. **Examples** of reckless behavior include failure to follow hand-hygiene guidelines, not performing the time-out before surgery, or not marking the surgical site. A culture of safety includes identifying and addressing issues related to systems that lead to unsafe behaviors. At the same time, though, hospitals must maintain accountability by establishing zero tolerance for reckless behavior. Accountability distinguishes between human error (such as a mix-up), at-risk behavior (**for example** taking shortcuts), and reckless behavior (such as ignoring required safety steps).

Hospital leadership evaluates the culture on a regular basis using a variety of methods, such as formal surveys, focus groups, staff interviews, and data analysis. Hospital leadership encourages teamwork and creates structures, processes, and programs that allow this positive culture to flourish. Hospital leadership must address undesirable behaviors of individuals working at all levels of the hospital, including management, clinical and administrative staff, licensed independent practitioners, and governing body members.

Measurable Elements of GLD.13

- ☐ 1. Hospital leadership establishes and supports an organizational culture that promotes accountability and transparency.
- 2. Hospital leadership develops and documents a code of conduct and identifies and corrects behaviors that are unacceptable.

3. Hospital leadership provides education and information (such as literature and advisories) relevant to the hospital's culture of safety to all individuals who work in the hospital.
 4. Hospital leadership defines how issues related to a culture of safety within the hospital are identified and managed.
 5. Hospital leadership provides resources to promote and support the culture of safety within the hospital.
 Measurable Elements of GLD.13.1
 1. Hospital leadership provides a simple, accessible, and confidential system for reporting issues relevant to a culture of safety in the hospital.
 2. Hospital leadership ensures that all reports related to the hospital's culture of safety are investigated in a timely manner.
 3. The hospital identifies systems issues that lead health care providers to engage in unsafe behaviors.
 4. Hospital leadership uses measures to evaluate and monitor the safety culture within the hospital and implement improvements identified from measurement and evaluation.
 5. Hospital leadership implements a process to prevent retribution against individuals who report issues related to the culture of safety.

Health Professional Education and Human Subjects Research

Note: This standard applies to hospitals that provide health professional education but do not meet the eligibility criteria for Academic Medical Center Hospital accreditation.

Standard GLD.14

Health professional education, when provided within the hospital, is guided by the educational parameters defined by the sponsoring academic program and the hospital's leadership.

Intent of GLD.14

Frequently, hospitals incorporate a teaching role in their mission and are the clinical setting for portions of medical, nursing, other health care practitioners, and other student training. **For example**, students and trainees in medicine may spend a few months gaining clinical experience in a community teaching hospital, or a nursing program may be based in the hospital. These hospitals serve an important role; however, they are not considered academic medical center hospitals for the purpose of these standards.

When the hospital participates in these types of training programs, the hospital

- provides a mechanism(s) for oversight of the program(s);
- obtains and accepts the parameters of the sponsoring academic program;
- has a complete record of all students and trainees within the hospital;
- has documentation of the enrollment status, licensure or certifications achieved, and academic classification of the students and trainees;
- understands and provides the required level of supervision for each type and level of student and trainee;
 and
- integrates students and trainees into the hospital's orientation, quality, patient safety, infection prevention and control, and other programs. (Also see GLD.1.1)

Measurable Elements of GLD.14

- 1. The hospital provides a mechanism(s) for oversight of the training program(s).
- 2. The hospital obtains and accepts the parameters of the sponsoring academic program.
- **1** 3. The hospital has a complete record of all students and trainees within the hospital.
- 4. The hospital has documentation of the enrollment status, licensure or certifications achieved, and academic classification of the students and trainees.
- 5. The hospital understands and provides the required level of supervision for each type and level of student and trainee.
- 6. The hospital integrates students and trainees into its orientation, quality, patient safety, infection prevention and control, and other programs.

Human Subjects Research

Note: This standard applies to hospitals that conduct human subjects research but do not meet the eligibility criteria for Academic Medical Center Hospital accreditation.

Standard GLD.15

Intent of GLD.15

Human subjects research on a large scale or small scale is a complex and significant endeavor for a hospital. Hospital leadership recognizes the required level of commitment and personal involvement required to advance scientific inquiry in the context of protecting the patients for whom they have made a commitment to diagnose and treat.

Hospital leadership's commitment to human subjects research is not separate from their commitment to patient care—commitment is integrated at all levels. Thus, ethical considerations, good communications, responsible leaders, regulatory compliance, and financial and nonfinancial resources are components of this commitment. One such resource is indemnity insurance to adequately compensate patients for adverse events due to the research protocol. Hospital leadership recognizes the obligation to protect patients irrespective of the sponsor of the research. (*Also see* GLD.1.1)

Measurable Elements of GLD.15

- 1. Hospital leadership identifies the official(s) responsible for maintaining the development of and compliance with all human subjects research policies and procedures.
- 2. Hospital leadership assumes responsibility for patient protection irrespective of the sponsor of the research.
- ☐ 3. Hospital leadership recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research.
- 4. Hospital leadership ensures that there is a source of indemnity insurance to adequately compensate patients participating in clinical research who experience an adverse event.

Standard GLD.16

Patients and families are informed about how to gain access to clinical research, clinical investigation, or clinical trials involving human subjects.

Intent of GLD.16

A hospital that conducts clinical research, clinical investigations, or clinical trials involving human subjects provides information to patients and families about how to gain access to those activities when relevant to the patients' treatment needs. When patients are asked to participate, they need information on which to base their decisions. That information includes

- expected benefits;
- potential discomforts and risks;
- alternatives that might also help them; and
- procedures that must be followed.

Patients are informed that they can refuse to participate or withdraw participation and that their refusal or withdrawal will not compromise their access to the hospital's services. The hospital has policies and procedures for providing patients and families with this information.

Measurable Elements of GLD.16

	Appropriate patients and families are identified and informed about how to gain access to clinical
	research, clinical investigations, or clinical trials relevant to their treatment needs.

- 2. Patients and families asked to participate are informed about expected benefits.
- 3. Patients and families asked to participate are informed about potential discomforts and risks.
- 4. Patients and families asked to participate are informed about alternatives that might also help them.
- 5. Patients and families asked to participate are informed about the procedures that must be followed.
- Patients and families are assured that their refusal to participate or withdraw from participation will not compromise their access to the hospital's services.

Standard GLD.17

Patients and families are informed about how patients who choose to participate in clinical research, clinical investigations, or clinical trials are protected.

Intent of GLD.17

A hospital that conducts clinical research, clinical investigations, or clinical trials involving human subjects knows that its first responsibility is to the patient's health and well-being. To assist with decisions regarding participation in clinical research, clinical investigations, or clinical trials, the hospital informs patients and families about

- the research and the patient's role in the research;
- the relative risks and benefits to the patient;
- the patient's rights related to withdrawal from participation in research;
- the patient's rights to confidentiality and security of information; and
- obtaining patient consent for participation in research.

Measurable Elements of GLD.17

1. Patients and families are informed about the research and the potential benefits and risks to patients who decide to participate.

	ndard GLD.18 ed consent is obtained before a patient participates in clinical research, clinical investigations, or clinical
4.	Patients and families are informed about the hospital's process for obtaining consent.
3.	Patients and families are informed about their rights to confidentiality and security of information. (Also see MOI.2)
2.	Patients and families are informed about their rights related to withdrawing from participation.

trials. ®

Intent of GLD.18When patients and families decide to participate in clinical research, clinical investigations, or clinical trials, informed consent is granted. The information provided at the time the decision to participate was made serves as the basis for the informed consent (also see PFR.5.1). The individual(s) providing the information and obtaining

Measurable Elements of GLD.18

the consent is noted in the patient record.

- ☐ 1. Informed consent is obtained when a patient decides to participate in clinical research, clinical investigations, or clinical trials.
- ☐ 2. The identity of the individual(s) providing the information and obtaining the consent is noted in the patient's record.
- 3. Consent is documented and dated in the patient's record by signature or record of verbal consent.

Standard GLD.19

The hospital has a committee or another way to oversee all research in the hospital involving human subjects. (9)

Intent of GLD.19

When the hospital conducts clinical research, investigations, or trials that involve human subjects, a committee or other mechanism such as a hospital-specific or shared Institutional Review Board (IRB) to provide oversight for all such activities in the hospital is established. The hospital develops a statement of purpose for the oversight activities. Oversight activities include the review process for all research protocols, a process to weigh the relative risks and benefits to the subjects, and processes related to the confidentiality and security of the research information.

Measurable Elements of GLD.19

- 1. The hospital has a committee or other mechanism such as a hospital-specific or shared Institutional Review Board (IRB) to oversee all research within the hospital.
- 2. The hospital develops a clear statement of purpose for the oversight activities.
- 3. Oversight activities include a review process.
- 4. Oversight activities include a process to weigh relative risks and benefits to subjects.
- 5. Oversight activities include processes to provide confidentiality and security of research information.

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Facility Management and Safety (FMS)

Changes to the FMS Chapter

Standard	Change	Explanation
FMS.1	No significant change	Rewords intent for clarity
FMS.2	Requirement change	Rewrites MEs to clarify requirements, including combining MEs 2 and 3 (4th edition); adds ME 4 about independent entities, which was previously FMS.4, ME 6 (4th edition)
FMS.3	Requirement change	Revises standard, intent, and MEs to incorporate requirements of FMS.3.1 (4th edition)
FMS.4- FMS.4.2	Requirement change	Revises standards, intent, and MEs to clarify expectations; defines <i>safety</i> and <i>security</i> and more clearly delineates requirements relevant to these terms
FMS.5 and FMS.5.1	Requirement change	Separates requirements of FMS.5 (4th edition) to emphasize the distinctions for managing all aspects of the hazardous materials and waste program; references the WHO list of hazardous materials and waste categories
FMS.6	Requirement change	Incorporates requirements of FMS.6.1 (4th edition) regarding testing the hospital's emergency management program
FMS.7 and FMS.7.1	Requirement change	Consolidates FMS.7, FMS.7.1, and FMS.7.2 (4th edition) and eliminates the following MEs (4th edition) to streamline requirements: FMS.7, MEs 2 and 3; FMS.7.1, ME 1; and FMS.7.2, ME 2
FMS.7.2	Renumbered; No significant change	Renumbers FMS.7.3 (4th edition) and minimally revises standard, intent, and MEs to clarify requirements; eliminates ME 3 (4th edition)
FMS.8	No significant change	Rewords MEs and combines MEs 3 and 4 (4th edition) to clarify requirements; replaces the term <i>medical equipment</i> (4th edition) with <i>medical technology</i>
FMS.8.1	Requirement change	Revises standard, intent, and MEs to clarify expectations related to monitoring and acting on medical technology problems; incorporates requirements of FMS.8.2 (4th edition)
FMS.9	New standard	Adds a new standard to emphasize the need for hospitals to have an established program that ensures utility systems operate effectively and efficiently

Standard	Change	Explanation
FMS.9.1	Renumbered; Requirement change	Moves requirement from FMS.10 (4th edition); revises standard, intent, and MEs for clarity; eliminates FMS.10, ME 1 (4th edition)
FMS.9.2	Renumbered	Combines and moves FMS.9 and FMS.9.1 (4th edition) to this standard for better alignment of similar requirements
FMS.9.2.1	Renumbered; Requirement change	Moves standard from FMS.9.2 (4th edition); changes requirement for testing of alternative sources of water and electricity to at least quarterly; adds ME 5 to emphasize the need for hospitals to have fuel stored on-site to support emergency power systems that require a fuel source
FMS.9.3	Renumbered; Requirement change	Moves standard from FMS.10.1 (4th edition); introduces time frame of at least quarterly for documenting monitoring of water quality and documenting testing of water used in renal dialysis; adds ME 3 to emphasize the need for hospitals to take action when water quality is found to be unsafe
FMS.10	Renumbered; Requirement change	Moves requirements from FMS.10.2 (4th edition); revises standard, intent, and MEs to better describe expectations related to the collection and analysis of monitoring data from the facility management programs; adds ME 3 to address the need to provide reports and recommendations to hospital leadership on a quarterly basis
FMS.11– 11.2	Requirement change	Incorporates FMS.11.3 (4th edition) into FMS.11; revises MEs of FMS.11 and FMS.11.2 to clarify requirements

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Leadership and Planning

Standard FMS.1

The hospital complies with relevant laws, regulations, and facility inspection requirements.

Intent of FMS.1

Laws, regulations, and inspections by local authorities determine in large part how a facility is designed, used, and maintained. All hospitals, regardless of size and resources, must comply with these requirements as part of their responsibilities to their patients, families, staff, and visitors. Such requirements may differ depending on the facility's age and location and other factors. **For example**, many building construction codes and fire safety

codes, such as for sprinkler systems, apply only to new construction. Hospitals begin by complying with laws and regulations.

Hospital leadership, including governance and senior management, are responsible for

- knowing what national and local laws, regulations, and other requirements apply to the hospital's facilities;
- implementing the applicable requirements or approved alternative requirements; and
- planning and budgeting for the necessary upgrading or replacement as identified by monitoring data or to meet applicable requirements and providing evidence of progress toward implementing the improvements. (Also see FMS.4.2)

When the hospital has been cited for not meeting requirements, hospital leadership takes responsibility for planning for and meeting the requirements in the prescribed time frame.

Measurable Elements of FMS.1

- 1. Hospital leadership and those responsible for facility management know what laws, regulations, and other requirements apply to the hospital's facilities.
- ☐ 2. Hospital leadership implements the applicable requirements or approved alternatives.
- ☐ 3. Hospital leadership ensures that the hospital meets the conditions of facility reports or citations from inspections by local authorities.

Standard FMS.2

Intent of FMS.2

To manage the risks within the environment in which patients are treated and staff work requires planning. The hospital develops one master program or individual programs that include the following:

- a) Safety and Security
 - Safety—The degree to which the hospital's buildings, grounds, and equipment do not pose a hazard or risk to patients, staff, and visitors
 - Security—Protection from loss, destruction, tampering, or unauthorized access or use
- b) Hazardous materials—Handling, storage, and use of radioactive and other materials are controlled, and hazardous waste is safely disposed.
- c) Emergencies—Response to epidemics, disasters, and emergencies is planned and effective.
- d) Fire safety—Property and occupants are protected from fire and smoke.
- e) Medical technology—Technology is selected, maintained, and used in a manner to reduce risks.
- f) Utility systems—Electrical, water, and other utility systems are maintained to minimize the risks of operating failures.

Such programs are written and are up to date in that they reflect present or recent conditions within the hospital's environment. There is a process for their review and updating. When the hospital has nonhospital entities within the patient care facilities to be surveyed (such as an independently owned coffee shop or gift shop), the hospital has an obligation to ensure that these independent entities comply with the facility management and safety programs.

- ☐ 1. There are written programs that address the risk areas a) through f) in the intent.
 - 2. The programs are current and are fully implemented.
- ☐ 3. The hospital has a process to review and to update the program(s) when changes in the hospital's environment occur or at a minimum, on an annual basis.

4. When independent entities are present within the patient care facilities to be surveyed, the hospital ensures that the entities comply with all aspects of the facility management programs identified in a) through d) of the intent.

Standard FMS.3

One or more qualified individuals oversee the planning and implementation of the facility management program to reduce and control risks in the care environment.

Intent of FMS.3

Hospitals work to provide safe, functional, and supportive facilities for patients, families, staff, and visitors. To reach this goal, the physical facility, equipment, medical technology, and people must be effectively managed. In particular, management must strive to

- reduce and control hazards and risks;
- prevent accidents and injuries; and
- maintain safe conditions.

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

- Hospital leadership plans the space, technology, and resources needed to safely and effectively support
 the clinical services provided.
- All staff are educated about the facility, how to reduce risks, and how to monitor and to report situations that pose risk.
- Performance criteria are used to evaluate important systems and to identify needed improvements.

Hospitals need to develop a facility/environment risk management program that addresses managing environmental risk through the development of facility management plans and the provision of space, technology, and resources. One or more individuals provide oversight to the program. In a small hospital, one individual may be assigned part-time. In a larger hospital, several engineers or other specially trained individuals may be assigned. Whatever the assignment, all aspects of the program must be managed effectively and in a consistent and continuous manner. Program oversight includes

- a) planning all aspects of the program, such as development of plans and providing recommendations for space, technology, and resources;
- b) implementing the program;
- c) educating staff;
- d) testing and monitoring the program;
- e) periodically reviewing and revising the program; and
- f) providing annual reports to the governing body on the effectiveness of the program.

Depending on the hospital's size and complexity, a facility/environment risk committee may be formed and given responsibility for overseeing the program and program continuity.

- 1. Program oversight and direction are assigned to one or more individuals qualified by experience and training.
- 2. Evidence of the training and experience of the qualified individual(s) is documented.
- 3. The individual(s) plans and implements the program, including elements a) through f) of the intent.

Safety and Security

Standard FMS.4

Standard FMS.4.1

Standard FMS.4.2

The hospital plans and budgets for upgrading or replacing key systems, buildings, or components based on the facility inspection and in keeping with laws and regulations.

Intent of FMS.4 Through FMS.4.2

The terms *safety* and *security* are often used synonymously in many countries; however, here they are defined differently. *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. *Security*, on the other hand, refers to protecting the organization's property and the patients, families, visitors, and staff from harm. 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 and injuries; to maintain safe and secure conditions for patients, families, staff, and visitors; and to reduce and to control hazards and risks. This is also important during periods of construction or renovation.

As part of the safety program, the hospital develops and implements a comprehensive, proactive risk assessment to identify areas in which the potential for injury exist. **Examples** of safety risks that pose a potential for injury or harm include sharp and broken furniture, linen chutes that do not close properly, broken windows, water leaks in the ceiling, and locations where there is no escape from fire. This periodic inspection is documented and helps the hospital design and carry out improvements and budget for longer-term facility upgrading or replacement.

Construction and renovation pose additional risks to the safety of patients, families, visitors, and staff, and include risk related to infection control, ventilation, traffic flow, garbage/refuse, and other risks. A preconstruction risk assessment is helpful in identifying these potential risks, as well as the impact of the construction project on services provided. The risk assessment should be performed during all phases of construction.

In addition to the safety program, the hospital must have a security program to ensure that everyone in the hospital is protected from personal harm and from loss or damage to property. Staff, vendors, and others identified by the hospital, such as volunteers or contract workers, are identified by badges (temporary or permanent) or other form of identification. Others, such as families or 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 other vulnerable patients unable 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. (*Also see* PFR.1.4, PFR.1.5, AOP.5.3, AOP.6.3, and FMS.1)

- ☐ 1. The hospital has a program to provide a safe physical facility.
- 2. The hospital has a documented, current, accurate inspection of its physical facilities.

	3.	The program includes assessing safety and security during times of construction and renovation and implementing strategies to reduce risks. (Also see PCI.7.5)
_		urable Elements of FMS.4.1 The hospital has a program to provide a secure environment, including monitoring and securing areas identified as security risks. (Also see AOP.5.3 and AOP.6.3)
	2.	The program ensures that all staff, contract workers, and vendors are identified.
	3.	All security risk areas and restricted areas are identified, documented, monitored, and kept secure.
Me □		urable Elements of FMS.4.2 The hospital plans and budgets to meet applicable laws, regulations, and other requirements.
	2.	The hospital plans and budgets for upgrading or replacing systems, buildings, or components needed for the continued operation of a safe, secure, and effective facility.
	3.	Hospital leadership applies the budgeted resources to provide for a safe and secure facility in

Hazardous Materials

Standard FMS.5

The hospital has a program for the inventory, handling, storage, and use of hazardous materials.

Output

Description:

Standard FMS.5.1

Intent of FMS.5 and FMS.5.1

A hazardous materials program is in place that includes identifying and safely controlling hazardous materials and waste throughout the facility. (Also see PCI.7.2) World Health Organization (WHO) identifies hazardous materials and waste by the following categories:

- Infectious waste
- Pathological and anatomical waste

accordance with approved plans.

- Hazardous pharmaceutical waste
- Hazardous chemical waste
- Waste with a high content of heavy metals
- Pressurized containers
- Sharps
- Highly infectious waste
- Genotoxic/cytotoxic waste
- Radioactive waste

The hospital considers these categories identified by WHO when developing an inventory of hazardous materials and waste. The hazardous waste program starts by doing a thorough search for all areas within the facility where hazardous materials and waste may be located. Documentation of this search should include information about the locations, types, and quantities of hazardous materials and waste being stored and should be updated when the location, storage, type, and quantities of hazardous materials has changed.

The hazardous materials program includes processes for

• the inventory of hazardous materials and waste that includes the material, the quantity, and the location;

- handling, storage, and use of hazardous materials;
- proper protective equipment and procedures during use, spill, or exposure;
- proper labeling of hazardous materials and waste;
- reporting and investigation of spills, exposures, and other incidents;
- proper disposal of hazardous waste; 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 includes information about the physical data of the material (such as its boiling point, flashpoint, and the like), its toxicity, what effects using the hazardous material may have on health, identification of proper storage and disposal after use, the type of protective equipment required during use, and spill-handling procedures, which include the required first aid for any type of exposure. Many manufacturers provide this information in the form of Material Safety Data Sheets (MSDS). (Also see AOP.5.3, AOP.5.6, AOP.6.6, MMU.3, and MMU.3.1)

ME	as	urable Elements of FW5.5
_	1.	The hospital identifies the type, location, and quantities of all hazardous materials and waste and has a complete and current inventory of all such materials within the hospital.
	2.	The program establishes and implements safe handling, storage, and use of hazardous materials and waste.
	3.	The program establishes and implements the proper protective equipment and procedures required during use. (Also see AOP.6.3, ME 3)
_	4.	The program establishes and implements proper labeling of hazardous materials and waste.
_	5.	The program establishes and implements documentation requirements, including any permits, licenses, or other regulatory requirements.
Me	as	urable Elements of FMS.5.1

1.	The program establishes and implements a reporting and investigation mechanism for spills, exposures and other incidents.
2.	The program establishes and implements procedures for the management of spills and exposures, including the use of proper protective equipment.
2	

- 3. Information about the hazardous material related to safe handling, spill-handling procedures, and procedures for managing exposures are up to date and available at all times.
- 4. The program establishes and implements the disposal of hazardous waste in a safe and legal manner.

Disaster Preparedness

Standard FMS.6

The hospital develops, maintains, and tests an emergency management program to respond to emergencies, epidemics, and natural or other disasters that have the potential of occurring within their community. (P)

Intent of FMS.6

Community emergencies, epidemics, and disasters may directly involve the hospital, such as damage to patient care areas as a result of an earthquake, or a flu epidemic that keeps staff from coming to work. The development of the program should begin by identifying the types of disasters that are likely to occur in the hospital's region and what the impact of these disasters would have on the hospital. For example, a hurricane or tsunami is more

likely to occur in areas where the ocean is near but unlikely to occur in countries surrounded by land. Facility damage or mass casualties on the other hand could potentially occur in any hospital.

It is just as important to identify the effects of a disaster as it is to identify the types of disasters. This helps in planning the strategies that are needed in the event that a disaster occurs. 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 personal responsibilities may be in conflict with the hospital requirements for responding to an emergency. 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 a disaster occurs, and what communication methods will be used within the community?

To respond effectively, the hospital develops a program to manage such emergencies. The program provides processes for

- a) determining the type, likelihood, and consequences of hazards, threats, and events;
- b) determining the hospital's role in such events;
- c) communication strategies for events;
- d) the managing of resources during events, including alternative sources;
- e) the managing of clinical activities during an event, including alternative care sites;
- f) the identification and assignment of staff roles and responsibilities during an event; and
- g) the process to manage emergencies when personal responsibilities of staff conflict with the hospital's responsibility for providing patient care.

The disaster preparedness 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 g) of the program during the year.

If the hospital experiences an actual disaster, activates its program, and debriefs properly afterward, this situation represents the equivalent to an annual test.

Measurable Elements of FMS.6

- 1. The hospital has identified the major internal and external disasters, such as community emergencies, epidemics, and natural or other disasters, as well as major epidemic events that pose significant risks of occurring, taking into consideration the hospital's geographic location.
- 2. The hospital identifies the probable impact that each type of disaster will have on all aspects of care and services.
- 3. The hospital establishes and implements a disaster program that identifies its response to likely disasters, including items a) through g) in the intent.
- 4. The entire program, or at least critical elements c) through g) of the program, is tested annually.
- ☐ 5. At the conclusion of every test, debriefing of the test is conducted.

Fire Safety

Standard FMS.7

The hospital establishes and implements a program for the prevention, early detection, suppression, abatement, and safe exit from the facility in response to fires and nonfire emergencies. ©

Standard FMS.7.1

Intent of FMS.7 and FMS.7.1

Fire is an ever-present risk in a hospital. Thus, every hospital needs to plan how it will keep its occupants safe in case of fire or smoke. In addition, nonfire emergencies, such as a toxic gas leak, can pose a threat to occupants. A hospital establishes a program in particular for

- the prevention of fires through the reduction of risks, such as safe storage and handling of potentially flammable materials, including flammable medical gases such as oxygen;
- hazards related to any construction in or adjacent to the patient-occupied buildings;
- safe and unobstructed means of exit in the event of a fire;
- early warning, early detection systems, such as smoke detectors, fire alarms, and fire patrols; and
- suppression mechanisms, such as water hoses, chemical suppressants, or sprinkler systems.

These actions, when combined, give patients, families, staff, and visitors adequate time to safely exit the facility in the event of a fire or smoke. These actions are effective no matter what the age, size, or construction of the facility. **For example**, a small, one-level brick facility will use different methods than a large, multilevel wooden facility.

The hospital's fire safety program identifies

- the frequency of inspecting, testing, and maintaining fire protection and safety systems, consistent with requirements;
- the program for safely evacuating the facility in the event of a fire or smoke;
- the process for testing all portions of the program during each 12-month period;
- the necessary education of staff to effectively protect and to evacuate patients when an emergency occurs; and
- the participation of staff members in at least one fire safety test per year.

A test of the program can be accomplished in multiple ways. For example, hospitals can assign a "fire marshal" for each unit and have 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. If they do not, this should be documented and a strategy for reeducation developed. 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. All inspections, testing, and maintenance are documented. (*Also see* PFR.1.5)

Measurable Flements of FMS 7

 uJ	diable Elements of Fino.
1.	The hospital establishes and implements a program to ensure that all occupants of the hospital's facilities are safe from fire, smoke, or other nonfire emergencies.
2.	The program includes the documented assessment of fire risks, including when construction is present in or adjacent to the facility.
3.	The program includes the early detection of fire and smoke.
4.	The program includes the abatement of fire and containment of smoke.
5.	The program includes the safe exit from the facility when fire and nonfire emergencies occur.

Measurable Elements of FMS.7.1

☐ 1. All staff participate in at least one fire and smoke safety program test per year. (Also see FMS.11–FMS.11.2)

2.	Staff can demonstrate how to bring patients to safety.
3.	Fire detection and abatement equipment and systems are inspected, tested, and maintained according to manufacturers' recommendations.
4.	Inspection, testing, and maintenance of equipment and systems are documented.

Standard FMS.7.2

Intent of FMS.7.2

The fire safety program that addresses limiting smoking

- applies to all patients, families, staff, and visitors; and
- eliminates smoking in the hospital's facilities or minimally limits smoking to designated non–patient care areas that are ventilated to the outside.

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.7.2

- ☐ 1. The fire safety program addresses eliminating or limiting smoking within the hospital facility.
- ☐ 2. The program applies to patients, families, visitors, and staff.
- 3. The program identifies who may grant patient exceptions for smoking and when those exceptions apply.

Medical Technology

Standard FMS.8

Intent of FMS.8

To ensure that medical technology is available for use and functioning properly, the hospital performs and documents

- an inventory of medical technology;
- regular inspections of medical technology;
- testing of medical technology according to its use and manufacturers' requirements; and
- performance of preventive maintenance.

Qualified individuals provide these services. Medical technology is inspected and tested when new and then on an ongoing basis, according to the technology's age, use, and manufacturers' instructions. Inspections, testing results, and any maintenance are documented. This helps ensure the continuity of the maintenance process and helps when doing capital planning for replacements, upgrades, and other changes. (Also see AOP.5.5, AOP.6.5, and COP.3.2)

Measurable Elements of FMS.8

- \Box 1. The hospital establishes and implements a medical technology program throughout the hospital.
- 2. There is an inventory of all medical technology.
- ☐ 3. Medical technology is inspected and tested when new and according to age, use, and manufacturers' recommendations thereafter.
- 4. The medical technology program includes preventive maintenance.
- □ 5. Staff providing these services are qualified and trained for the services being provided.

Standard FMS.8.1

Intent of FMS.8.1

The hospital has a system in place for monitoring and acting on medical technology hazard notices, recalls, reportable incidents, problems, and failures sent by the manufacturer, supplier, or regulatory agency. Some countries require reporting of any medical technology 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 technology incidents. The medical technology management program addresses the use of any medical technology with a reported problem or failure, or that is the subject of a hazard notice or is under recall. (Also see AOP.5.5 and AOP.6.5)

Measurable Elements of FMS.8.1

- 1. The hospital has a system in place for monitoring and acting on medical technology hazard notices, recalls, reportable incidents, problems, and failures.
- ☐ 2. When laws and regulations require, the hospital reports any deaths, serious injuries, or illness that are a result of medical technology.
- 3. The medical technology management program addresses the use of any medical technology with a reported problem or failure, or that is the subject of a hazard notice or is under recall.

Utility Systems

Standard FMS.9

The hospital establishes and implements a program to ensure that all utility systems operate effectively and efficiently.

Standard FMS.9.1

Utility systems are inspected, maintained, and improved.

Intent of FMS.9 and FMS.9.1

Utilities can be defined as the systems and equipment that support essential services that provide for safe health care. Such systems include electrical distribution, water, ventilation and airflow, medical gases, plumbing, heating, waste, and communication and data systems. Effective utility function throughout the hospital creates the patient care environment. The safe, effective, and efficient operation of utility and other key systems in the hospital is essential for patient, family, 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.

A good utilities management program ensures the reliability of the utility systems and minimizes the potential risks. For example, waste contamination in food-preparation areas, inadequate ventilation in the clinical laboratory, oxygen cylinders that are not secured when stored, leaking oxygen lines, and frayed electrical lines all pose hazards. To avoid these and other hazards, the hospital has a process for regularly inspecting such systems and performing preventive and other 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, maintained, and, when necessary, improved.

Measurable Elements of FMS.9

1	1	The hospital	inventories	ite utility	cycteme	components	and ma	ine the d	istribution	of them
_	1.	THE HOSPItal	mivemones.	us uumiv	SVSICIIIS	COHIDOHEIRS	and ma	ios ine u	181111111111111	or mem.

- 2. The hospital identifies, in writing, inspection and maintenance activities for all operating components of utility systems on the inventory.
- ☐ 3. The hospital identifies, in writing, the intervals for inspecting, testing, and maintaining all operating components of the utility systems on the inventory, based on criteria such as manufacturers' recommendations, risk levels, and hospital experience.
- 4. The hospital labels utility system controls to facilitate partial or complete emergency shutdowns.

Measurable Elements of FMS.9.1

- 1. Utility systems and components are inspected based on hospital-developed criteria.
- ☐ 2. Utility systems and components are tested based on hospital criteria.
- ☐ 3. Utility systems and components are maintained based on hospital criteria.
- 4. Utility systems and components are improved when necessary.

Standard FMS.9.2

The hospital utility systems program ensures that potable water and electrical power are available at all times and establishes and implements alternative sources of water and power during system disruption, contamination, or failure.

Standard FMS.9.2.1

The hospital tests its emergency water and electrical systems and documents the results.

Intent of FMS.9.2 and FMS.9.2.1

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 clean water and electrical power is essential to meet patient care needs. Regardless of the type of system and level of its resources, a hospital needs to protect patients and staff in emergencies, such as system failure, interruption, or contamination.

An emergency power system is required for all hospitals that intend to provide continuous service under emergency conditions. Such a system provides sufficient power to maintain essential functions during power failures. It also reduces the risks associated with such failures. Emergency and backup power sources are tested

under planned circumstances that simulate actual load requirements. Improvements are made when necessary, such as enhancing electrical service to areas with new medical technology or other equipment.

Water quality can change suddenly from many causes, some of which occur outside of the hospital, such as a break in the supply line to the hospital. When there is a disruption in the usual source of water supplied to the organization, emergency potable water supplies must be immediately available.

To prepare for such emergencies, the hospital

- identifies the equipment, systems, and locations that pose the highest risk to patients and staff (**for example**, it identifies where there is a need for illumination, refrigeration, life support, and clean water for cleaning and sterilization of supplies);
- assesses and minimizes the risks of utility system failures in these areas;
- plans emergency power and clean water sources for these areas and needs;
- tests the availability and reliability of emergency sources of power and water;
- documents the results of tests; and
- ensures that the testing of alternative sources of water and electricity occurs at least quarterly or more
 frequently if required by local laws, regulations, manufacturers' recommendations, or conditions of the
 sources for power and water. Conditions of the sources of power and water that may increase the
 frequency of testing include
 - o repeated repair of the water system;
 - o frequent contamination of the water source;
 - o unreliable electrical grids; and
 - o recurrent, unpredictable power outages.

necessary amount of on-site fuel stored.

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 an authority having jurisdiction specifies the amount.

Measurable Elements of FMS.9.2 1. Potable water is available 24 hours per day, 7 days a week. 2. Electrical power is available 24 hours a day, 7 days a week. 3. The hospital has identified the areas and services at greatest risk when power fails or water is contaminated or interrupted. 4. The hospital seeks to reduce the risks of such events. The hospital plans alternative sources of power and water in emergencies. Measurable Elements of FMS.9.2.1 1. The hospital tests alternative sources of water at least quarterly or more frequently if required by local laws and regulations or conditions of the source of water. 2. The hospital documents the results of such tests. 3. The hospital tests alternative sources of electricity at least quarterly or more frequently if required by local laws and regulations, manufacturers' recommendations, or conditions of the source of electricity. 4. The hospital documents the results of such tests.

5. When emergency sources of power require a fuel source, the hospital establishes and has available, the

Standard FMS.9.3

Designated individuals or authorities monitor water quality regularly.

Intent of FMS.9.3

As stated in FMS.9.2 and FMS.9.2.1, water quality is prone to sudden change, including changes outside the control of the hospital. Water quality is also a critical factor in clinical care processes, such as renal dialysis. Thus, the hospital establishes a process to monitor water quality, including biological testing of water used in renal dialysis. Actions are implemented when water quality is found to be unsafe.

Monitoring is performed 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 monitoring can be carried out by individuals designated by the hospital, such as staff from the clinical laboratory, or by public health or water control authorities outside the hospital judged competent to perform such tests. Whether performed by qualified hospital staff or by authorities outside the hospital, it is the responsibility of the hospital to ensure that the testing is completed and documented.

Measurable Elements of FMS.9.3

- 1. Water quality is monitored 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 monitoring is documented.
- 2. Water used in renal dialysis is tested and testing is documented according to industry standards 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.
- ☐ 3. Actions are taken and documented when water quality is found to be unsafe.

Facility Management Program Monitoring

Standard FMS.10

The hospital collects and analyzes data from each of the facility management programs to support planning for replacing or upgrading medical technology, equipment, and systems, and reducing risks in the environment.

Intent of FMS.10

Monitoring each of the facility management programs through data collection and analysis provides information that helps the hospital prevent problems, reduce risks, make decisions on system improvements, and plan for upgrading or replacing medical technology, equipment, and utility systems. The monitoring requirements for the facility management programs are coordinated with the requirements as identified in GLD.11. Monitoring data are documented and quarterly reports are provided to hospital leadership.

	1.	Monitoring	data are col	lected and	analyzed for	or each of	the facility	management	programs.
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- 2. Monitoring data are used to support planning for replacing or upgrading medical technology, equipment, and systems, and reducing risks in the environment.
- ☐ 3. Reports on monitoring data and recommendations are provided to hospital leadership on a quarterly basis.

Staff Education

Standard FMS.11

The hospital educates, trains, and tests all staff about their roles in providing a safe and effective patient care facility.

Standard FMS.11.1

Staff members are trained and knowledgeable about their roles in the hospital's programs for fire safety, security, hazardous materials, and emergencies.

Standard FMS.11.2

Staff are trained to operate and to maintain medical technology and utility systems.

Intent of FMS.11 Through FMS.11.2

Staff are the hospital's primary source of contact with patients, families, and visitors. Thus, they need to be educated and trained to carry out their roles in identifying and reducing risks, protecting others and themselves, and creating a safe and secure facility. (Also see FMS.7.1, ME 1)

Each hospital must decide the type and level of training for staff and then carry out and document a program for this training and education. The program can include group instruction, printed educational materials, a component of new staff orientation, or some other mechanism that meets the hospital's needs. The program includes instruction on the processes for reporting potential risks, reporting incidents and injuries, and handling hazardous and other materials that pose risks to themselves and others.

Staff responsible for operating or maintaining medical technology receive special training. The training can be from the hospital, the manufacturer of the technology, or some other knowledgeable source.

The hospital plans a program designed to periodically test staff knowledge on emergency procedures, including fire safety procedures; the response to hazards, such as the spill of a hazardous material; and the use of medical technology that poses 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.

	1.	Education is provided on an annual basis for each component of the hospital's facility management and safety program to ensure that all staff on all shifts can effectively carry out their responsibilities. (Also see AOP.5.3, ME 4 and AOP.6.3, ME 4)
	2.	The education includes visitors, vendors, contract workers, and others as identified by the hospital.
	3.	Staff knowledge is tested regarding their roles in each of the facility management programs.
	4.	Training, testing, and the results of testing are documented for each staff member.
		urable Elements of FMS.11.1 Staff members can describe and/or demonstrate their roles in response to a fire.
_		otali members can describe and, or demonstrate their roles in response to a me.
		Staff can describe and/or demonstrate actions to eliminate, to minimize, or to report safety, security, and other risks.

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	emergencies and disasters.
	Staff members can describe and/or demonstrate procedures and their roles in internal and community

Measurable Elements of FMS.11.2

- 1. Staff are trained to operate medical technology according to their job requirements.
- 2. Staff are trained to operate utility systems according to their job requirements.
- ☐ 3. Staff are trained to maintain medical technology according to their job requirements.
- ☐ 4. Staff are trained to maintain utility systems according to their job requirements.

Reference

1. Prüss A, Giroult E, Rushbrook P, editors. Safe Management of Wastes from Health-Care Activities. Geneva: World Health Organization, 1999. Accessed Jun 24, 2013. http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/index.html.

Staff Qualifications and Education (SQE)

Changes to the SQE Chapter

Standard	Change	Explanation
SQE.2	No significant change	Eliminates ME 5 (4th edition)
SQE.6.1	Requirement change	Adds one ME to emphasize the need for department/service leaders to keep the staffing plan current through a coordinated process
SQE.8	Requirement change	Incorporates requirements of SQE.8.2 (4th edition); adds one ME to emphasize the need for hospitals to provide time and facilities for staff education and training
SQE.8.2	Renumbered; Requirement change	Renumbers SQE.8.4 (4th edition); adds new language to intent and MEs regarding staff vaccination and immunization programs and workplace violence prevention programs
SQE.9– SQE.9.2	Requirement change	Provides definitions of key terms <i>credentials</i> , <i>medical staff</i> , <i>verification</i> , <i>appointment</i> , and <i>reappointment</i> ; reorganizes and separates out standards and MEs to clarify requirements for determining medical staff membership; revises the requirement for primary source verification
SQE.10	Requirement change	Adds new language to intent and MEs to clarify requirements regarding the privilege delineation process for medical staff members
SQE.11	Requirement change	Provides definitions of key terms and expectations; reorganizes and revises intent and MEs to clarify requirements for monitoring and evaluation of medical staff members; adds ME 5 to emphasize the need to document and take action on findings that affect the appointment or privileges of medical staff members
SQE.12	Requirement change	Separates out and clarifies requirements for reappointment and renewal of clinical privileges of medical staff members based on ongoing monitoring and evaluation
SQE.13	Renumbered; Requirement change	Renumbers SQE.12 (4th edition) and revises the requirement for primary source verification
SQE.14 and SQE.14.1	Renumbered; No significant change	Renumbers SQE.13 and SQE.14 (4th edition) and adds minor wording changes and one ME to clarify requirements
SQE.15	Requirement change	Combines MEs 4 and 5 (4th edition) for clarity

Standard	Change	Explanation
SQE.16 and SQE.16.1		Adds one ME to SQE.16 to clarify requirements and renumbers SQE.17 (4th edition)

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): None.

Standards, Intents, and Measurable Elements

Planning

Standard SQE.1

Leaders of hospital departments and services define the desired education, skills, knowledge, and other requirements of all staff members.

Intent of SQE.1

The department/service leaders define staffing requirements to meet the needs of patients. They define the desired education, skills, knowledge, and any other requirements for individual positions or for classes of similar positions; **for example**, intensive care nurses. To project staffing needs, department/service leaders use factors such as the following:

- The hospital's mission
- The mix of patients served by the hospital and the complexity and severity of their needs
- The diagnostic and clinical services provided by the hospital
- The volume of inpatients and outpatients
- The medical technology used in patient care

The hospital complies with laws and regulations that identify required education levels, skills, or other requirements of individual staff members or that define staffing numbers or a mix of staff for the hospital. (Also see QPS.1, ME 2 and GLD.8)

Measurable Elements of SQE.1

- 1. The hospital's mission, volume and mix of patients, services, and medical technology are used in planning.
- 2. The desired education, skills, and knowledge are defined for staff.
- 3. Applicable laws and regulations are incorporated into the planning.

Standard SQE.1.1

Each staff member's responsibilities are defined in a current job description.

Intent of SQE.1.1

Individual staff members who are not licensed to practice independently have their responsibilities defined in current job descriptions. The job descriptions are the basis for their assignments, orientation to their work, and evaluation of how well they fulfill job responsibilities.

Job descriptions are also needed for health professionals when

- a) the individual serves in primarily a managerial role, such as a department manager, or in dual clinical and managerial roles, with the managerial responsibilities identified in a job description;
- b) the individual has some clinical responsibilities for which he or she has not been authorized to practice independently, such as an independent practitioner learning a new role or new skills;
- the individual is in an educational program and under supervision, and the academic program identifies, for each stage or level of training, what can be done independently and what must be under supervision.
 The program description can serve as the job description in such cases; and
- d) the individual is permitted to temporarily provide services in the hospital; **for example**, a nurse from a temporary staffing agency. (*Also see* SQE.10)

When a hospital uses national or generic job descriptions (**for example**, a job description for a "nurse"), it is necessary to augment this type of job description with specific job responsibilities for the types of nurses (**for example**, intensive care nurse, pediatric nurse, or operating theatre nurse, among others). For those permitted by law and the hospital to practice independently, there is a process to identify and to authorize the individual to practice based on education, training, and experience. (*Also see* SQE.9) The requirements of this standard apply to all types of "staff" who require job descriptions (**for example**, full-time, part-time, employed, voluntary, or temporary). (*Also see* PCI.1)

Measurable Elements of SQE.1.1

- 1. Each staff member not permitted to practice independently has a job description.
- ☐ 2. Those individuals identified in a) through d) in the intent, when present in the hospital, have job descriptions appropriate to their activities and responsibilities or have been privileged if noted as an alternative. (Also see AOP.3, ME 1)
- ☐ 3. Job descriptions are current according to hospital policy.

Standard SQE.2

Leaders of hospital departments and services develop and implement processes for recruiting, evaluating, and appointing staff as well as other related procedures identified by the hospital.

Intent of SQE.2

The hospital provides an efficient, coordinated, or centralized process for

- recruiting individuals for available positions;
- evaluating the training, skills, and knowledge of candidates; and
- appointing individuals to the hospital's staff.

If the process is not centralized, similar criteria, processes, and forms result in a uniform process across the hospital for similar types of staff; **for example**, for nurses or physical therapists. Department/service leaders participate by recommending the number and qualifications of staff needed to provide clinical services to patients, as well as nonclinical support functions, and to fulfill any teaching, research, or other departmental responsibilities. Department and service leaders also help make decisions about individuals to be appointed to the staff. Thus, the standards in this chapter complement the Governance, Leadership, and Direction standards that describe a department/service leader's responsibilities.

Measurable Elements of SQE.2

☐ 1. The hospital establishes and implements a process to recruit staff. (Also see GLD.3.3, ME 1)

_	۷٠	The hospital establishes and implements a process to evaluate the qualifications of new start.
	3.	The hospital establishes and implements a process to appoint individuals to the staff.
	4.	The hospital establishes and implements a process that is uniform across the hospital for similar types of staff

Standard SQE.3

The hospital uses a defined process to ensure that clinical staff knowledge and skills are consistent with patient needs.

Intent of SQE.3

Qualified staff members are hired by the hospital through a process that matches the requirements of the position with the qualifications of the prospective staff member. This process also ensures that the staff member's skills are initially and over time consistent with the needs of patients.

For the hospital's health professional staff who are independent practitioners (that is, they do not practice under job descriptions), the process is identified in SQE.9 through SQE.12.

For clinical staff under job descriptions, the process includes the following:

- An initial evaluation to ensure that he or she can actually assume those responsibilities in the job description. This evaluation is carried out before or at the time of starting to perform work responsibilities. The hospital may have a "probationary" or other period during which the clinical staff member is closely supervised and evaluated, or the process may be less formal. Whatever the process, the hospital ensures that staff providing high-risk services or providing care to high-risk patients are evaluated at the time they begin providing care, before the probationary or orientation period is completed. This evaluation of necessary skills, and knowledge and desired work behaviors, is carried out by the department or service to which the staff member is assigned.
- The hospital then defines the process for and the frequency of the ongoing evaluation of staff abilities.

Ongoing evaluation ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. Although such evaluation is best carried out in an ongoing manner, there is at least one documented evaluation of each clinical staff member working under a job description each year. (*Also see* COP.3.1, ASC.3.1, MMU.6, GLD.11.1, and SQE.11)

Measurable Elements of SQE.3

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	1.	The hospital uses a defined process to match clinical staff knowledge, skills, and competency with patient needs.
	2.	New clinical staff members are evaluated at the time they begin their work responsibilities.
	3.	The department or service to which the individual is assigned conducts the evaluation.
	4.	The hospital defines the frequency of ongoing clinical staff evaluation.
	5.	There is at least one documented evaluation of each clinical staff member working under a job description each year or more frequently as defined by the hospital. (Also see SOE.11, ME 1)

Standard SQE.4

The hospital uses a defined process to ensure that nonclinical staff knowledge and skills are consistent with hospital needs and the requirements of the position.

Intent of SQE.4

The hospital seeks staff that can competently fill the requirement of nonclinical positions. The supervisor of the staff member provides an orientation to the position and ensures that the worker can fulfill the responsibilities of the job description. The staff member receives the required level of supervision and on a periodic basis is evaluated to ensure continuing competence in the position. (Also see AOP.5.2 and AOP.6.2)

Measurable Elements of SQE.4

as defined by the hospital.

1.	The hospital uses a defined process to match nonclinical staff knowledge and skills with the requirements of the position.
2.	New nonclinical staff are evaluated at the time they begin their work responsibilities.
3.	The department or service to which the individual is assigned conducts the evaluation.
4.	The hospital defines the frequency of ongoing nonclinical staff evaluation.

□ 5. There is at least one documented evaluation of nonclinical staff members each year or more frequently

Standard SQE.5

Intent of SQE.5

Each staff member in the hospital, including those permitted by law and the hospital to work independently, has a record(s) with information about his or her qualifications; results of evaluations, including individual performance of job responsibilities and competencies; and work history. The records are standardized and kept current according to hospital policy. (Also see in SQE.9, SQE.13, and SQE.15)

Measurable Elements of SQE.5

 reasonable Elements of OQE.0		
1.	Personnel files for each staff member are standardized and current and maintained according to hospital policy.	
2.	Personnel files contain the qualifications of the staff member.	
3.	Personnel files contain the job description of the staff member when applicable.	
4.	Personnel files contain the work history of the staff member.	
5.	Personnel files contain the results of evaluations.	
6.	Personnel files contain a record of in-service education attended by the staff member.	

Standard SQE.6

A staffing strategy for the hospital, developed by the leaders of hospital departments and services, identifies the number, types, and desired qualifications of staff. ©

Standard SQE.6.1

The staffing strategy is reviewed on an ongoing basis and updated as necessary.

Intent of SQE.6 and SQE.6.1

Appropriate and adequate staffing is critical to patient care as well as to all teaching and research activities in which the hospital may be engaged. Staff planning is carried out by department/service leaders. The planning process uses recognized methods for determining levels of staffing. For example, a patient acuity system is used

to determine the number of licensed nurses with pediatric intensive care experience to staff a 10-bed pediatric intensive care unit.

The strategy is written and identifies the number and types of required staff and the skills, knowledge, and other requirements needed in each department and service. The strategy addresses

- the reassignment of staff from one department or service to another in response to changing patient needs or staff shortages;
- the consideration of staff requests for reassignment based on cultural values or religious beliefs; and
- compliance with local laws and regulations.

Planned and actual staffing is monitored on an ongoing basis, and the strategy is updated as necessary. There is a coordinated process for the department/service leaders to update the overall strategy. (Also see GLD.7 and GLD.9, ME 2)

Measurable Elements of SQE.6

- 1. The hospital's department/service leaders develop a written strategy for staffing the hospital in a manner that complies with local laws and regulations.
- 2. The number, types, and desired qualifications of staff are identified in the strategy using a recognized staffing method. (*Also see* AOP.6.2, ME 5)
- ☐ 3. The strategy addresses the assignment and reassignment of staff.

Measurable Elements of SQE.6.1

- ☐ 1. The effectiveness of the staffing strategy is monitored on an ongoing basis.
- ☐ 2. The strategy is revised and updated when necessary.
- 3. The strategy is coordinated through a process that involves the department/service leaders.

Standard SQE.7

All clinical and nonclinical staff members are oriented to the hospital, the department or unit to which they are assigned, and to their specific job responsibilities at appointment to the staff.

Intent of SQE.7

The decision to appoint an individual to the staff of a hospital sets several processes in motion. To perform well, a new staff member, no matter what his or her employment status, needs to understand the entire hospital and how his or her specific clinical or nonclinical responsibilities contribute to the hospital's mission. This is accomplished through a general orientation to the hospital and his or her role in the hospital and a specific orientation to the job responsibilities of his or her position. The orientation includes the reporting of medical errors, infection prevention and control practices, the hospital's policies on telephone medication orders, and so on (also see PCI.11 and GLD.9, ME 4). Contract workers, volunteers, and students and trainees are also oriented to the hospital and their specific assignments or responsibilities, such as patient safety and infection prevention and control.

Measurable Elements of SQE.7

- 1. New clinical and nonclinical staff members are oriented to the hospital, to the department or unit to which they are assigned, and to their job responsibilities and any specific assignments.
- 2. Contract workers are oriented to the hospital, to the department or unit to which they are assigned, and to their job responsibilities and any specific assignments.
- ☐ 3. Volunteers are oriented to the hospital and assigned responsibilities.
- 4. Students and trainees are oriented to the hospital and assigned responsibilities.

Standard SQE.8

Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge.

Intent of SQE.8

The hospital collects data from several sources to understand its staff's ongoing education needs. The results of quality and safety measurement activities are one source of information to identify staff education needs. Also, monitoring data from the facility management program, the introduction of new medical technology, skill and knowledge areas identified through the review of job performance, new clinical procedures, and future plans to provide new services represent such sources of data. The hospital has a process to gather and to integrate data from sources to plan the staff education program. Also, the hospital determines which staff, such as health professional staff, are required to obtain continuing education to maintain their credentials and how the education of these staff will be monitored and documented. (Also see GLD.3.3, ME 3)

To maintain acceptable staff performance, to teach new skills, and to provide training on new medical technology and procedures, the hospital provides or arranges for facilities, educators, and time for ongoing in-service and other education. This education is relevant to each staff member as well as to the continuing advancement of the hospital in meeting patient needs. **For example**, medical staff members may receive education on infection prevention and control, advances in medical practice, culture of safety, or new medical technology. (*Also see* MOI.8) Each staff member's educational achievements are documented in his or her personnel record.

Hospital leadership supports the commitment to ongoing staff in-service education by making available space, equipment, and time for education and training programs. The availability of current scientific information supports the education and training. The education and training can take place in a centralized location or in several smaller learning and skill development locations throughout the facility. The education can be offered once to all or repeated for staff on a shift-by-shift basis to minimize the impact on patient care activities.

Measurable Elements of SQE.8

- The hospital uses various sources of data and information, including the results of quality and safety measurement activities, to identify staff education needs.
 Education programs are planned based on these data and information.
 Hospital staff are provided ongoing in-service education and training. (Also see AOP.5.3, ME 4 and AOP.6.3, ME 4)
- 4. The education is relevant to each staff member's ability to meet patient needs and/or continuing education requirements. (*Also see* AOP.5.3, ME 4 and AOP.6.3, ME 4)
- ☐ 5. The hospital provides adequate time and facilities for all staff to participate in relevant education and training opportunities.

Standard SQE.8.1

Staff members who provide patient care and other staff identified by the hospital are trained and can demonstrate appropriate competence in resuscitative techniques.

Intent of SQE.8.1

Each hospital identifies those staff to be trained in resuscitative techniques and the level of training (basic or advanced) appropriate to their roles in the hospital. The appropriate level of training for those identified is repeated based on the requirements and/or time frames identified by a recognized training program, or every two years if a recognized training program is not used. There is evidence to show if each staff member attending the training actually achieved the desired competency level. (Also see COP.3.2)

Measurable Elements of SQE.8.1

- ☐ 1. Staff members who provide patient care and other staff identified by the hospital to be trained in cardiac life support are identified.
- **2**. The appropriate level of training is provided with sufficient frequency to meet staff needs.
- ☐ 3. There is evidence to show if a staff member passed the training.
 - 4. The desired level of training for each individual is repeated based on the requirements and/or time frames established by a recognized training program, or every two years if a recognized training program is not used.

Standard SQE.8.2

Intent of SQE.8.2

A hospital's staff health and safety program is important to maintain staff physical and mental health, satisfaction, productivity, and safe conditions for work. Because of their contact with patients and patients' infective material, many health care workers are at risk for exposure to and possible transmission of vaccine-preventable diseases.^{1–5} Identifying epidemiologically important infections, determining staff at high risk for these infections, and implementing screening and prevention programs (such as immunizations, vaccinations, and prophylaxis) can significantly reduce the incidence of infectious disease transmission.^{1–5} (*Also see* PCI.5, ME 2)

Violence in the workplace has become an increasingly common problem in health care organizations.^{6–10} Staff shortages, increased patient acuity, and the misconception that violence does not occur in health care organizations—or if violence does occur, it is part of the job—are just a few of the barriers to acknowledging that workplace violence exists and to developing violence prevention programs. (*Also see* QPS.7)

Staff health and safety must be a part of the hospital's quality and patient safety program. How a hospital orients and trains staff, provides a safe workplace, maintains equipment and medical technology, prevents or controls health care—associated infections, and many other factors determine the health and well-being of staff. (Also see PCI.5.1, ME 2) A staff health and safety program can be located within the hospital or be integrated into external programs. Whatever the staffing and structure of the program, staff understand how to report, to be treated for, and to receive counseling and follow-up for injuries such as those that may result from needlesticks, exposure to infectious diseases, or workplace violence; the identification of risks and hazardous conditions in the facility; and other health and safety matters. The program may also provide for initial employment health screening, periodic preventive immunizations and examinations, and treatment for common work-related conditions, such as back injuries, or more urgent injuries.

The design of the program includes staff input and draws upon the hospital's clinical resources as well as those in the community.

Measurable Elements of SQE.8.2

- ☐ 1. The hospital provides, and incorporates into the hospital quality and safety program, a staff health and safety program that is responsive to urgent and nonurgent staff needs through direct treatment and referral.
- 2. The hospital identifies epidemiologically significant infections, as well as staff that are at high risk for exposure to and transmission of infections, and implements a staff vaccination and immunization program.
- ☐ 3. The hospital provides evaluation, counseling, and follow-up of staff exposed to infectious diseases that is coordinated with the infection prevention and control program.

4.	The hospital identifies areas for potential workplace violence and implements measures to reduce the
	risk.

5. The hospital provides evaluation, counseling, and follow-up treatment of staff who are injured as a result of workplace violence.

Determining Medical Staff Membership

Standard SQE.9

Standard SQE.9.1

Standard SQE.9.2

There is a uniform, transparent decision process for the initial appointment of medical staff members. ®

Intent of SQE.9 Through SQE.9.2

Explanations of terms and expectations found in these standards are as follows:

Credentials

Credentials are documents that are issued by a recognized entity to indicate completion of requirements or the meeting of eligibility requirements, such as a diploma from a medical school, specialty training (residency) completion letter or certificate, completion of the requirements of a medical professional organization, a license to practice, or recognition of registration with a medical or dental council. These documents, some of which are required by law or regulation, but some by hospital policy, must be verified from the original source that issued the document.

Credentials can also be documents from individuals and entities that address some aspect of the applicant's professional history or competency, such as letters of recommendation, a history of all previous hospital medical staff appointments, records of previous clinical care, health history, picture, or police background check, **for example**. These documents may be required by hospital policy as part of the credential-gathering process, but are not verified from the source that issued the document unless required by hospital policy. This requirement for verification of the credential will vary by the position the applicant is seeking. **For example**, for an applicant for leader of a department/clinical service, the hospital may want to verify information regarding the individual's previous administrative positions and experience. Also, for clinical positions, the hospital may require a certain number of years of experience and thus would verify this level of experience.

Medical Staff

Medical staff are all physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services. All classifications of appointments, all types and levels of staff (employed, honorary, contract, visiting, and private community staff members), are included. Visiting staff include those who are *locum tenentes*, or invited experts, "master class" teachers, and others allowed to provide patient care services temporarily. A hospital must define those other practitioners, such as "house officers," "hospitalists," and "junior doctors," that are no longer in training, but may or may not be permitted by the hospital to practice independently. The term *medical staff* is thus inclusive of all physicians and other professionals permitted to treat patients with partial or full independence, regardless of their relationship to the hospital (**for example**,

employees or independent consultants). Note that in some cultures traditional medicine practitioners, such as acupuncturists, chiropractors, and others, may be permitted by law and the hospital to practice independently. Thus, they are considered medical staff members, and these standards apply in full. (Also see GLD.6.2)

Verification

Verification is the process of checking the validity and completeness of a credential from the source that issued the credential. This process can be accomplished by an inquiry to a secure online database of, **for example**, those individuals licensed in the hospital's city or country. The process can also be accomplished by documenting a telephone conversation with the issuing source, or by sending an e-mail or conventional postal letter inquiry with the source. Verification of credentials from outside the country may be more complex and in some cases not possible. There should however be evidence of a credible effort to verify the credential. A credible effort is characterized by multiple (at least two within 60 days) attempts by various methods (**for example**, phone, e-mail, and letter) with documentation of the attempts and result(s).

The three following situations are acceptable substitutes for a hospital performing primary source verification of credentials:

- 1) Applicable to hospitals overseen directly by governmental bodies, the government's verification process, supported by the availability of published governmental regulations about primary source verification; plus government licensure, or equivalent such as a registration; and the granting of specific status (for example, consultant, specialist, and others) are acceptable. As with all third-party verification processes, it is important to verify that the third party (for example, a government agency) implements the verification process as described in policy or regulations and that the process meets the expectations described in these standards.
- 2) Applicable to all hospitals, an affiliated hospital that has already conducted primary source verification of the medical staff applicant, is acceptable as long as the affiliated hospital has current Joint Commission International (JCI) accreditation with "full compliance" on its verification process found in SQE.9.1, MEs 1 and 2 (SQE.9, ME 3, in JCI's fourth edition hospital standards). *Full compliance* means the hospital's Official Survey Findings Report indicates that all measurable elements are fully met, or any not met or partially met measurable element required to be addressed by Strategic Improvement Plan (SIP) actions have been addressed and are now in full compliance.
- 3) Applicable to all hospitals, the credentials have been verified by an independent third party, such as a designated, official, governmental, or nongovernmental agency, as long as the following conditions apply: Any hospital that bases its decisions in part on information from a designated, official, governmental, or nongovernmental agency should have confidence in the completeness, accuracy, and timeliness of that information. To achieve this level of confidence in the information, the hospital should evaluate the agency providing the information initially and then periodically thereafter to ensure that JCI standards continue to be met.

It is important to understand the process for issuing some credentials. For example, does the government agency that issues the license to practice base its decision on any or all of the following: verification of education, an examination of competence, training by a medical specialty association, or membership and payment of fees? Also, if admission to a specialty education program is based on verification of education and experience to date, the hospital does not need to verify education again. The process used by the government agency is documented by the hospital. If the hospital does not have direct knowledge of the process used by the agency to verify education, or the hospital has never had an opportunity to verify that the agency carries out the process as described, then the hospital needs to perform its own verification. (Also see SQE.13, ME 3 and SQE.15, ME 3)

Exception for SQE.9.1, ME 1, for initial surveys only. Primary source verification is required for new practitioners who joined the medical staff within the twelve (12) months prior to the initial JCI accreditation survey. All other practitioners must have primary source verification completed within twelve months of the initial survey. This process is accomplished over the twelve-month postsurvey period according to a plan that places priority on the verification of the credentials of active practitioners providing high-risk services.

Note: This exception refers only to the *verification* of credentials. All medical staff members have to have their credentials gathered and reviewed, and their privileges granted. There is no "phasing in" of this process.

Appointment

Appointment is the process of reviewing an initial applicant's credentials to decide if the individual is qualified to provide patient care services that the hospital's patients need and the hospital can support with qualified staff and technical capabilities. For initial applicants, the information reviewed is primarily from outside sources. Hospital policy identifies the individuals or mechanism accountable for this review, any criteria used to make decisions, and how decisions will be documented. Hospital policy identifies the process of appointment of independent practitioners for emergency needs or a temporary period. For such individuals, the appointment and identification of privileges are not made until at minimum licensure has been verified.

Reappointment

Reappointment is the process of reviewing the medical staff member's file to verify

- continued licensure;
- that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies;
- that the file contains sufficient documentation for seeking new or expanded privileges or duties in the hospital; and
- that the medical staff member is physically and mentally able to provide patient care and treatment without supervision.

The information for this review is from both internal and external sources. When a clinical department/service (for example, a subspecialty service) does not have a director/leader, there is a hospital policy that identifies who will do the review of the professionals in that department/service. The credential file of a medical staff member should be a dynamic source of information and under constant review. For example, when a medical staff member presents a certificate of achievement related to an advanced degree or advanced specialty training, the new credential should be immediately verified from the issuing source. Similarly, when an outside agency investigates a sentinel event related to a medical staff member and issues sanctions, this information should be used promptly to reevaluate the clinical privileges of the medical staff member. To ensure that medical staff files are complete and accurate, the files are reviewed at least every three years, and a note in the file indicates any actions taken or that no action is necessary and the appointment to the medical staff continues.

Medical staff membership may not be granted if the hospital does not have the special medical technology or staff to support the professional practice of the individual. **For example**, a nephrologist seeking to provide dialysis services at the hospital, may not be granted medical staff membership if the hospital does not provide such services.

Finally, when an applicant's licensure/registration has been verified from the issuing source, but other documents—such as education and training—have yet to be verified, the individual may be granted medical staff membership, and privileges are identified for the applicant. However, these individuals may not practice independently until all credentials have been verified. Such supervision is clearly defined in hospital policy as to level, conditions, and duration. (Also see SQE.1.1, SQE.3, and SQE.5)

Measurable Flements of SQF 9

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1.	The hospital has an ongoing, uniform process to manage the credentials of medical staff members.
2.	Medical staff members permitted by laws, regulations, and the hospital to provide patient care without supervision are identified.
3.	Education, licensure/registration, and other credentials required by law or regulation are copied by the hospital and maintained for each medical staff member in their personnel file or in a separate credential file.
4.	All credentials required by hospital policy are copied by the hospital and maintained for each medical staff member in his or her personnel file or in a separate credential file.

Measurable Elements of SQE.9.1

- 1. Education, licensure/registration, and other credentials required by law or regulation or issued by recognized education or professional entities as the basis for clinical privileges are verified from the original source that issued the credential.
 - 2. Additional credentials required by hospital policy are verified from the source that issued the credential when required by hospital policy.
 - 3. When third-party verification is used, the hospital verifies that the third party (**for example**, a government agency) implements the verification process as described in policy or regulations and that the process meets the expectations described in the intent.

Measurable Elements of SQE.9.2

- 1. Medical staff appointments are made according to hospital policy and are consistent with the hospital's patient population, mission, and services provided to meet patient needs.
- 2. Appointments are not made until at least licensure/registration has been verified from the primary source, and the medical staff member then provides patient care services under supervision until all credentials required by laws and regulations have been verified from the original source.
- □ 3. The method of supervision, frequency of supervision, and accountable supervisors are documented in the credential file of the individual.

The Assignment of Medical Staff Clinical Privileges

Standard SQE.10

Intent of SQE.10

The determination of a medical staff member's current clinical competence and making a decision about what clinical services the medical staff member will be permitted to perform, often called *privileging*, is the most critical determination a hospital will make to protect the safety of patients and to advance the quality of its clinical services.

Considerations for clinical privilege delineation at initial appointment include the following:

- Decisions regarding a practitioner's clinical competence, and thus what clinical privileges he or she is to be granted, are based primarily on information and documentation received from outside the hospital. The source may include specialty education programs, letters of recommendation from previous medical staff appointments and/or close colleagues, and any quality data that may be released to the hospital. In general, these sources of information, other than those from educational institutions such as medical specialty programs, are not verified from the source unless required by hospital policy. Although these outside sources may not give clear, objective evidence of current clinical competence, at least the areas of presumed competence are identified. Ongoing professional practice review (see SQE.11) will validate the areas of presumed competence.
- There is no one best way to delineate those clinical activities the new medical staff member is privileged to perform. Specialty training programs may identify and list the general competencies of that specialty in areas of diagnosis and treatment—with the hospital assigning privileges to diagnose and treat patients in those specialty competency areas. Other organizations may choose to list out in detail each type of patient and treatment procedure. (*Also see* AOP.1, ME 3; ASC.3.1; MMU.4.2; and MMU.6)
- Within each specialty area the process of privilege delineation is uniform; however, this process may not be the same in all specialty areas. Thus, the privileges will be different for general surgeons, pediatricians,

dentists, or radiologists, **for example**; however, within each of these groups the process for privilege delineation will be standardized. For family practitioners, primary care practitioners, and others that provide a variety of general medicine, obstetrics, pediatrics, and other services, the privilege delineation for these practitioners identifies which "specialty" services can be provided.

- The decision as to how clinical privileges are delineated in a specialty area is linked with other processes, including
 - selection by the department/service leaders of what processes are to be monitored through data collection (see GLD.11.1 and SQE.1.1);
 - o use of those data in the ongoing monitoring and evaluation process of the medical staff in the department/service (see SQE.11); and
 - o use of the monitoring data in the process of reappointment and the renewal of privileges (see SQE.12).
- In addition to the privileges granted in relation to the individual's education and training, the hospital identifies areas of high risk, such as the administration of chemotherapeutic agents, other classes of drugs, or high-risk procedures for which the medical staff member is explicitly granted such privileges or denied such privileges. The high-risk procedures, drugs, or other services are identified by each specialty area and evident in the privilege delineation process. Finally, some procedures may be high risk due to the instrumentation used, such as in the case of robotic and other computerized or remotely operated surgical or therapeutic technology. Also, implantable medical devices require skills in implantation, calibration, and monitoring for which privileges should be specifically granted. (Also see ASC.7.4)
- Also, privileges are not granted if the hospital does not have the special medical technology or staff to support the exercise of a privilege. **For example**, a nephrologist competent to do dialysis, or a cardiologist competent to insert stents, are not privileged for these procedures if the hospital does not provide such services.
- Finally, when an applicant's licensure/registration has been verified from the issuing source, but other documents—such as education and training—have yet to be verified, privileges are identified for the applicant. However, these applicants may not practice independently until all credentials have been verified by the processes described above. Such supervision is clearly defined in hospital policy as to level, conditions, and duration.

Note: When a medical staff member also has administrative responsibilities, such as chair or chief of a clinical department, administrator of the hospital, or other such position, the responsibilities for this role are identified in a job description (*see* SQE.1.1). Hospital policy identifies the primary source verification of the credentials presented in support of this administrative role.

The privilege delineation process

- a) is standardized, objective, and evidence-based;
- b) is documented in hospital policies;
- c) is active and ongoing as the credentials of medical staff members change;
- d) is followed for all classes of medical staff membership; and
- e) can be demonstrated as to how the procedure is used effectively.

The clinical privileges of all medical staff members are made available by printed copy, electronic copy, or other means to those individuals or locations (**for example**, operating room, emergency department) in the hospital in which the medical staff member will provide services. The medical staff member is provided a copy of his or her clinical privileges. Updated information is communicated when the clinical privileges of a medical staff member change. (*Also see* GLD.6.2 and SQE.3)

Measurable Elements of SQE.10

- 1. The privilege delineation process used by the hospital meets criteria a) through e) found in the intent.
- 2. The clinical privileges of all medical staff members are made available by printed copy, electronic copy, or other means to those individuals or locations (**for example**, operating room, emergency department) in the hospital in which the medical staff member will provide services.

3. Each medical staff member provides only those services that have been specifically granted by the hospital.

Ongoing Monitoring and Evaluation of Medical Staff Members

Standard SQE.11

Intent of SQE.11

Explanations of terms and expectations found in these standards are as follows:

Ongoing Monitoring and Evaluation

Ongoing monitoring and evaluation compose the process of continuously accumulating and analyzing data and information on the behaviors, professional growth, and clinical results of medical staff members. The department/service leader is responsible for the integration of the data and information on medical staff and taking appropriate actions. Immediate actions may be to counsel the staff member, place him or her under supervision, limit privileges, or other measures intended to limit risks to patients and improve quality of care and patient safety. Longer-term actions include synthesizing the data and information into a recommendation for continued medical staff membership and clinical privileges. This process occurs at least every three years. Other actions may be to note to other medical staff members the benchmark behaviors and clinical results evident in the data and information of the medical staff member.

The ongoing monitoring and evaluation of medical staff members provides critical information to the process of maintaining medical staff membership and to the process of granting clinical privileges. (Also see SQE.9 through SQE.9.2) Although three-year cycles are required for renewing medical staff membership and clinical privileges, the process is intended to be ongoing and dynamic. Critical quality and patient safety incidents can arise if a medical staff member's clinical performance issues are not communicated and acted on when they arise.

The process of ongoing monitoring and evaluation is intended to

- improve individual practices as they relate to high-quality, safe patient care;
- provide the basis for reducing variation within a department/service through comparisons among colleagues and the development of practice guidelines and clinical protocols; and
- provide the basis for improving the results of the entire department/service through comparisons with external benchmark practices and published research and clinical results.

The ongoing monitoring and evaluation of medical staff members encompasses three general areas—behaviors, professional growth, and clinical results.

Behaviors

Medical staff members are models and mentors in creating a safe culture in a hospital. A safe culture is characterized by full participation by all staff, without fear of reprisal or marginalization. Safe cultures also include high respect between professional groups in which disruptive and other behaviors do not occur. Staff feedback through surveys and other mechanisms can shape desired behaviors and can support medical staff role models.

An evaluation of behaviors can include

- evaluation of whether a medical staff member understands and supports the hospital's code of behavior and the identification of acceptable and unacceptable behaviors;
- an absence of reported behaviors by the medical staff member that are identified as unacceptable; and

• gathering, analysis, and use of information and data from staff surveys and other sources regarding the culture of safety in the hospital.

The ongoing monitoring and evaluation process should indicate, as part of the review process, the relevant achievements and challenges of the medical staff member in efforts to be a full participant in a safe and just culture.

Professional Growth (errata)

Medical staff members grow and mature as the organizations in which they practice evolve, introducing new patient groups, technologies, and clinical science. Each medical staff member, to varying degrees, will reflect growth and improvement in the following important dimensions of health care and professional practice:

- a) Patient care, including provision of patient care that is compassionate, appropriate, and effective for health promotion, disease prevention, treatment of disease, and care at the end of life. (Potential measures include frequency of preventive services and reports from patients and families.) (Also see PRF.3)
- b) Medical/clinical knowledge, including knowledge of established and evolving biomedical, clinical, epidemiologic, and social-behavioral sciences, as well as the application of knowledge to patient care and the education of others. (Potential measures include application of clinical practice guidelines, including the adaptation and revision of guidelines, participation in professional conferences, and publications.) (Also see GLD.11.2)
- c) Practice-based learning and improvement, including use of scientific evidence and methods to investigate, evaluate, and continuously improve patient care based on self-evaluation and lifelong learning. (Examples of potential measures include self-motivated clinical inquiry/research, acquiring new clinical privileges based on study and acquiring new skills, and full participation in meeting requirements of professional specialty requirements or continuing education requirements of licensure.)
- d) Interpersonal and communication skills, including establishment and maintenance of effective exchange of information and collaboration with patients, their families, and other members of health care teams. (Examples of potential measures include participation in teaching rounds, team consultations, team leadership, and patient and family feedback.)
- e) Professionalism, including commitment to continuous professional development, ethical practice, an understanding and sensitivity to diversity, and a responsible attitude toward patients, their profession, and society. (Examples of potential measures include an opinion leader within the medical staff on clinical and professional issues, service on an ethics panel or discussions of ethical issues, keeping appointed schedules, and community participation.)
- f) System-based practices, including awareness of and responsiveness to the larger contexts and systems of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care. (Examples of potential measures include understanding the meaning of frequently used, hospitalwide systems, such as the medication system; and awareness of the implications of the overuse, underuse, and misuse of systems.)
- g) Stewardship of resources, including understanding of the need for stewardship of resources and practicing cost-conscious care, including avoiding the overuse and misuse of diagnostic tests and therapies that do not benefit patient care but add to health care costs. (Examples of potential measures include participation in key purchasing decisions within their practice area, participating in efforts to understand appropriate use of resources, and being aware of the cost to patients and payers of the services they provide.) (Also see GLD.7)

The ongoing monitoring and evaluation process should recognize, as part of the review process, the relevant areas of achievement and potential improvement of the medical staff member in these professional growth areas.

Clinical Results

The ongoing monitoring and evaluation process for a medical staff member reviews information common to all medical staff members as well as specific information related to the clinical privileges of the member and the services provided by his or her specialty.

Hospitalwide Data Sources. Hospitals collect a variety of data for use in management; **for example**, reporting to health authorities to support allocation of resources or payment of services. To be useful in the ongoing evaluation of an individual medical staff member, such hospitalwide data

- need to be collected in such a manner that individual practitioners can readily be identified;
- must relate to the clinical practice of the individual medical staff member; and
- can be benchmarked internally and/or externally to understand individual practitioner patterns.

Examples of such potential sources of data include length of stay, frequency of diagnostic testing, blood usage, and usage of certain drugs, among others.

Department-Specific Data Sources. Data are also collected at the level of each department/service. The department/service leader sets the priorities for measurement in the department for purposes of monitoring as well as improvement. The measures are specific to the services provided and the clinical privileges of the individual medical staff members within the department. As with hospitalwide data, to be useful in the ongoing evaluation of an individual department/service member, the data

- need to be collected in a manner such that individual practitioners can readily be identified;
- must relate to the clinical practice of the individual medical staff member; and
- can be benchmarked within the department/service and/or externally to understand individual practitioner patterns.

Examples of such potential department/service data include frequency of clinical procedures performed, complications, outcomes, and use of resources such as consultants, among others.

Also, it is important to note that it is not anticipated that any department/service will have the capacity or need to monitor all the listed privileges of every practitioner. It is more feasible to collect data on key services or some aspect of key services on the department level for which all or most department/service staff members have privileges.

Thus, there is no one set of data that will suffice to monitor and evaluate all medical staff members. The choice of data, the frequency of monitoring and analysis, and the actual use of the data and documentation in the record of the medical staff member are very specific to the department/service, to the relevant profession, and to the privileges of the practitioner. The monitoring and evaluation of medical staff members is supported by a variety of data sources, including electronic and paper records, observations, and peer interactions.

An important final step is to ask the question: "How is this practitioner doing compared to other colleagues within his or her department and in comparison to professional colleagues in other hospitals, regions, or countries?" The internal comparison is primarily to reduce variation in practice and outcomes within the department and learn from the best practices within the department. The external comparison is to ensure that the hospital achieves best practices within the respective profession. Each department will have knowledge of those professional databases, clinical practice guidelines, and scientific literature sources that describe those desirable benchmark practices. For example, oncology registries can be helpful, or data from practitioners using the same science (clinical practice guidelines). Similarly, a national or international surgical society may collect outcome or complication data.

In summary, the ongoing medical staff member monitoring and evaluation process

- is standardized by type of medical staff member and/or department or clinical services unit;
- uses the monitoring data and information for internal comparisons to reduce variation in behaviors, professional growth, and clinical results;
- uses the monitoring data and information for external comparisons with available, objective, evidence-based best practice or benchmark sources of clinical result data and information;
- is conducted by the individual's department or service head, senior medical manager, or a medical staff review body;
- includes the monitoring and evaluation of senior medical staff and department heads by an appropriate professional (also see GLD.11.1, ME 1); and
- provides information that will be documented in the medical staff member's file, including the results of reviews, actions taken, and the impact of those actions on privileges (if any).

Finally, while the process of monitoring and evaluation of medical staff members is intended to be ongoing, and data and information may be accumulated on an ongoing basis, hospital policy requires a review at least once during a 12-month period. The review is conducted by the individual's department or service head, a senior medical manager, or a medical staff review body. Findings, conclusions, and any actions taken or recommended are recorded in the medical staff member's file. When the findings affect the appointment or privileges of the medical staff member, there is a process to take action on the findings. Such immediate "for cause" actions are documented in the practitioner's file and are reflected in the list of clinical privileges. Notification is sent to those sites in which the practitioner provides services. (*Also see* QPS.4 and SQE.3)

Measurable Elements of SQE.11

- ☐ 1. All medical staff members are included in an ongoing professional practice monitoring and evaluation process as defined by hospital policy and standardized at the department/service level. (Also see SQE.3, ME 5)
- ☐ 2. The monitoring and evaluation process identifies areas of achievement and potential improvement related to the behaviors, professional growth, and clinical results of the medical staff member compared to other department/service medical staff members.
- ☐ 3. The clinical results of data and information available on medical staff members are reviewed with objective and evidence-based information, as available, for external benchmarking.
- 4. The data and information from the monitoring are reviewed at least every 12 months by the individual's department or service head, senior medical manager, or medical staff body, and the results, conclusions, and any actions taken are documented in the medical staff member's credentials file and other relevant files.
- 5. When the findings affect the appointment or privileges of the medical staff member, there is a process to take action on the findings, and such "for cause" actions are documented in the practitioner's file and are reflected in the list of clinical privileges. Notification is sent to those sites in which the practitioner provides services.

Medical Staff Reappointment and Renewal of Clinical Privileges

Standard SQE.12

Intent of SQE.12

Explanations of terms and expectations found in these standards are as follows:

Reappointment

Reappointment is the process of reviewing, at least every three years, the medical staff member's file to verify

- continued licensure;
- that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies;
- that the file contains sufficient documentation for seeking new or expanded privileges or duties in the hospital; and
- that the medical staff member is physically and mentally able to provide patient care and treatment without supervision.

The information for this review is gathered from the internal, ongoing monitoring and evaluation of the medical staff member, as well as from external sources such as regulatory or professional organizations or agencies. Hospital policy identifies the individual, such as the leader of a specialty service; or mechanism, such as a medical staff office when a department/service leader is not present or accountable for this review; any criteria used to make decisions; and how decisions will be documented. The credential file of a medical staff member should be a dynamic source of information and under constant review. For example, when a medical staff member presents a certificate of achievement related to an advanced degree or advanced specialty training, the new credential should be immediately verified from the issuing source. Similarly, when an outside agency investigates a sentinel event related to a medical staff member and issues sanctions, this information should be used promptly to reevaluate the clinical privileges of the medical staff member. To ensure that medical staff files are complete and accurate, the files are reviewed at least every three years, and a note in the file indicates any actions taken or that no action is necessary and the appointment to the medical staff continues.

Considerations for clinical privilege delineation at reappointment include the following:

- Medical staff members may be granted additional privileges based on advanced education and training. The
 education and training are verified from the source providing the education or training or issuing the
 credential. The full exercise of the added privilege may be delayed until the verification process is
 complete or when there is a required period of supervised practice prior to granting an unrestricted new
 privilege; for example, a required number of supervised cases of robotic surgery.
- Medical staff members may have their privileges continued, limited, reduced, or terminated based on
 - o the results of the ongoing professional practice review process (see SQE.11);
 - o limitations placed on the individual's privileges by an outside professional, governmental, or regulatory agency;
 - o the hospital's findings from an evaluation of a sentinel or other event;
 - o the health of the practitioner; or
 - o the request of the practitioner. (Also see SQE.3 and SQE.10)

Measurable Elements of SQE.12

- ☐ 1. Based on the ongoing monitoring and evaluation of the medical staff member, the hospital determines, at least every three years, if medical staff membership and clinical privileges are to continue with or without modification.
- 2. There is evidence in the file of each medical staff member that all credentials that require periodic renewal, payment of a registration fee, or other action by the medical staff member are current.
- ☐ 3. Credentials obtained subsequent to initial appointment are evident in the file of the medical staff member and have been verified from the primary source prior to use in modifying or adding to clinical privileges.
- 4. The renewal decision is documented in the medical staff member's credential file and includes the identification of the reviewer and any special conditions identified during the review.

Nursing Staff

Standard SQE.13

The hospital has a uniform process to gather, to verify, and to evaluate the nursing staff's credentials (license, education, training, and experience).

Intent of SQE.13

The hospital needs to ensure that it has a qualified nursing staff that appropriately matches its mission, resources, and patient needs. The nursing staff are responsible for providing direct patient care. In addition, nursing care contributes to the overall patient outcomes. The hospital must ensure that nurses are qualified to provide

nursing care and must specify the types of care they are permitted to provide if not identified in laws or regulations. The hospital ensures that each nurse is qualified to provide safe and effective care and treatment to patients by

- understanding the applicable laws and regulations that apply to nurses and nursing practice;
- gathering all available credentials on each nurse, including at least
 - o evidence of education/training;
 - o evidence of current licensure;
 - o evidence of current competence through information from other sources in which the nurse was employed; and
 - o letters of recommendation and/or other information the organization may require, such as health history, pictures, among others; and
- verification of the essential information, such as current registry or licensure, particularly when such
 documents are periodically renewed, and any certifications and evidence of completion of specialized or
 advanced education.

The hospital needs to make every effort to verify essential information, even when the education took place in another country and a significant time ago. Secure websites, documented phone confirmation from the source, written confirmation, and third parties, such as a designated, official governmental or nongovernmental agency, can be used. The situations described for medical staff in the intent of SQE.9 are considered acceptable substitutes for an organization performing primary source verification of nurse credentials.

Standards compliance requires that primary source verification is carried out for

- new nurse applicants beginning 12 months prior to initial accreditation survey; and
- current employed nurses during a period of 12 months following the initial survey. This is accomplished according to a plan that places priority on the verification of the credentials of nurses providing high-risk services, such as in the operating theatre, emergency department, or intensive care unit.

When verification is not possible, such as with the loss of records in a disaster, this is documented.

The hospital has a process that ensures that the credentials of each contract nurse have also been gathered, verified, and reviewed to ensure current clinical competence prior to assignment. The hospital gathers and maintains a file of each nurse's credentials. The files contain current licenses when regulations require periodic renewal. There is documentation of training related to any additional competencies. (Also see SQE.5)

Measurable Elements of SQE.13

1.	The hospital has a standardized procedure to gather the credentials of each nursing staff member.
2.	Licensure, education/training, and, when available, experience, are documented.
3.	Licensure and education/training are verified from the original source according to the parameters found in the intent of SQE.9.
4.	There is a record maintained of the credentials of every nursing staff member.
5.	The hospital has a process to ensure that the credentials of contract nurses are valid and complete prior to assignment.
6.	The hospital has a process to ensure that nurses who are not employees of the hospital, but accompany private physicians and provide services to the hospital's patients, have valid credentials. (Also see GLD.6)

Standard SQE.14

The hospital has a standardized process to identify job responsibilities and to make clinical work assignments based on the nursing staff member's credentials and any regulatory requirements.

Standard SQE.14.1

The hospital has a standardized process for nursing staff participation in the hospital's quality improvement activities, including evaluating individual performance when indicated.

Intent of SQE.14 and SQE.14.1

Review of the qualifications of the nursing staff member provides the basis for assigning job responsibilities and clinical work assignments (see SQE.3). Work assignments may be described in more detail in a job description (see SQE.1.1) or described in other ways or documents that support how nurse staffing assignments are made (see SQE.6), such as assignment to geriatric or pediatric units or to high-acuity units. Assignments made by the hospital are consistent with any applicable laws and regulations regarding nursing responsibilities and clinical care.

The nursing staff's essential clinical role requires them to actively participate in the hospital's clinical quality improvement program. If at any point during clinical quality measurement, evaluation, and improvement, a nursing staff member's performance is in question, the hospital has a process to evaluate that individual's performance. The results of reviews, actions taken, and any impact on job responsibilities are documented in the nurse's credentials or other file.

Measurable Elements of SQE.14

- ☐ 1. Licensure, education/training, and experience of a nursing staff member are used to make clinical work assignments.
- ☐ 2. The process takes into account relevant laws and regulations.
- ☐ 3. The process supports nurse staffing plans.

Measurable Elements of SQE.14.1

- ☐ 1. Nursing staff participate in the hospital's quality improvement activities. (Also see QPS.1, ME 4)
- 2. The performance of individual nursing staff members is reviewed when indicated by the findings of quality improvement activities. (*Also see* GLD.11.1, ME 2)
- ☐ 3. Appropriate information from the review process is documented in the nurse's credentials or other file.

Other Health Care Practitioners

Standard SQE.15

The hospital has a uniform process to gather, to verify, and to evaluate other health professional staff members' credentials (license, education, training, and experience).

Intent of SQE.15

Hospitals employ or may permit a variety of other health professionals to provide care and services to their patients or to participate in patient care processes. For example, these professionals include nurse midwives, surgical assistants, emergency medical care specialists, pharmacists, and pharmacy technicians. In some countries or cultures, this group also includes traditional healers or those who provide alternative services or services that complement traditional medical practice (for example, acupuncture, herbal medicine). Often, these individuals do not actually practice in the hospital; instead, they refer to the hospital or provide continuing or follow-up care for patients in the community. Many of these professionals complete formal training programs and receive licenses or certificates or are registered with local or national authorities. Others may complete less-formal apprentice programs or other supervised experiences.

For those other health professionals permitted to work or to practice in the hospital, the hospital is responsible for gathering and verifying their credentials. The hospital must ensure that other health professional staff are qualified to provide care and treatments and must specify the types of care and treatment they are permitted to provide if not identified in laws or regulations. The hospital ensures that other health professionals are qualified to provide safe and effective care and treatment to patients by

- understanding the applicable laws and regulations that apply to such practitioners;
- gathering all available credentials on each individual, including at least evidence of education and training, evidence of current licensure or certification when required; and
- verification of the essential information, such as current registry, licensure, or certification.

The hospital needs to make every effort to verify essential information relevant to the individual's intended responsibilities, even when the education took place in another country and a significant time ago. Secure websites, documented phone confirmation from the source, written confirmation, and third parties, such as a designated, official governmental or nongovernmental agency, can be used.

The situations described for medical staff in the intent of SQE.9 are acceptable substitutes for a hospital performing primary source verification for the credentials of other health professional staff.

Standards compliance requires that primary source verification is carried out for

- new applicants beginning four months prior to initial accreditation survey; and
- current employed health professionals during a period of three years postsurvey.

When there is no required formal education process, licensure, or registry process or other credential or evidence of competency, this is documented in the individual's record. When verification is not possible, such as with the loss of records in a disaster, this is documented in the individual's record. The hospital gathers and maintains a file of each health professional's credentials. The files contain current licenses or registry when regulations require periodic renewal. (Also see SQE.5)

Measurable Elements of SQE.15

1.	The hospital has a standardized process to gather the credentials of each health professional staff member.
2.	Licensure, education/training, and, when available, experience, are documented.
3.	Licensure and education/training are verified from the original source according to the parameters found in the intent of SQE.9.
4.	There is a record maintained on other health professional staff members that contains copies of an required license, certification, or registration.

5. The hospital has a process to ensure that other staff who are not employees of the hospital but accompany private physicians and provide services to the hospital's patients have valid credentials that are comparable to the hospital's requirement for credentials.

Standard SQE.16

The hospital has a uniform process to identify job responsibilities and to make clinical work assignments based on other health professional staff members' credentials and any regulatory requirements.

Standard SQE.16.1

The hospital has a uniform process for other health professional staff members' participation in the hospital's quality improvement activities.

Intent of SQE.16 and SQE.16.1

The hospital is responsible for identifying the types of activities or range of services these individuals will provide in the hospital. This can be accomplished through agreements, job assignments, job descriptions (see SQE.1.1),

or other methods. In addition, the hospital defines the level of supervision (consistent with existing laws and regulations), if any, for these professionals. Other health professionals are included in the hospital's quality management and improvement program.

Measurable Elements of SQE.16

- Licensure, education, training, and experience of other health professional staff members are used to make clinical work assignments.
- ☐ 2. The process takes into account relevant laws and regulations.
- ☐ 3. The process supports the staffing process for other health professionals.

Measurable Elements of SQE 16.1

- ☐ 1. Other health professional staff participate in the hospital's quality improvement activities. (Also see QPS.1, ME 4)
- 2. The performance of other health professional staff members is reviewed when indicated by the findings of quality improvement activities. (*Also see* GLD.11.1, ME 3)
- 3. Appropriate information from the review process is documented in the health professional's file.

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Management of Information (MOI)*

Changes to the MOI Chapter

Standard	Change	Explanation
MOI.1	Renumbered	Moves requirement from MCI.9 (4th edition)
MOI.2	Renumbered; No significant change	Moves and combines requirements of MCI.10 and MCI.11 (4th edition); rewords intent and MEs for clarity
MOI.3- MOI.5	Renumbered; No significant change	Renumbers standards from the 4th edition with minor text changes to improve clarity: MOI.3 (previously MCI.12); MOI.4 (previously MCI.13); MOI.5 (previously MCI.14)
MOI.6	Renumbered; Requirement change	Moves requirement from MCI.15 (4th edition) and adds new language in intent and MEs to emphasize the need for hospitals to assess, test, and evaluate health information technology systems prior to and following implementation
MOI.7 and MOI.8	Renumbered; No significant change	Renumbers standards from the 4th edition with minor text changes to improve clarity: MOI.7 (previously MCI.16) and MOI.8 (previously MCI.17)
MOI.9	Renumbered; Requirement change	Moves standard from MCI.18 (4th edition) and revises standard, intent, and MEs to streamline and clarify requirements
MOI.9.1	New standard	Introduces a new standard that consolidates requirements for ensuring proper implementation of policies, procedures, plans, and other documents that guide clinical and nonclinical practices
MOI.10- MOI.12	Renumbered; No significant change	Renumbers several standards from the 4th edition with minor text changes to improve clarity: MOI.10 (previously MCI.19); MOI.10.1 (previously MCI.19.1); MOI.10.1.1 (previously MCI.19.2); MOI.11.1 (previously MCI.19.3); MOI.12 (previously MCI.19.4)

^{*} The "Management of Information" (MOI) chapter in this edition was named "Management of Communication and Information" (MCI) chapter in the 4th edition standards.

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the 4th edition of this manual and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the 4th edition standards but were deleted from this edition (listed with 4th edition numbers): MCI.2, MCI.3, MCI.6, MCI.7.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a $^{\textcircled{p}}$ icon after the standard text.

Standards, Intents, and Measurable Elements

Information Management

Standard MOI.1

The hospital plans and designs information management processes to meet internal and external information needs.

Intent of MOI.1

Information is generated and used during patient care and for managing a safe and effective hospital. The ability to capture and to provide information requires effective planning. Planning incorporates input from a variety of sources, including the following:

- The health care practitioners
- The hospital's managers and department/service leaders
- Those outside the hospital who need or require data or information about the hospital's operation and care processes

The planning also includes the hospital's mission, services provided, resources, access to affordable technology, and support for effective communication among caregivers. The priority information needs of these sources influence the hospital's information management strategies and ability to implement those strategies. The strategies meet the needs of the hospital based on the hospital's size, complexity of services, availability of trained staff, and other human and technical resources. The information processes are comprehensive and include all of the departments and services of the hospital. Planning for the management of information does not require a formal written information program but does require evidence of a planned approach that identifies the hospital's information needs. (Also see ACC.3)

Measurable Elements of MOI.1

- ☐ 1. The information needs of those who provide clinical services are considered in the planning process.
- 2. The information needs of those who manage the hospital are considered in the planning process.
- The information needs and requirements of individuals and agencies outside the hospital are considered in the planning process.
- 4. The planning is based on the hospital's size and complexity.

Standard MOI.2

Information privacy, confidentiality, and security—including data integrity—are maintained. ®

Intent of MOI.2

The hospital maintains the privacy and confidentiality of data and information and is particularly careful about preserving the confidentiality of sensitive data and information. The balance between data sharing and data confidentiality is addressed. The hospital determines the level of privacy and confidentiality maintained for different categories of information (**for example**, the patient record, research data, and quality data; *see* PFR.1.3 and GLD.17, ME 3).

Maintaining data integrity is an important aspect of information management. The information contained in a database must be accurate in order to assure the reliable interpretation of results from data analysis.

Policies and procedures address security procedures that allow only authorized staff to gain access to data and information. Access to different categories of information is based on need and defined by job title and function, including students in academic settings. An effective process defines

- who has access to data and information;
- the information to which an individual has access;
- the user's obligation to keep information confidential;
- the process for maintaining data integrity; and
- the process followed when confidentiality, security, or data integrity are violated.

Note: For confidentiality of patient clinical records, see MOI.11.

Measurable Elements of MOI.2

_	1.	The hospital has a written process that protects the confidentiality, security, and integrity of data and information.
_	2.	The process is based on and consistent with laws and regulations.

- 3. The process identifies the level of confidentiality maintained for different categories of data and information.
- 4. Those persons who need or have a job position permitting access to each category of data and information are identified.
- □ 5. Compliance with the process is monitored.

Standard MOI.3

The hospital determines the retention time of records, data, and information.

Intent of MOI.3

The hospital determines the retention time of patient clinical records and other data and information. Patient clinical records and other data and information are retained for sufficient periods to comply with laws and regulations and to support patient care, management, legal documentation, research, and education. The retention of records, data, and information is consistent with the confidentiality and security of such information. When the retention period is complete, patient clinical records and other records, data, and information are destroyed in a manner that does not compromise confidentiality and security.

Measurable Elements of MOI.3

 u	diable Elements of Mens
1.	The hospital determines the retention time of patient clinical records and other data and information.
2.	The retention process provides expected confidentiality and security.
3.	Records, data, and information are destroyed in a manner that does not compromise confidentiality and
	security.

Standard MOI.4

The hospital uses standardized diagnosis codes, procedure codes, symbols, abbreviations, and definitions.

Intent of MOI.4

Standardized terminology, definitions, vocabulary, and nomenclature facilitate comparison of data and information within and among hospitals. In addition, standardization prevents miscommunication and potential errors. The uniform use of 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. In addition, when one abbreviation is used for multiple medical terms, confusion as to what the author means may

result in medical errors. Abbreviations and symbols are also standardized and include a do-not-use listing. Such standardization is consistent with recognized local and national standards.

Measurable Elements of MOI.4

- ☐ 1. Standardized diagnosis codes are used and use monitored.
- 2. Standardized procedure codes are used and use monitored.
- ☐ 3. Standardized definitions are used.
- 4. Standardized symbols are used, and those not to be used are identified and monitored.
- 5. Standardized abbreviations are used, and those not to be used are identified and monitored.

Standard MOI.5

The data and information needs of those in and outside the hospital are met on a timely basis in a format that meets user expectations and with the desired frequency.

Intent of MOI.5

The format and methods of disseminating data and information to the intended user are tailored to meet the user's expectations. Dissemination strategies include

- providing only the data and information the user requests or needs;
- formatting the report to aid use in the decision process;
- providing reports with the frequency needed by the user;
- linking sources of data and information; and
- providing interpretation or clarification of data.

Measurable Elements of MOI.5

- 1. Data and information dissemination meet user needs.
- Users receive data and information on a timely basis.
- ☐ 3. Users receive data and information in a format that aids its intended use.
- 4. Staff have access to the data and information needed to carry out their job responsibilities.

Standard MOI.6

Health information technology systems are assessed and tested prior to implementation within the hospital and evaluated for quality and patient safety following implementation.

Intent of MOI.6

Health information technology can significantly improve patient safety by automating and streamlining work, providing a seamless transition of patient health information, and offering safety mechanisms that potentially reduce the risk of errors. For example, medications errors can be greatly reduced through the implementation of a computerized prescribing mechanism and the use of bar codes for medication administration. However, when not evaluated and tested prior to implementation, health information technology can pose increased risks to patients.

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 allow interfaces with existing systems. Consequently, thorough evaluation and testing 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 providers, as well as patients and families. This level of complex integration requires coordinated participation from key health information technology stakeholders, such as clinical, nonclinical, and managerial staff, in the selection process, implementation, and adoption of technology.

All or part of integrating new and existing health information technology may be done through contracted services. The same level of assessment and testing prior to implementation and evaluation following implementation would be required for contracted services. In addition, oversight for the contract must be provided by an individual with knowledge and experience related to health information technology (*also see* GLD.6 and GLD.6.1).

Following implementation of information technology systems, it is important for the hospital to have a process in place 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; and what effects the technology has on improving patient safety, reducing errors, and enhancing the hospital's performance.

Measurable Elements of MOI.6

- ☐ 1. Health information technology stakeholders participate in selection, implementation, and evaluation of information technology.
- ☐ 2. Health information technology systems are assessed and tested prior to implementation.
- ☐ 3. Health information technology systems are evaluated following implementation for usability, effectiveness, and patient safety.

Standard MOI.7

Records and information are protected from loss, destruction, tampering, and unauthorized access or use. (9)

Intent of MOI.7

Patient records and other data and information are secure and protected at all times. **For example**, active patient records are kept in areas where only authorized health professional staff have access, and records are stored in locations where heat, water, fire, or other damage is not likely to occur. The hospital implements processes to prevent unauthorized access to electronically stored information. (Also see PFR.1.3, ME 3)

Measurable Elements of MOI.7

- 1. Records and information are protected from loss.
- ☐ 2. Records and information are protected from damage or destruction.
- 3. Records and information are protected from tampering and unauthorized access or use.

Standard MOI.8

Decision makers and other staff members are educated and trained in the principles of information use and management.

Intent of MOI.8

Individuals in the hospital who generate, collect, analyze, and use data and information are educated and trained to effectively participate in using and managing information. This education and training enable these individuals to

- understand security and confidentiality of data and information;
- use measurement instruments, statistical tools, and data analysis methods;

- assist in interpreting data;
- use data and information to help in decision making;
- educate and support the participation of patients and families in care processes; and
- use measures to assess and to improve care and work processes.

Individuals are educated and trained according to their responsibilities, job descriptions, and data and information needs.

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. (Also see SQE.8)

Measurable Elements of MOI.8

- ☐ 1. Decision makers and others are provided education on the principles of information use and management.
- 2. The education is related to the data and information needs of the individual and job responsibilities.
- 3. Clinical and managerial data and information are integrated as needed to support decision making.

Management and Implementation of Documents

Standard MOI.9

Intent of MOI.9

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

These processes for developing and maintaining policies, procedures, and programs are implemented.

Measurable Elements of MOI.9

- 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.9.1

Intent of MOI.9.1

Throughout the accreditation standards found in this manual, policies, procedures, plans, and other written documents are required (noted with the icon P, as above). These documents are required, as they reduce process variation and reduce the risk inherent in processes. This is particularly important in clinical processes to improve quality and patient safety.

A tracking system allows each document to be identified by title, date of issue, edition and/or current revision date, number of pages, who authorized issue and/or reviewed the document, and database identification (if applicable). The tracking system helps staff quickly locate a policy relevant to their assignment or a particular situation. For example, staff in the emergency department can quickly locate the policy on informed consent when an unaccompanied minor requires a surgical procedure.

There is a process to ensure that staff members have read and are familiar with policies, procedures, and plans relevant to their work. This process may be part of the orientation of staff members to their department and their responsibilities, or may be part of groupwide or hospitalwide special training sessions. Most importantly, when a policy, procedure, or plan is relevant to the assignment of an individual, the intended actions described in the document are evident in the actions of the individual.

Measurable Elements of MOI.9.1

- ☐ 1. Required policies, procedures, and plans are available, and staff understand how to access those documents relevant to their responsibilities.
- 2. Staff are trained and understand those documents relevant to their responsibilities.
- ☐ 3. The requirements of the policies, procedures, and plans are fully implemented and evident in the actions of individual staff members.
- 4. The implementation of policies, procedures, and plans is monitored, and the information supports full implementation.

Patient Clinical Record

Standard MOI.10

Standard MOI.10.1

The clinical record contains sufficient information to identify the patient, to support the diagnosis, to justify the treatment, and to document the course and results of treatment.

Intent of MOI.10 and MOI.10.1

Every patient assessed or treated in a hospital as an inpatient, outpatient, or emergency care patient has a clinical record. The record is assigned an identifier unique to the patient, or some other mechanism is used to link the patient with his or her clinical record. A single record and a single identifier enable the hospital to easily locate patient clinical records and to document the care of patients over time.

The content, format, and location of entries for a patient's clinical record is standardized to help promote the integration and continuity of care among the various practitioners of care to the patient. The hospital determines the specific data and information recorded in the clinical record of each patient assessed or treated on an inpatient, outpatient, or emergency basis. The clinical record needs to present sufficient information to support the diagnosis, to justify the treatment provided, to document the course and results of the treatment, and to facilitate the continuity of care among health care practitioners. (*Also see* COP.2.2 and MMU.4.1)

Measurable Elements of MOI.10

- ☐ 1. A clinical record is initiated for every patient assessed or treated by the hospital.
- 2. Patient clinical records are maintained through the use of an identifier unique to the patient or some other effective method.
- 3. The specific content, format, and location of entries for patient clinical records is standardized and determined by the hospital.

Measurable Elements of MOI.10.1

- ☐ 1. Patient clinical records contain adequate information to identify the patient.
- 2. Patient clinical records contain adequate information to support the diagnosis. (Also see AOP.1.1)
- Patient clinical records contain adequate information to justify the care and treatment. (Also see AOP.1.2)
- 4. Patient clinical records contain adequate information to document the course and results of treatment. (Also see COP.2.1, ME 6; COP.3, ME 2; ASC.5; and ASC.7)

Standard MOI.10.1.1

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

Intent of MOI.10.1.1

The record of each patient receiving emergency care includes the arrival and departure times. This information is captured for all emergency department patients, including those who are discharged from the hospital, transferred to another facility, or admitted as inpatients. Departure time may be when the patient physically leaves the emergency department to go home or to another facility, or the time at which the patient is moved to another unit as an inpatient. For patients who are discharged from the emergency department, the clinical record includes the conclusions at termination of treatment, the patient's condition at discharge, and follow-up care instructions. (*Also see* ACC.1.1, ME 5)

Measurable Elements of MOI.10.1.1

- ☐ 1. The clinical records of all emergency patients include arrival and departure times.
- The clinical records of discharged emergency patients include conclusions at the termination of treatment.
- 3. The clinical records of discharged emergency patients include the patient's condition at discharge.
- 4. The clinical records of discharged emergency patients include any follow-up care instructions.

Standard MOI.11

The hospital identifies those authorized to make entries in the patient clinical record.

Output

Description:

Standard MOI.11.1

Every patient clinical record entry identifies its author and when the entry was made in the record.

Intent of MOI.11 and MOI.11.1

Access to information contained in the patient clinical record is based on need and defined by job title and function, including students in academic settings. An effective process defines

- who has access to patient clinical records;
- which information in the patient clinical record to which an individual has access;
- the user's obligation to keep information confidential; and
- the process followed when confidentiality and security are violated.

One aspect of maintaining the security of patient information is to determine who is authorized to obtain a patient clinical record and to make entries into the patient clinical record. The hospital develops a policy to authorize such individuals. There is a process to ensure that only authorized individuals make entries in patient clinical records and that each entry identifies the author of the entry and the date. The policy must also include the process for how entries in the patient record are corrected or overwritten. The time of the entry is also noted, such as for timed treatments or medication orders. (Also see COP.2.2, MMU.4.2, and MOI.2)

Measurable Elements of MOI.11

	modelable Element of month		
	1.	Those authorized to make entries in the patient clinical record are identified in hospital policy. (Also se IPSG.2)	
	2.	There is a process to ensure that only authorized individuals make entries in patient clinical records.	
	3.	There is a process that addresses how entries in the patient record are corrected or overwritten.	
	4.	Those authorized to have access to the patient clinical record are identified in hospital policy.	
	5.	There is a process to ensure that only authorized individuals have access to the patient clinical record	
Measurable Elements of MOI.11.1			

- 1. The author can be identified for each patient clinical record entry.
- 2. The date of each patient clinical record entry can be identified.
- 3. The time of each patient clinical entry can be identified.

Standard MOI.12

As part of its monitoring and performance improvement activities, the hospital regularly assesses patient clinical record content and the completeness of patient clinical records.

Intent of MOI.12

Each hospital determines the content and format of the patient clinical record and has a process to assess record content and the completeness of records. That process is a part of the hospital's performance improvement activities and is carried out regularly. Patient clinical 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 clinical professionals who are authorized to make entries in the patient record. The review focuses on the timeliness, completeness, legibility, and so forth of the record and clinical information. Clinical record content required by laws or regulations is included in the review process. The hospital's clinical record review process includes records of patients currently receiving care as well as records of discharged patients.

Measurable Elements of MOI.12

- 1. A representative sample of active and discharged patient clinical 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 records or to manage patient records.
- ☐ 3. The review focuses on the timeliness, legibility, and completeness of the clinical record.
- 4. Record contents 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.

Section IV: Academic Medical Center Hospital Standards



The Medical Professional Education (MPE) and Human Subjects Research Programs (HRP) standards for Academic Medical Center Hospitals were developed and first published in 2012 to recognize the unique resource such centers represent for health professional education and human subjects research in their community and country. These standards also present a framework for including medical education and human subjects research into the quality and patient safety activities of academic medical center hospitals. Unless deliberately included in the quality framework, education and research activities often are the unnoticed partners in patient care quality monitoring and improvement.

The standards are divided into two chapters, as medical education and clinical research are most frequently organized and administered separately within academic medical centers. For all hospitals meeting the eligibility criteria in the "Summary of Key Accreditation Policies" section of this publication, compliance with the requirements in these two chapters, in addition to the other requirements detailed in this fifth edition manual, will result in an organization being deemed accredited under the Joint Commission International Standards for Academic Medical Center Hospitals.

Organizations with questions about their eligibility for Academic Medical Center Hospital accreditation should contact JCI Accreditation's Central Office at jciaccreditation@jcrinc.com.

Medical Professional Education (MPE)

Changes to the MPE Chapter

The requirements of these standards have not changed from the expanded 4th edition standards for academic medical center hospitals; however, terminology—in particular, the term *trainee*—has been revised for greater clarity.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Standard MPE.1

Those responsible for governance and leadership of the hospital approve and monitor the participation of the hospital in providing medical education.

Intent of MPE.1

Integrating education of medical students and trainees into a hospital's operations requires a significant commitment of time, energy, and resources. *Trainees* include interns, residents, house officers, and fellows. Decisions on the integration of education and operations are best made at the highest decision-making level of the hospital. When the decision to provide medical education involves a network or consortia of organizations, governance is fully informed as to all the relationships and accountabilities. As the governance level also is responsible for decisions related to the hospital's mission, strategic plans, resource allocation, and quality program (*see* GLD.1.1 through GLD.1.6), it is necessary to make this an integrated decision. **For example**, is the commitment to educate medical students and trainees consistent with the hospital's mission, and how will this commitment be portrayed to the public and the hospital's patients?

The governance and leadership of the hospital are also responsible for obtaining, reviewing, and agreeing to the education program parameters of the sponsoring academic program.

A set of metrics, relevant to the education programs within the hospital, is selected and reported to governance and hospital leadership on an annual basis for a review of the scope and activities of the program, achievement of program goals, any relevant regulatory compliance issues, and the satisfaction of patients and staff with the program.

Measurable Elements of MPE.1

1.	The decision to provide medical education is made at the highest level of governance and leadership of
	the hospital, is consistent with the hospital's mission, and is documented.

2.	Hospital governance and leadership obtain, review, and accept the parameters of the participating
	medical school, and this action is documented.

u	3.	Hospital g	governance :	and leade	rship end	orse a set o	of metrics	to monitor and	l evaluate	the ongoing	
		operation	of medical	education	program	s, and the	re is docun	nented review of	of the mor	nitoring data.	

4.	Hospital governance and leadership review, at least annually, the medical education programs within
	the hospital, and the review is documented.
5.	The review includes the satisfaction of patients and staff with the clinical care provided under the

Standard MPE.2

program.

The hospital's clinical staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

Intent of MPE.2

Providing a rich and meaningful learning experience for medical students and trainees requires many factors, in addition to governance and hospital leadership commitment. The clinical staff of the hospital must be adequate in number and in expertise to advance medical student and trainee education. **For example**, nursing staff numbers support the educational program, and nursing staff understand their relationship to the educational program.

The hospital's patient population is sufficient in number and needs to support the education and clinical learning experience. There must also be adequate classroom space, off-duty study and rest facilities, and print and online resources to support an effective learning environment. In addition, adequate opportunities and time for learning and interactions with clinical staff must be provided. Contemporary technology needs to be available so that evidence-based health care practices can be taught.

Measurable Elements of MPE.2

)	1.	There is evidence that the clinical staff of the hospital are in adequate number and have the education,
		training, and competence to support and advance the education of medical students and trainees.

- 2. There is evidence that the hospital's patient population is adequate in number and clinical needs to support the education of medical students and trainees.
- ☐ 3. There is evidence that the hospital's facilities, technology, and other resources support the education of medical students and trainees.

Standard MPE.3

Clinical teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

Intent of MPE.3

Those clinical staff who have responsibility for medical student and trainee education and supervision are clearly identified so that the medical students and trainees and other hospital staff understand educational accountabilities and authority. **For example**, when any hospital staff member has a comment, concern, or other matter related to the educational program or medical students and trainees, he or she will understand who is accountable for receiving and acting on that information.

The relationship of the clinical teaching staff of the hospital to the sponsoring academic institution(s) needs to be clear. **For example**, when academic titles are conferred on clinical staff members, it is clear if titles are earned or honorary, how those titles are to be used, and what the titles mean to the public. The hospital has a complete listing of clinical teaching staff with their medical and academic titles. Any requirements for the renewal or redesignation of academic titles are monitored for compliance (also see SQE.9 through SQE.11).

Measurable Elements of MPE.3

Clinical teaching staff are identified to hospital staff, and there is a complete list of clinical teaching staff, including both professional and academic titles.

_	۷.	Start are educated about these individuals, their accountabilities, and their authority.
	3.	The hospital has a process in place to monitor academic titles and requirements for renewal or redesignation and to keep such titles up to date.

Standard MPE.4

The hospital understands and provides the required frequency and intensity of medical supervision for each type and level of medical student and trainee.

O

Intent of MPE.4

Supervision is required to ensure safe patient care and ensure that the training program is a learning experience for the medical student and trainee. The required level of supervision is consistent with the level of training and level of competence of the medical student and trainee. The hospital understands that medical student and trainee competence cannot be assumed and must be demonstrated early in the training program.

Each medical student and trainee understands the clinical supervision process, including who is to provide the supervision and the frequency of the supervision. For example, a medical student understands whether supervision is provided by a resident or by the patient's primary physician or by a medical school faculty member. Medical students and trainees also understand whether the supervision includes daily signing of all notes and orders, signing of the care plan and progress notes every other day, or making a separate entry in the patient's record. Likewise, it is clear as to how the evidence of that supervision is documented, including the frequency and location of the documentation. Finally, to ensure a uniform learning experience, the hospital has identified and monitors the uniform expectations for the mentoring/supervision process.

NE	as	urable Elements of MPE.4
_	1.	Hospital policy identifies the required level of supervision for each level of medical student and trainee.
	2.	The level to be provided is based on the demonstrated competency of the medical student and trainee.
	3.	Each medical student and trainee understands the level, frequency, and documentation of his or her supervision.
	4.	The hospital provides the required level of supervision for each medical student and trainee.
	5.	There is a uniform process for documenting the required supervision that is consistent with hospital policy, program goals, and the quality and safety of patient care.
_	6.	The hospital has established uniform expectations for all staff providing supervision to ensure that the process results in uniform medical student and trainee experiences.

7. Patient care records are reviewed for compliance with the documentation requirements and frequency.

Standard MPE.5

Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

Intent of MPE.5

Medical education programs in hospitals require an effective management structure and a commitment of staff time for their coordination and daily operation. The agreements between the hospital and the medical school need to be established and then monitored. There is an accurate list of all medical students and trainees in the hospital. For each medical student and trainee, there is documentation of

- a) enrollment status;
- b) academic classification;
- c) any required licensure or certification;

- d) reports of medical student and trainee achievements;
- e) identification of medical student and trainee competencies;
- f) any known factors that will require accommodation; and
- g) any known factors that may influence the level of supervision required.

When an academic program is sponsored by the hospital, it is determined how and where these activities are conducted.

Measurable Elements of MPE.5

- ☐ 1. The operational structure for medical education in the hospital has been determined and is in operation as required.
- ☐ 2. The management structure for medical education in the hospital has been determined and is in operation as required.
- 3. There is a complete and current list of all medical students and trainees in the hospital.
- 4. For each medical student and trainee, there is documentation of at least a) through g) of the intent.

Standard MPE.6

Intent of MPE.6

Training programs and their students are a critical factor in overall quality of care and patient safety. Although it would be desirable for each medical student and trainee to have basic education on quality and patient safety in his or her respective academic program, this rarely happens. Thus, the hospital must have a planned and deliberate program to introduce such concepts, support the medical students and trainees in complying with relevant policies and guidelines, and include medical students and trainees in all quality and safety monitoring programs. For example, medical students and trainees would be educated to comply with the International Patient Safety Goals.

Also, required clinical practice guidelines, surgical time-out procedures, medication-ordering policies, and other mechanisms to reduce variation in care processes—and thus reduce the risk in those processes—are part of all medical students' and trainees' initial orientation and ongoing training and monitoring. The orientation for the medical student and trainee includes at least

- a) hospital quality and patient safety program (also see GLD.4, GLD.4.1, GLD.5, GLD.11, and GLD.11.2);
- b) infection control program (also see PCI.5);
- c) medication safety program (also see MMU.1);
- d) the International Patient Safety Goals;
- e) all other required hospital orientation, including at the department and unit level (also see SQE.7); and
- f) any ongoing required education.

Those persons providing medical student and trainee supervision ensure that all medical students and trainees are knowledgeable about these quality and safety programs and are included in the monitoring process. (Also see MOI.9.1)

Measurable Elements of MPE.6

- ☐ 1. All medical students and trainees are provided an orientation that includes at least a) through f) of the intent.
- ☐ 2. Medical students and trainees are included in the data collection for the hospital's quality monitoring programs.
- ☐ 3. Those supervising medical students and trainees ensure that the medical students and trainees are knowledgeable of the programs and participate in the programs.

4. Medical students and trainees can demonstrate knowledge of these programs.
 5. Those supervising medical students and trainees consider compliance with these programs in their evaluation of medical student and trainee performance.

Standard MPE.7

Medical trainees who provide care or services within the hospital—outside of the parameters of their academic program—are granted permission to provide those services through the hospital's established credentialing, privileging, job specification, or other relevant processes.

Intent of MPE.7

The laws and regulations in many countries permit trainees, as they advance in their program, to provide services to the hospital outside of their academic program. For example, a trainee may provide medical care in the hospital's emergency department in evenings or on weekends, or may function as the "house doctor" during the night shift. In these circumstances, the individual trainee must be evaluated and given permission to provide those services through the normal established processes for such professionals as described in the Staff Qualifications and Education (SQE) standards. His or her work is evaluated as required by the SQE standards.

Measurable Elements of MPE.7

- 1. The hospital determines what types of trainees and under which circumstances trainees can be hired or otherwise engaged by the hospital to provide patient care or other services.
- ☐ 2. Trainees providing such services are credentialed and privileged for the services being provided. (*Also see* SQE.9 and SQE.10)
- ☐ 3. Trainees providing such services are evaluated for the services being provided. (Also see SQE.11)

Human Subjects Research Programs (HRP)

Note: This chapter was previous entitled "Human Subject Research Programs." The title was changed to reflect the most common usage of the terminology in the field.

Changes to the HRP Chapter

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Standard	Change	Explanation
HRP.1– HRP.6	No significant change	Changes terminology for clarity
HRP.7 and HRP.7.1	Requirement change	Revises standards, intent, and MEs to clarify requirements; incorporates requirements of HRP.7.2 (4th edition); includes additional requirements for informed consent in the MEs for HRP.7

Note: This table lists changes to requirements in this chapter only. Requirements that were in this chapter in the expanded 4th edition of this manual (published in July 2012 and effective in January 2013) and are now contained either in their entirety or in part in another chapter of this 5th edition are listed in that chapter's "Changes" table.

The following standards appeared in this chapter of the expanded 4th edition standards but were deleted from this edition (listed with expanded 4th edition numbers): None.

Note: Some standards require the hospital to have a written policy or procedure for specific processes. Those standards are indicated by a \bigcirc icon after the standard text.

Standards, Intents, and Measurable Elements

Standard HRP.1

Hospital leadership is accountable for the protection of human research subjects.

Standard HRP.1.1

Hospital leadership complies with all regulatory and professional requirements and provides adequate resources for effective operation of the research program.

Output

Description

De

Intent of HRP.1 and HRP.1.1

Human subjects research is a complex and significant endeavor for a hospital. Hospital leadership recognizes the required level of commitment and personal involvement required to advance scientific inquiry in the context of protecting the patients for whom they have made a commitment to diagnose and treat.

Department/service leaders' commitment to human subjects research is not separate from their commitment to patient care—commitment is integrated at all levels. Thus, ethical considerations, good communication, responsible leaders of departments and services, regulatory compliance, and financial and nonfinancial resources are components of this commitment. One such resource is adequate indemnity insurance to compensate patients for adverse events due to the research protocol. Hospital leadership recognizes the obligation to protect patients irrespective of the sponsor of the research.

Hospital leadership is knowledgeable about and complies with those sources of regulation and professional standards specific for clinical research, such as those from the International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards (see Endnotes at the end of this chapter; also see GLD.12.1).

Measurable Elements of HRP.1

- 1. Hospital leadership establishes and promotes a code of ethical professional behavior.
- 2. Hospital leadership, verbally and in writing, communicates within the hospital their commitment to protect human subjects research participants and support the code of ethical professional behavior.
- 3. Hospital leadership identifies the official(s) responsible for maintaining the development of and compliance with all human subjects research policies and procedures.
- 4. Hospital leadership assumes responsibility for patient protection irrespective of the sponsor of the research.

Measurable Elements of HRP.1.1

- ☐ 1. Hospital leadership recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research.
- 2. Hospital leadership has a process for budgeting to provide adequate resources for effective operation of the research program.
- 3. Hospital leadership provides or ensures that there is adequate indemnity insurance to compensate patients participating in clinical research who experience an adverse event.

Standard HRP.2

Hospital leadership establishes the scope of research activities.

Intent of HRP.2

Research activities can be limited to one clinical unit or spread throughout a hospital. The research can be of one or more types—for example, related to devices, drugs (experimental and off-label), or behavioral change. To ensure that adequate control and resources support all the research within the hospital, it is important that the hospital leadership makes deliberate decisions regarding the scope of the research activities, including types and locations. Leadership is also responsible for ensuring an adequate number of properly trained staff to serve as principal investigators and other members of the research team. There is documentation of the required qualifications. Leadership also must set parameters for when a staff member of the hospital may participate as a research subject.

Measurable Elements of HRP.2

- ☐ 1. Hospital leadership identifies the program scope in terms of drugs, medical devices, testing, and other potential research topics and methodologies.
- 2. Hospital leadership identifies those facilities that will be included in the research function.
- 3. Hospital leadership identifies the qualifications of staff permitted to participate in the research program as principal investigators or other members of the research team.
- 4. There is documentation of the qualifications of staff permitted to participate in the research program.
- 5. Hospital leadership identifies those circumstances in which staff can serve as research subjects.

Standard HRP.3

Intent of HRP.3

The sponsor of a research protocol must be qualified and accountable. Thus, hospital leadership must have clear requirements for sponsors of research within their hospital. Sponsors are accountable for every aspect of the specific research, including

- monitoring the quality and safety of the research;
- ensuring that the research methods and processes are ethical;
- using trained and qualified research teams;
- protecting the data generated in terms of reliability and validity;
- ensuring that the results and reporting are statistically accurate, ethical, and unbiased;
- protecting the privacy and confidentiality of subject data; and
- ensuring that patient or research incentives do not compromise the integrity of the research.

Measurable Elements of HRP.3

1.	The requirements include that sponsors comply with the hospital's policies and processes for
	monitoring and evaluating the quality, safety, and ethics of the research.
2.	The requirements include that sponsors use research teams that are trained and qualified to conduct the research.

- ☐ 3. The requirements include that sponsors protect the privacy and confidentiality of subject data. (Also see PFR.1.3 and MOI.2)
- 4. The requirements include that sponsors ensure that the research data are reliable and valid and the results and reporting are statistically accurate, ethical, and unbiased.
- 5. The requirements include that sponsors do not permit patient or researcher incentives that would compromise the integrity of the research.

Standard HRP.3.1

When one or more of the research-related duties and functions of the sponsor are provided through an outside commercial or academic contract research organization, the accountabilities of the outside contract research organization are clearly defined.

Output

Description:

Intent of HRP.3.1

Human subjects research has many components, some of which a sponsor may choose to contract to an outside organization, usually termed a contract research organization. Such components may include recruiting subjects, conducting the research, providing data management, or serving as the research review mechanism. The hospital and sponsor are responsible for the careful selection of a contract research organization, the clear delineation of accountability, and the monitoring of compliance under the contract. When regulations relate to the duties transferred by the sponsor to the contract research organization, the sponsor monitors compliance with those regulations as a part of contract review.

Measurable Elements of HRP.3.1

☐ 1. The hospital establishes and implements a process to determine the activities and responsibilities of a contract research organization.

2.	The duties and functions transferred by the sponsor to the contract research organization are contained in a written contract.
3.	The contract specifies that the contract research organization or sponsor is responsible for monitoring and evaluating the quality, safety, and ethics of the research.
4.	The sponsor is responsible for monitoring the contract.

Standard HRP.4

Intent of HRP.4

One of the most important functions related to human subjects research is review and monitoring by an independent group of individuals, commonly referred to as an Institutional Review Board (IRB), an ethics committee, or similar designation. The composition, scope of responsibilities, and other factors may be described in laws or regulations. This group monitors all aspects of the research protocol to ensure patient protection and safe research. This function may be contracted to an outside organization such as a contract research organization. The policies, procedures, and structure of this research review function are specified by hospital leadership, as well as which functions may or may not be transferred to a contract research organization. Also, hospital leadership is responsible for identifying the types of research that are exempt from this review function and the documentation of the activities of the review group. This documentation is an important component of leadership's responsibility to review, at least on an annual basis, how well the research review function is operating.

Measurable Elements of HRP.4

1.	Hospital leadership identifies and supports the structure and operational requirements of the research review function.
2.	The research review function complies with applicable laws and regulations.
3.	Hospital leadership specifies the requirements of entities outside of the hospital that provide all or a portion of the research review function, such as a contract research organization.
4.	Hospital leadership clearly identifies research that is exempt from the research review process.
5.	Hospital leadership specifies the requirements for documentation of the activities of the research review function.
6.	Hospital leadership provides for a review of all research review processes at least annually.

Standard HRP.5

The hospital identifies and manages conflicts of interest with research conducted at the hospital. ®

Intent of HRP.5

Conflicts of interest can arise from many sources and in many forms for those sponsoring or participating in human subjects research. The conflicts may be financial (such as payment for recruitment of certain types of subjects) or nonfinancial (such as trips to speak at conferences). The research review process can identify and mitigate such conflicts, or the hospital can use or develop another type of mechanism to monitor and mitigate conflicts. The mechanism includes education about what constitutes a conflict and how conflicts can be successfully managed. (*Also see* GLD.12)

Measurable Elements of HRP.5

- ☐ 1. The hospital specifies the requirements for managing conflicts of interest, both financial and nonfinancial.
- 2. The hospital specifies the individuals, committees, and others for whom the requirements apply.
- ☐ 3. The hospital has an ongoing education and monitoring process to ensure compliance with the requirements.

Standard HRP.6

The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

Intent of HRP.6

Human subjects research may involve new types of surgical procedures, the use of new pharmaceuticals or the off-label use of current formulary drugs, the use of adult treatment modalities on pediatric populations, and many other research topics and methodologies. Of primary importance is the inclusion of research activities in the routine process of the hospital; **for example**, the ordering, dispensing, and administration process for medications under study. Routine processes also include the reporting of adverse events through the quality and patient safety monitoring processes. Thus, reporting an adverse event related to a hospital patient on a research protocol should be to the quality monitoring mechanism of the hospital as well as to the sponsor of the research or the contract research organization.

Reporting events related to research protocols can provide vital information toward understanding the overall quality and safety of patient care in the hospital. **For example**, a significant adverse event when a drug is used for an off-label purpose is important patient safety information that should be part of the hospital's ongoing medication monitoring process. Equally important is the handling and disposal of certain experimental research pharmaceuticals, which should be a component of the management of hazardous materials. Also, medical technology used in experimental procedures should be monitored and maintained.

Thus, every aspect of the human subjects research program should be evaluated as to which quality and safety programs of the hospital are applicable, and then the reporting and monitoring processes ongoing within the hospital should be included in the research program. This should also be the case when some research activities are provided by a contract research organization. (Also see GLD.4)

Measurable Elements of HRP.6

- ☐ 1. The research program is a component of the hospital's processes to report and act on sentinel events, adverse events of other types, and the processes to learn from near misses. (Also see MMU.7.1, QPS.7, QPS.8, and QPS.9)
- □ 2. The research program is included in the hospital's programs for hazardous material management, medical technology management, and medication management. (Also see FMS.5, FMS.8, and MMU.1)
- 3. The evaluation of staff participating in the research program is incorporated into the ongoing monitoring processes of professional performance. (Also see SQE.11)

Standard HRP.7

The hospital establishes and implements an informed consent process that enables patients to make informed and voluntary decisions about participating in clinical research, clinical investigations, or clinical trials.

Standard HRP.7.1

The hospital informs patients and families about how to gain access to clinical research, clinical investigations, or clinical trials and includes protections for vulnerable populations to minimize potential coercion or undue influence.

①

Intent of HRP.7 and HRP.7.1

A hospital that conducts clinical research, clinical investigations, or clinical trials involving patients knows that its first responsibility is to patients' health and well-being. The hospital provides information to patients and families about how to gain access to research that is relevant to the patients' treatment needs.

To assist patients and families with decisions regarding participation in research, the hospital establishes policies and procedures for obtaining informed consent (also see PFR.5). Through the informed consent process, patients and families gain an understanding of the research and the patients' roles in the research, allowing them to make autonomous decisions to participate or not. The information provided during the informed consent process includes

- an explanation of the research, duration of patient participation, and procedures to be followed by patients;
- expected benefits;
- potential discomforts and risks;
- alternative treatments and procedures that might also be beneficial;
- extent to which confidentiality of records will be maintained;
- compensation or medical treatments available if injury occurs;
- a statement that participation is voluntary;
- assurance that refusal to participate or withdrawal from participation will not compromise care or access to the hospital's services; and
- who to contact with questions about the research.

Safeguards are put into place through the hospital's research review function to protect vulnerable patients who may be at risk for coercion or undue influence to participate in research projects. Vulnerable patients include children, prisoners, pregnant women, persons with mental disabilities, persons who are economically or educationally disadvantaged, and others who have diminished or no capacity to make informed or voluntary decisions to participate in research. Another group that can be considered a vulnerable population is staff of the hospital. Staff may feel under pressure to participate; **for example**, when the principal investigator is their supervisor.

When patients decide to participate in research and grant consent, the individual providing the information and obtaining the consent is noted in the patient record. At times, a research protocol may be altered based on early findings; **for example**, a drug dose may be changed. Patient consent is obtained again under these and similar circumstances. (Also see PFR.5.2)

Measurable Elements of HRP.7

- 1. Patients asked to participate are informed about the research, duration of patient's participation, procedures to be followed, and who to contact with questions about the research.
 2. Patients asked to participate are informed about the expected benefits, potential risks, and alternative treatments and procedures that might also help them.
- 2 3. Patients asked to participate are informed about the extent to which confidentiality of records will be maintained.
- Patients asked to participate are informed about the compensation or medical treatments available if injury occurs.
- ☐ 5. Patients asked to participate are assured that participation is voluntary and refusal to participate or withdrawal at any time will not compromise care or access to hospital services.

• 6. Through the research review function, the hospital establishes and implements how consent for participation will be obtained and documented and under which circumstances consent will be obtained again during the research.

Measurable Elements of HRP.7.1

- 1. Patients and families are identified and informed about how to gain access to clinical research, clinical investigations, or clinical trials relevant to their treatment needs.
- 2. Through the research review function, the hospital establishes and implements safeguards to protect the safety, rights, and well-being of vulnerable patients, including children, prisoners, pregnant women, persons who are mentally disabled, persons who are economically or educationally disadvantaged, and others who may be at risk for coercion or undue influence.
- ☐ 3. Through the research review function, the hospital establishes and implements safeguards to protect the safety, rights, and well-being of hospital staff who may be at risk for coercion or undue influence.

Endnotes

International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards

Clinical studies should be carried out according to International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards. This provides a unified standard for the European Union, Japan, and the United States, as well as for Australia, Canada, the Nordic countries, and WHO. Thus, any country that adopts this guideline technically follows this same standard. The ICH is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objectives of such harmonization are a more economical use of human, animal, and material resources and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to protect public health. This mission is embodied in the Terms of Reference of ICH.

Specifically pertaining to contract research organizations (CROs) providing clinical-trials services, the ICH-GCP (E6 1.20) defines a *CRO* as: "a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions." Furthermore, it states that:

- (5.2.1) A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.
- (5.2.2) Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.
- (5.2.3) Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.
- (5.2.4) All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor.

Summary of Key Accreditation Policies

Note: This section is a high-level summary of Joint Commission International's (JCI's) accreditation policies for hospitals. Full policies and procedures will be posted on JCI's public website starting in late 2013 at http://www.jointcommissioninternational.org/accreditation-policies.

Seeking JCI Accreditation

Basis of the Accreditation Process

Evaluation of compliance with the JCI International Standards for Hospitals is the basis of the hospital accreditation process. Once accredited, hospitals are expected to demonstrate continuous compliance with current editions of the standards at all times of the accreditation cycle. Standards are updated every three years.

JCI defines the effective date of its standards as the date published on the cover of standards editions, after which JCI conducts all related accreditation activities using those standards. JCI publishes its standards at least six months in advance of the effective date to provide time for hospitals to come into full compliance with the revised and new standards by the effective date. Any on-site or other accreditation-related activity (**for example**, videoconference, extension survey, for-cause survey, among others) or evidence of compliance submitted (**for example**, data, policy and procedures, root cause analysis and action plan, or self-assessment) after the effective date are consistent with the current edition of the standards.

Accreditation Time Line

Every hospital prepares for its initial or triennial JCI on-site survey differently. A sample time line followed by many hospitals appears below.

- 12–24 months before survey—Obtain JCI standards and begin education on the standards and implementation of the expectations.
- 6–9 months before survey—Assess readiness; new initial applicants complete the initial registration
 process (IRP). Once approved, then complete and submit the electronic application (E-App) for survey,
 if ready. Accredited hospitals update their electronic profile, review the E-App, submit for the triennial
 survey and schedule dates.
- 4–6 months before survey—Receive and complete and sign the JCI survey contract.
- 2 months before survey—JCI Survey Team Leader contacts the hospital to determine the survey logistics and agenda.
- On-site survey
- Within 15 days after the survey—Receive accreditation decision and Official JCI Accreditation Findings Report from JCI.
- 6–9 months before triennial survey date—Update and submit E-App for survey and schedule survey dates.

Applying for Accreditation

The Process

A hospital seeking JCI accreditation begins the accreditation process by completing a survey application, or E-App, available electronically at https://customer.jointcommissioninternational.org/. The E-App provides detailed information and key statistics that create a hospital profile needed for JCI to manage its accreditation process, develop a contract for survey, and plan the survey agenda and on-site evaluation process.

Organizations applying for JCI accreditation or certification for the first time (known as *initial applicants*) must complete an initial registration process (IRP) via JCI's website at http://www.jointcommissioninternational.org.

Hospitals already accredited or certified apply for continued accreditation or certification via E-App on *JCI Direct Connect (see* below) four to six months prior to the survey dates requested. The hospital must notify JCI within 30 days—or at least 30 days before the scheduled survey date—of any change to the information reported in the survey application.

JCI Direct Connect

JCI provides each accredited and/or certified organization with access to JCI Direct Connect, JCI's secure, password-protected client portal. JCI Direct Connect contains the following:

- E-App
- Important accreditation- or certification-related due dates
- Official reports, e-mails, and announcements
- Continuous-compliance tools
- Current accreditation or certification manual and survey process guide
- A publicity kit for appropriate use of JCI Gold Seal of ApprovalTM with advice on promoting the hospital's accreditation or certification

Organizations receive access to JCI Direct Connect when first applying for accreditation or certification and receive incremental access to more of the site's content and services as they proceed through the accreditation or certification process. Only fully accredited and certified organizations receive access to all of JCI Direct Connect's content and services.

Types of Surveys

Full Survey

The survey of all the hospital standards throughout an entire organization. This may be the initial survey, triennial survey, or validation survey. Definition of each follow.

- *Initial Survey*—The first full on-site survey of a hospital
 - Follow-up Survey—An on-site evaluation scheduled 120 days following an initial survey to evaluate those measurable elements (MEs) scored "not met" or "partially met" that resulted in the hospital's failure to meet the accreditation decision rules.
- Triennial Survey—The survey of a hospital after a three-year cycle of accreditation
 - O Follow-up Survey—An on-site evaluation scheduled 120 days following a triennial survey to evaluate those MEs scored "not met" or "partially met" that resulted in the hospital's failure to meet the accreditation decision rules.
- Validation Survey—JCI may conduct a second full survey in volunteer organizations as a component of JCP's internal quality improvement monitoring processes. This survey has no impact on the hospital's accreditation status and is conducted at no charge to the hospital.

Focused Survey

Focused surveys are on-site surveys limited in scope, content, and length and designed to gather information on specific issues, standards, or MEs. JCI conducts the following types of focused surveys:

- For-Cause Survey—JCI learns of potentially serious standards noncompliance, serious patient care or safety issues, regulatory issues or sanctions, or other serious issues within an accredited hospital or certified program that may have placed the hospital At Risk for Denial of Accreditation.
- Extension Survey—JCI may conduct an extension survey when the hospital notifies JCI before the change
 or within 15 days of changes in such core information from the hospital's profile, including, but not
 limited to, the following:
 - A change in hospital ownership and/or name
 - The revocation or restriction of operational licenses or permits, any limitation or closure of patient care services, any sanctions of professional or other staff, or other actions under laws and regulations brought by relevant health authorities
 - Alteration or changes in use of patient care buildings, construction of new or expansion of patient care buildings, or the occupation of buildings in new locations in the community, to expand the types and volume of patient care services 25 percent or more than was stated in the hospital's profile or was not reported as a patient care location in the E-App, or was not included in the scope of the previous accreditation survey
 - O Intentional expansion of the hospital's capacity to provide services in the absence of new, renovated, or expanded facilities by 25 percent or greater, as measured by patient volume, scope of services, or other relevant measures
 - O The addition or deletion of one or more types of health care services, such as addition of a dialysis unit or discontinuation of trauma care
 - O The hospital has merged with, consolidated with, or acquired an unaccredited site, service, or program for which there are applicable JCI standards.

The Survey Process

Purpose of a Survey

An accreditation survey is designed to assess a hospital's compliance with JCI standards based on

- interviews with staff and patients and other verbal information;
- on-site observations of patient care processes;
- review of policies, procedures, clinical practice guidelines, patient records, personnel records, governmental and/or regulatory compliance reports, and other documents requested from the hospital;
- review of quality and patient safety improvement data, performance measures, and outcomes;
- conduct individual patient tracers (i.e., evaluate a patient's care experience through the hospital care process); and
- conduct focused tracers of organizationwide systems or processes (for example, medication
 management, infection control, hazardous waste and materials, or other high-risk, high/low volume,
 problem-prone systems and processes.

Scheduling the Survey

JCI and the hospital select the survey date and prepare the survey agenda together to meet the hospital's needs and the requirements for an efficient survey. To reduce surveyor travel costs, JCI makes every effort to coordinate the scheduling of surveys of other hospitals in a specific country or region.

Planning the Survey Agenda

JCI assigns each hospital a client service representative to serve as the primary contact between the hospital and JCI. This individual assists in the coordination of the survey planning and is available to the hospital to answer any questions about hospital profile and its E-App, policies, procedures, or accreditation issues. The client service representative works with the survey team leader in coordinating logistics for the on-site survey with the hospital and prepares a survey agenda based on the size, type, and complexity of the hospital. The agenda specifies the sites JCI surveyors will visit, the type of interviews surveyors will conduct, the personnel interviewed, and the documents that must be provided to the surveyors.

The Survey Team

Highly qualified international surveyors perform the survey. JCI conducts surveys in the English language; however, JCI makes every effort to use surveyors fluent in the language(s) used at the organization. If JCI surveyors with the appropriate language capabilities are not available, JCI works with the organization to identify qualified interpreters. A typical hospital survey team consists of a physician, nurse, and hospital administrator.

Cancellation of a Survey

JCI or a hospital may cancel a survey without penalty or damages when events such as acts of God, wars, terrorism, or other similar emergencies or other circumstances make it impossible, illegal, or unreasonable to go forward with a survey. Cancellation due to any of the reasons cited above must be communicated in writing as soon as practically possible. If the hospital cancels the survey 30 or fewer days prior to the start date of the survey for any reason or reasons other than those stated above, JCI will require payment of 50 percent of the survey fees to recover JCI's administrative costs and the airline travel cancellation fees. In the event that JCI cancels the survey for any reason or reasons other than those previously stated, JCI does not charge the organization a fee.

Postponement of a Survey

A hospital may postpone a survey that has already been scheduled without penalty or damages when one or more of the following situations occur:

- A natural disaster or another major unforeseen event that totally or substantially disrupts operations
- A major strike that causes the organization to stop accepting patients, cancel surgery and/or other elective procedures, and transfer patients to other hospitals
- Patients, the organization, or both are being moved to another building during the dates of the scheduled survey

JCI reserves the right to conduct an on-site survey if the organization continues to provide patient care services under any of the above circumstances. Hospital renovation projects do not prevent JCI from conducting the on-site survey.

In rare circumstances, JCI may, at its discretion, approve a request to postpone a survey for an organization not meeting any of the criteria described above. In such cases, JCI may charge the organization a fee to defray costs for airline cancellation penalties and other JCI administrative costs.

Cost of Surveys

Calculation of Costs

JCI posts the average cost of an initial or triennial full hospital survey on its website. JCI bases its accreditation survey fee on several factors, including the volume, type, and complexity of services provided by the hospital; the number of locations or care settings included in the survey; and the number of surveyors and survey days required to conduct the evaluation of compliance with JCI standards. Surveyor time for report preparation is included in the calculated survey days. JCI charges the hospital for any required follow-up surveys, for focused surveys, and for some hospital-initiated survey postponements or cancellations.

Travel Costs

In addition to survey fees, the hospital is responsible for paying all travel costs for the surveyors. This includes transportation (airfare, train, and car) and reasonable hotel accommodations and meals, including a set daily rate for meals and incidental expenses.

Payment Schedule of Survey Fees

JCI bills organizations for accreditation fees using one of two options, noted below. JCI requests that organizations identify their preferred billing option by selecting and signing for the desired option on the last page of their accreditation contract.

Payment Option I—The organization receives an invoice for 100 percent of the survey fees (in US dollars) at least 45 days before the start date of the survey. Payment must be made by wire transfer 21 days or more before the start date of the survey. At the conclusion of the survey, if the organization achieves accreditation, JCI sends the accreditation certificate immediately to the organization, along with the Official Survey Findings Report. JCI then bills the organization for the surveyors' expenses related to travel and maintenance within 30 days of the conclusion of the survey. The organization must pay surveyors' expenses upon receipt of the invoice.

Payment Option II—Organizations selecting this option pay survey fees via two separate invoices. JCI sends the first invoice, for 50 percent of the total survey fees, 45 days before the survey and the second, for the remaining 50 percent, at the survey's conclusion. JCI also sends a third invoice, for the surveyors' expenses for travel and maintenance, after the survey. Once JCI renders the accreditation decision and the organization has paid all survey fees, JCI sends the Official Survey Findings Report and accreditation certificates to the organization via regular mail.

The On-Site Survey

Scope of the Survey

The scope of a JCI survey is determined by the information in the hospital's E-App. All patient care buildings/settings and all patient units identified on the application are included in the survey. All standards contained in the current edition of the *Joint Commission International Accreditation Standards for Hospitals* are applicable unless the hospital does not provide that service (**for example**, does not provide laboratory services on site).

Survey Process

The tracer methodology is the foundation of the JCI on-site survey process. In the tracer methodology, surveyors select representative patients from the hospital's patient population and trace each patient's care experience through the hospital; and will also trace several key clinical and managerial systems and processes. This exercise allows surveyors to identify standards compliance issues evident in one or more steps of the patient care and management processes or in the interfaces between processes.

In addition, surveyors interview staff individually and in groups, observe patient care, speak to patients and their families, review patient records, review staff personnel records, and review policies and procedures and other documents.

Hospitals should consult their Hospital Survey Process Guide—which JCI provides to hospitals once they have returned a signed contract for survey to JCI—for detailed descriptions of what takes place during a typical initial or triennial survey, including detailed descriptions of all survey activities, required documentation, and other resources.

The surveyors confer with the organization's chief executive officer and other leaders at a leadership conference at the end of each survey. During this conference, the surveyors provide preliminary information about their findings. It is important to note that any preliminary information is not final until review by the JCI Accreditation Program has been completed.

If, during the survey, the surveyors identify any condition they believe poses a serious threat to public or patient safety, they notify the JCI Accreditation Program. In those circumstances, JCI decides whether to issue an expedited Denial of Accreditation decision and if it should inform relevant public authorities.

Report of the Survey

The survey team leaves a draft of their report of standards compliance at the exit interview and will, upon request of the hospital's leaders, report their findings to the hospital staff at a closing conference. Surveyor findings are not considered final until reviewed by the Accreditation Program staff. The survey team will indicate to the hospital when the findings point to the need for a follow-up survey within 120 days to gather further evidence related to all MEs scored "not met" or "partially met." No accreditation status is determined until the gathering

of any required follow-up compliance information is completed. When all compliance information is reported to the Accreditation Program office, the hospital will receive the final official report within 10 days.

Revision of the Survey Findings Report

The hospital has seven (7) days from the last day of the survey to request, in writing or by e-mail, revision of the report related to one or more survey findings. Appropriate data and supporting information must accompany the request. The Accreditation Program staff review the materials and contacts the hospital and/or surveyors as needed in evaluating the information. When the request for revision of the report would change the survey outcome, the JCI Accreditation Committee then considers the request for revision and makes the final accreditation decision.

Accreditation Decisions

JCI's accreditation decisions are based on whether or not the hospital meets JCI's accreditation decision rules. JCI's Accreditation Committee considers all information from the initial or triennial full survey and any required follow-up survey in making its decision regarding accreditation. The outcome is that the organization meets the criteria for accreditation or does not meet the criteria and is denied accreditation.

Appeal of Decisions to Deny or Withdraw Accreditation

Hospitals have the right to appeal adverse accreditation decisions. If, based on a full or focused survey, or a threat-to-life health and safety situation, there is a decision to deny or to withdraw accreditation, an organization has 10 calendar days from receipt of its Official Survey Findings Report or notice of accreditation withdrawal to notify JCI, in writing or by e-mail, of its intent to appeal the decision.

A hospital then has an additional 30 days to submit to JCI, in writing or by e-mail, acceptable data and information to support its appeal. JCI Accreditation Program staff review and evaluate the submitted materials within 30 calendar days of receipt and also may request additional documents and materials. After evaluation of the submitted materials, JCI Accreditation Program staff prepare a memo for review by the Appeal Review Committee. If, after JCI review of any submitted materials, the decision to deny or to withdraw accreditation is confirmed, an organization may, at its own expense, appear before the JCI Accreditation Appeals Review Committee to support its appeal. The Appeal Review Committee reviews the relevant appeal documents, prepares an analysis, and presents its recommendation at a subsequent JCI Accreditation Committee who will make a final determination of the hospital's accreditation status. JCI will not review a hospital's appeal of an adverse accreditation decision unless all the survey fees and expenses are paid in full when the appeal is submitted to JCI.

Public Disclosure and Confidentiality

Confidentiality

JCI keeps confidential all matters having to do with the accreditation process except

- an accredited hospital's status (that is, whether the organization is accredited, was denied accreditation, or if accreditation was withdrawn by JCI); and
- the number of complaints an organization has had that met the JCI criteria for review.

The official accreditation status of a hospital is noted on the JCI website as either Accredited (and the date that decision was made) or Accreditation Withdrawn (and the date). JCI posts the status of Accreditation Withdrawn on the JCI website for one year. When an organization withdraws from the accreditation process, JCI posts this and the date of the withdrawal on the JCI website. The accredited hospital may release more detailed information on its accreditation status, up to and including its Official Survey Findings Report, to whomever it wishes. However, when a hospital disseminates inaccurate information about its accreditation process status, JCI reserves the right to clarify information that would otherwise be considered confidential.

JCI provides to the individual submitting a complaint that met the criteria for review

- the applicable standards reviewed;
- any standards for which Recommendations for Improvement were issued as a result of the review; and, when applicable,
- any change in the hospital's accreditation status.

Accreditation Award Display and Use

JCI provides each hospital with a certificate of accreditation at the time of initial accreditation and at the time of each accreditation renewal. The certificate and all copies remain JCI's property. Certificates must be returned if the organization is issued a new certificate reflecting a name change or the organization's accreditation is withdrawn or denied for any reason.

A hospital accredited by JCI must be accurate in describing to the public the nature and meaning of its accreditation award and must not misrepresent its accreditation status or the facilities and services to which the accreditation award applies. JCI supplies each hospital receiving accreditation with appropriate publicity guidelines for announcing the accreditation award.

Maintaining Accreditation

Length of Accreditation Awards

An accreditation award is valid for three years unless revoked by JCI. The award is retroactively effective on the first day after JCI completes the hospital's survey or, when a follow-up survey is required, completes any follow-up survey(s). At the end of the hospital's three-year accreditation cycle, JCI reevaluates the hospital for renewal of its accreditation award.

Strategic Improvement Plan (SIP)

A Strategic Improvement Plan (SIP) is a required written plan of action that the hospital develops in response to "not met" findings identified in the JCI Official Survey Findings Report. The written SIP is expected to

- establish the strategies/approach that the hospital will implement to address each "not met" finding;
- describe specific actions the hospital will use to achieve compliance with the "not met" standards/MEs cited;
- describe specific steps the hospital will use to communicate and educate its employees, physicians, and
 others in implementing actions to achieve compliance with the "not met" standards/MEs cited;
- describe methodology to prevent reoccurrence and to sustain improvement over time; and
- identify the measures that will be used to evaluate the effectiveness of the improvement plan.

The SIP must demonstrate that the hospital's actions lead to full compliance with the standards and MEs. The SIP is reviewed and approved and accepted by the JCI Accreditation Office staff after the Accreditation or Certification Letter and Gold Seal have been awarded.

Reporting Requirements Between Surveys

JCI requires ongoing communication throughout the three-year accreditation cycle between the accredited hospital and JCI Accreditation Program to ensure that the hospital continues to meet the accreditation requirements after becoming accredited. Accreditation is neither automatically transferred nor continued if significant changes occur within the accredited organization. Please see the "Accreditation Participation Requirements" (APR) section for the list of changes that must be reported.

When Accreditation Is at Risk

Hospitals may be At Risk for Denial for Accreditation when JCI Accreditation Program staff determines that one or more of the following conditions are present in an organization or have occurred:

1) An immediate threat to patient safety, public health, or staff safety

- 2) The organization does not possess a license, certificate, and/or permit, as, or when, required by applicable laws and regulations, to provide the health care services for which the organization is seeking accreditation.
- 3) The organization's license, certificate, and/or permit to provide health care services has been temporarily or permanently restricted or removed and/or clinical departments/services have been limited or closed by a local or national regulatory body or authority based on quality and safety conditions, incidents, or events or other legal or regulatory situations.
- An individual who does not possess a license, registration, or certification is providing or has provided health care services
- 5) The organization submitted falsified documents or misrepresented information in seeking to achieve or to retain accreditation. (See APR.2)
- The organization has not met the accreditation policy for Reporting Requirements Between Surveys. (See APR.1)
- 7) The organization fails to submit an acceptable Strategic Improvement Plan (SIP) within 120 days of the organization's survey.

JCI Accreditation Program staff and surveyors may identify the conditions during an on-site survey, during the review of a survey report or postsurvey follow-up activity, or from a complaint submitted against the hospital or after removal or restriction of its license/permit to operate by a national or other regulatory body or authority. When the surveyors find that the condition is substantiated and not resolved, Denial of Accreditation is recommended to the Accreditation Committee.

Reporting Sentinel Events

Accredited hospitals voluntarily report sentinel events to JCI. JCI may also become aware of a sentinel event by some other means, such as communication from a patient, a family member, an employee of the organization, a surveyor, or through the media. Sentinel events include

- a) an unanticipated death, for example,
 - o death that is unrelated to the natural course of the patient's illness or underlying condition (**for example**, death from a postoperative infection or a hospital-acquired pulmonary embolism);
 - o death of a full-term infant;
 - o suicide;
- major permanent loss of function unrelated to the patient's natural course of illness or underlying condition;
- c) wrong-site, wrong-procedure, wrong-patient surgery;
- d) transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;
- e) infant abduction or an infant sent home with the wrong parents; and
- f) rape, workplace violence such as assault (leading to death or permanent loss of function), or homicide (willful killing) of a patient, staff member, practitioner, visitor, or vendor while on site at the hospital.

Such events are called *sentinel* because they signal a need for immediate investigation and response. The terms *sentinel event* and *medical error* are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.

The appropriate response by a hospital to a sentinel event includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements. JCI Accreditation Program staff review the root cause analysis and action plan with the hospital to help ensure improvement that will reduce the risk of a similar event occurring in the future.

During the on-site survey, surveyors assess the hospital's compliance with sentinel event—related standards (QPS.7, **for example**). If, during the survey, an unreported sentinel event is identified by the survey team, the hospital's CEO and others are informed that the event has been reported to JCI for further review.

Managing a Complaint or Quality Concern

JCI's Office of Quality and Safety Monitoring reviews complaints, concerns, and inquiries related to accredited hospitals. These communications may be received from a variety of sources, such as directly from patients, families, or health care practitioners, from governmental agencies in the form of reports, or through media reports. In hospitals that do not have an efficient and effective process to manage and resolve complaints, staff and patients bring those unresolved issues to JCI's attention.

Following its review of a reported quality concern, JCI may take a number of actions, including

- recording the information for trending purposes and possible action in the future;
- obtaining the involved hospital's response to the concern; or
- conducting a for-cause survey.

Accreditation Renewal

The JCI Accreditation Program reminds the hospital to update its E-App before the hospital's triennial accreditation due date and notify JCI of its intention to be reaccredited. JCI then schedules the survey, making every effort to synchronize the next survey date with the conclusion of the previous three-year accreditation cycle. JCI works with the hospital and others in the country or region that are also due for surveys to schedule the appropriate survey date(s) in an effort to maximize resources and reduce travel expenses. A hospital's previous accreditation status may remain in effect up to two months after the subsequent full accreditation survey to accomplish any required follow-up.

Glossary

accreditation Determination by the Joint Commission International (JCI) accrediting body that an eligible health care organization complies with applicable JCI standards.

accreditation decisions Categories of accreditation that an organization can achieve based on a JCI survey. These decision categories are as follows:

Accredited The organization demonstrates acceptable compliance with all standards and International Patient Safety Goals.

Denial of Accreditation The organization is consistently not in compliance with JCI standards and International Patient Safety Goals, JCI withdraws its accreditation for other reasons, or the organization voluntarily withdraws from the accreditation process.

accreditation framework The structures and processes in an organization that are necessary for an accrediting organization to do the following:

- Consistently and reliably evaluate applicant organizations against standards
- Recruit and send out trained evaluators
- Reach consistent and defensible accreditation decisions
- Carry out related policies and procedures

accreditation process A continuous process whereby health care organizations are required to demonstrate to JCI that they are providing safe, high-quality care, as determined by compliance with JCI standards and International Patient Safety Goal recommendations. The key component of this process is an on-site evaluation of an organization by JCI surveyors.

Accreditation Program (JCI) See JCI Accreditation Program

accreditation survey An evaluation of an organization to assess its compliance with applicable standards and to determine its accreditation status. The JCI accreditation survey includes the following:

- Evaluation of documents provided by organization staff that show compliance
- Verbal information about the implementation of standards or examples of their implementation that enables compliance to be determined
- On-site observations by surveyors
- Tracking of patients through the care process by the tracer methodology
- Education about standards compliance and performance improvement

full survey The survey of all the hospital standards throughout an entire organization. This may be the initial survey, triennial survey, or validation survey.

initial survey The first full on-site survey of a hospital. This may include a follow-up survey (an on-site evaluation scheduled 120 days following an initial survey to evaluate those measurable elements scored "not met" or "partially met" that resulted in the hospital's failure to meet the accreditation decision rules).

triennial survey The survey of a hospital after a three-year cycle of accreditation. This may include a follow-up survey (an on-site evaluation scheduled 120 days following an triennial survey to evaluate those measurable elements scored "not met" or "partially met" that resulted in the hospital's failure to meet the accreditation decision rules).

validation survey A second full survey that JCI may conduct in volunteer organizations as a component of JCI's internal quality improvement monitoring processes. This survey has no impact on the hospital's

accreditation status and is conducted at no charge to the hospital.

focused survey On-site surveys limited in scope, content, and length and designed to gather information on specific issues, standards, or measurable elements. JCI conducts the following types of focused surveys:

for-cause survey Conducted when JCI learns of potentially serious standards noncompliance, serious patient care or safety issues, regulatory issues or sanctions, or other serious issues within an accredited hospital or certified program that may have placed the hospital At Risk for Denial of Accreditation.

extension survey JCI may conduct an extension survey when the hospital notifies JCI before the change or within 15 days of changes in such core information from the hospital's profile, such as name, ownership, licensing, construction and renovation, adding or eliminating service, among others.

acute care A branch of health care in which necessary treatment of a disease is provided for only a short period of time for a brief but severe episode of illness. Many hospitals are acute care facilities with the goal of discharging the patient as soon as the patient is deemed healthy and stable, with appropriate discharge instructions.

adverse event An unanticipated, undesirable, or potentially dangerous occurrence in a health care organization.

ambulatory care Types of health care services provided to individuals on an outpatient basis. Ambulatory care services are provided in many settings ranging from freestanding surgical facilities to cardiac catheterization centers.

anesthesia and sedation The administration of medication to an individual, in any setting, for any purpose, by any route to induce a partial or total loss of sensation for the purpose of conducting an operative or other procedure. Definitions of four levels of anesthesia and sedation include the following:

minimal sedation (anxiolysis) A

drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

procedural (or moderate) sedation (formerly "conscious sedation") ${\bf A}$

drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

deep sedation/analgesia A

drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous impaired. (errata)

appointment The process of reviewing an initial applicant's credentials to decide if the individual is qualified to provide patient care services that the hospital's patients need and the hospital can support with qualified staff and technical capabilities. *Also see* reappointment.

best practice Clinical, scientific, or professional technique, method, or process that is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice. These practices, also sometimes referred to as *good practice* or *better practice*, are typically evidence based and consensus driven.

capital cost The cost of investing in the development of new or improved facilities, services, or equipment. Does not include operational costs.

care plan See plan of care.

certification

1. The procedure and action by which an authorized organization evaluates and certifies

that an individual, institution, or program meets requirements, such as standards. Certification differs from accreditation in that certification can also be applied to individuals (**for example**, a medical specialist).

2. The process by which a nongovernmental agency or association certifies that an individual has met predetermined qualifications specified by that agency or association.

cleaning Removal of all visible dust, soil, and any other visible material that microorganisms might find favorable for continued life and growth. This is usually done by scrubbing with hot water and detergent.

clinical pathology Services relating to solving clinical problems, particularly using laboratory methods in clinical diagnosis. Includes clinical chemistry, bacteriology and mycology, parasitology, virology, clinical microscopy, hematology, coagulation immunohematology, immunology, serology, and radiobioassay.

clinical pathway An agreed-on treatment regime that includes all elements of care by organizing, sequencing, and scheduling major interventions by clinicians and other staff. Also known as *critical paths* and *care maps*.

clinical practice guidelines Systematic statements that help practitioners and patients choose appropriate health care for specific clinical conditions (**for example**, recommendations on the case management of diarrhea in children under the age of 5 years). The practitioner is guided through all steps of consultation (questions to ask, physical signs to look for, lab exams to prescribe, assessment of the situation, and treatment to prescribe).

clinical record *See* patient record/medical record/clinical record.

clinical staff See staff.

clinical trial Therapy testing in three or sometimes four stages depending on the purpose, size, and scope of the test. "Phase I" trials evaluate the safety of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques to determine the safe dosage range (if appropriate). They involve a small number of healthy subjects. The trial usually lasts about one year. "Phase II"

trials are usually controlled to assess the effectiveness and dosage (if appropriate) of the drugs, devices, or techniques. These studies involve several hundred volunteers, including a limited number of patients with the target disease or disorder. The trial usually lasts about two years. "Phase III" trials verify the effectiveness of the drugs, devices, or techniques determined in Phase II studies. Phase II patients are monitored to identify any adverse reactions from long-term use. These studies involve groups of patients large enough to identify clinically significant responses. The trial usually lasts about three years. "Phase IV" trials study the drugs, devices, or techniques that have been approved for general sale. These studies are often conducted to obtain more data about a product's safety and efficacy.

competence A determination of an individual's skills, knowledge, and capability to meet defined expectations, as frequently described in a job description.

confidentiality

- 1. The restricted access to data and information to individuals who have a need, a reason, and permission for such access.
- 2. An individual's right to personal and informational privacy, including for his or her health care records.

contamination The presence of an infectious agent on an animate or inanimate surface.

continuity of care The degree to which the care of individuals is coordinated among practitioners, among organizations, and over time. *Also see* handover.

continuum of care Matching the individual's ongoing needs with the appropriate level and type of care, treatment, and services within an organization or across multiple organizations.

contracted services Services provided through a written agreement with another organization, agency, or individual. The agreement specifies the services or personnel to be provided on behalf of the applicant organization and the fees to provide these services or personnel.

credentialing The process of obtaining, verifying, and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization. The

process of periodically checking staff qualifications is called *recredentialing*.

credentials Evidence of competence, current and relevant licensure, education, training, and experience. Other criteria may be added by a health care organization. *Also see* competence; credentialing.

culture of safety Also known as a *safe culture*, an organizational culture that encourages any individual staff member (clinical or administrative) to report concerns about safety or the quality of care without retaliatory action from the hospital.

curative services Services provided to overcome disease and to promote recovery. Curative services or therapy are different from palliative services, which give relief but not cure. *Also see* palliative services.

data Facts, clinical observations, or measurements collected during an assessment activity. Data before they are analyzed are called *raw data*.

disaster See emergency.

discharge The point at which an individual's active involvement with an organization or program is terminated and the organization or program no longer maintains active responsibility for the care of the individual.

discharge summary A section of a patient record that summarizes the reasons for admittance, the significant findings, the procedures performed, the treatment rendered, the patient's condition on discharge, and any specific instructions given to the patient or family (**for example**, follow-up, medications).

disinfection The use of a chemical procedure that eliminates most disease-producing organisms, but not all microbial forms.

do-not-use list A written catalog of abbreviations, acronyms, and symbols that are not to be used throughout an organization—whether handwritten or entered as free text into a computer—due to their potentially confusing nature.

efficiency The relationship between the outcomes (results of care) and the resources used to deliver care. **For example**, when two programs use the same amount of resources, the one that

achieves a higher immunization coverage rate is the more efficient. Increasing efficiency involves achieving the same outputs with fewer resources or more outputs with the same amount of resources.

elope Intentionally leaving a health care organization without notifying the organization and against medical advice.

emergency

- 1. An unanticipated or sudden occasion, as in emergency surgery needed to prevent death or serious disability.
- 2. A natural or man-made event that significantly disrupts the environment of care (for example, damage to the organization's building[s] and grounds due to severe winds, storms, or earthquakes); that significantly disrupts care and treatment (for example, loss of utilities, such as power, water, or telephones, due to floods, civil disturbances, accidents, or emergencies in the organization or its community); or that results in sudden, significantly changed or increased demands for the organization's services (for example, bioterrorist attack, building collapse, or plane crash in the organization's community). Some emergencies are called disasters or potential injury-creating events (PICEs).

emergent A classification of acuity used in the triage systems to signify that the patient's condition is life-threatening and requires immediate intervention. *Also see* urgent.

employment practices Analysis, screening, or other methods used to recruit, hire, select, transfer, promote, provide benefits, or similarly affect employees or future employees.

environmental management plan(s) The organization's written document describing the process it has in place for the following areas of its operations: safety and security, hazardous materials, emergencies, fire safety, medical technology, and utility systems. The plan identifies specific procedures that describe mitigation, preparedness, response and recovery strategies, actions, and responsibilities.

equipment maintenance program, preventive See maintenance program, preventive.

equipment maintenance program, routine See maintenance program, routine.

evidence-based (or scientific-based)

guidelines Making clinical decisions based on empirical evidence or, in the absence of empirical evidence, expert consensus (such as consensus statements promoted by professional societies). The approach requires understanding conflicting results and assessing the quality and strength of evidence. Finally, practitioners must know how this applies to patient care and health care policy.

failure mode and effects analysis

(FMEA) A systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur.

falsification (of information) Fabrication, in whole or in part, of any information provided by an applicant or accredited organization to JCI.

family The person(s) with a significant role in the patient's life. This may include a person(s) not legally related to the patient. This person(s) is often referred to as a surrogate decision maker if authorized to make care decisions for a patient if the patient loses decision-making ability.

fellow See trainee, medical.

framework An outline, overview, or "skeleton" of interconnected items that can be modified at any time by adding or deleting items.

full operation Criteria indicating the the hospital's readiness for comprehensive on-site evaluation against all relevant JCI standards, based on a list of all clinical services currently provided for inpatients and outpatients; utilization statistics for clinical services showing consistent inpatient and outpatient activity levels and types of services provided for at least four months or more prior to submission of the hospital's electronic application (E-App); and all inpatient and outpatient clinical services, units, and departments. *See* General Eligibility Requirements in this manual.

functional status The ability of individuals to take care of themselves physically and emotionally according to the expected norms of their age group. Functional status may be divided into "social,"

"physical," and "psychological" functions. Functional status may be assessed by asking questions during periodic health examinations or using formal screening instruments. Also see measure.

governance The individual(s), group, or agency that has ultimate authority and responsibility for establishing policy, maintaining quality of care, and providing for organization management and planning. Other names for this group include board, board of trustees, board of governors, board of commissioners, and governing body. Governance may be a group of individuals (such as a community board), one or more individual owners, or in the case of public hospitals, the Ministry of Health. Any individual, entity, or group responsible for the requirements found in JCI standards is considered the governance of the hospital. Also see leaders and leadership.

handover The transition of a patient from one health care provider to another. Also known as a *bandoff* or a *transition of care*.

harvesting, of organs Removal of an organ for means of transplantation.

hazardous materials and waste Materials whose handling, use, and storage are guided or defined by local, regional, or national regulation, hazardous vapors, and hazardous energy sources. Although JCI identifies infectious waste as falling into this category of materials, not all laws and regulations define infectious or medical waste as hazardous waste.

hazard vulnerability analysis The

identification of potential emergencies and the direct and indirect effects these emergencies may have on the health care organization's operations and the demand for its services.

health care-associated infection(s)

(HAIs) Any infection(s) acquired by an individual while receiving care or services in a health care organization. Common HAIs are urinary infections, surgical wound infections, pneumonia, and bloodstream infections.

health care organization A generic term used to describe many types of organizations that provide health care services. This includes ambulatory care centers, behavioral/mental health institutions, home care organizations, hospitals, laboratories, and long term care organizations. Also known as a *health care institution*.

standards For purposes of JCI accreditation, standards that are organized according to what is done directly or indirectly to provide for a safe,

done directly or indirectly to provide for a safe, effective, and well-managed organization and facility (**for example**, prevention and control of infection, facility management, staff qualifications).

independent practitioner Any individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license. In many countries, licensed independent practitioners include physicians, dentists, some categories of nurses, podiatrists, optometrists, and chiropractors. *Also see* practitioner.

infectious waste *See* hazardous materials and waste.

information management The creation, use, sharing, and disposal of data or information across an organization. This practice is critical to the effective and efficient operation of organization activities. It includes the role of management to produce and to control the use of data and information in work activities, information resources management, information technology, and information services.

information technology maintenance program, preventive *See* maintenance program, preventive.

information technology maintenance program, routine *See* maintenance program, routine.

informed consent Agreement or permission accompanied by full information on the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins the procedure or treatment. After receiving this information, the patient either consents to or refuses such a procedure or treatment.

inpatient Generally, persons who are admitted to and housed in a health care organization at least overnight.

in-service education Organized education, usually provided in the workplace, designed to enhance the skills of staff members or to teach

them new skills relevant to their jobs and disciplines.

integrated provider (system) A health care provider organization that offers a broad corporate system for managing a diversified health care delivery system. The system typically includes one or more hospitals, a large group practice, a health plan, and other health care operations. Health care practitioners are employees of the system or in a tightly affiliated practitioner group. The system can provide several levels of health care to patients in the same geographic areas.

intent A brief explanation of a standard's rationale, meaning, and significance. Intents may contain examples of compliance and detailed expectations of the standard that are evaluated in the on-site survey process.

intern See trainee, medical.

invasive procedure A procedure involving puncture or incision of the skin or insertion of an instrument or foreign material into the body.

JCI Accreditation Program The division of JCI responsible for administration of all activities related to organizational health care accreditation or certification.

job description Explanation of an employment position, including duties, responsibilities, and conditions required to perform the job.

leaders and leadership In JCI standards, the term leaders is used to indicate that one or more individuals are accountable for the expectation(s) found in the standards. Leadership is used to indicate that a group of leaders is collectively accountable for the expectation(s) found in the standards. A leader is an individual who sets expectations, develops plans, and implements procedures to assess and to improve the quality of the organization's governance, management, clinical, and support functions and processes. The leaders described in the JCI standards include at least the leaders of the governing body, the chief executive officer and other senior managers, departmental leaders, the elected and the appointed leaders of the medical staff and the clinical departments and other medical staff members in organizational administrative positions, and the nurse executive and other senior nursing leaders. Also see governance.

levels of care A classification of health care service levels. They are divided by the kind of care given, the number of people served, and the people providing the care. The main levels of care are primary, secondary, and tertiary. Levels of care classified by the acuity of the patient or intensity of the services provided are emergency, intensive, and general. *Also see* continuum of care.

licensure A legal right that is granted by a government agency in compliance with a statute governing an occupation (such as physicians, dentists, nurses, psychiatry, or clinical social work, or the operation of a health care facility).

maintenance program, preventive The planned, scheduled, visual, mechanical, engineering, and functional evaluation of equipment conducted before using new equipment and at specified intervals throughout the equipment's lifetime. The purpose is to maintain equipment performance within manufacturers' guidelines and specifications and to help ensure accurate diagnosis, treatment, or monitoring. It includes measuring performance specifications and evaluating specific safety factors.

maintenance program, routine The performance of basic safety checks—that is, the visual, technical, and functional evaluations of equipment—to identify obvious deficiencies before they have a negative impact. It normally includes inspections of the case, power cord, structural frame, enclosure, controls, indicators, and so on.

measure

- 1. To collect quantifiable data about a function, system, or process (one "measures").
- 2. A quantitative tool.

medical device See medical technology.

medical equipment See medical technology.

medical record *See* patient record/medical record/clinical record.

medical staff All physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services, regardless of the organization's

classification of appointment, employment status, contract, or other arrangements with the individual to provide such patient care services.

medical student See student, medical.

medical technology Fixed and portable medical devices and equipment used for the direct diagnosis, treatment, monitoring, and care of individuals. Similar terms include *medical equipment* and *medical devices*.

medical technology maintenance program, preventive See maintenance program, preventive.

medical technology maintenance program, routine *See* maintenance program, routine.

medical waste *See* hazardous materials and waste.

medication Any prescription medications; sample medications; herbal remedies; vitamins; nutriceuticals; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, to treat, or to prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; and intravenous solutions (plain, with electrolytes and/or drugs).

medication, high-risk or high-alert Those drugs that carry a risk for errors that can lead to significant adverse outcomes.

medication error Any preventable event that may cause inappropriate medication use or jeopardize patient safety. *Also see* sentinel event.

mission statement A written expression that sets forth the purpose, or "mission," of an organization or one of its components. The generation of a mission statement usually precedes the formation of goals and objectives.

monitoring The review of information on a regular basis. The purpose of monitoring is to identify the changes in a situation. **For example**, the health information specialist of the district health management team reports every month the cases of meningitis occurring in villages at risk.

multidisciplinary Including representatives of a range of professions, disciplines, or service areas.

near miss Any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such a "near miss" falls within the scope of the definition of an adverse event. *Also see* adverse event.

nonclinical staff See staff.

nosocomial infection(s) *See* health care—associated infection(s).

nutritional care Interventions and counseling to promote appropriate nutrition intake. This activity is based on nutrition and information about food, other sources of nutrients, and meal preparation. It includes the patient's cultural background and socioeconomic status.

nutrition therapy Medical treatment that includes enteral and parenteral nutrition.

observation The time during which a patient is watched closely by a caregiver (or caregivers).

organizational chart A graphic representation of titles and reporting relationships in an organization, sometimes referred to as an *organogram* or *organization table*.

outcome The effect(s) that an intervention has on a specific health problem. It reflects the purpose of the intervention. **For example**, the outcome(s) of a rural health education program on safe drinking water could be fewer diarrhea episodes in children under 5 or decreased child mortality by diarrhea.

outpatient Generally, persons who do not need the level of care associated with the more structured environment of an inpatient or a residential program. In many countries, outpatient care is also known as "ambulatory care." In some countries, outpatients are considered "admitted" to a health care organization; in others, outpatients are considered "registered." *Also see* ambulatory care.

palliative services Treatments and support services intended to alleviate pain and suffering rather than to cure illness. Palliative therapy may include surgery or radiotherapy undertaken to reduce or to shrink tumors compressing vital structures and thereby to improve the quality of

life. Palliative services include attending to the patient's psychological and spiritual needs and supporting the dying patient and his or her family.

patient An individual who receives care, treatment, and services. For JCI standards, the patient and family are a single unit of care.

patient care process The act of providing accommodations, comfort, and treatment to an individual. This implies responsibility for safety, including treatment, services, habilitation, rehabilitation, or other programs requested by the organization or network for the individual.

patient-centered standards For purposes of JCI accreditation, standards that are organized according to what is done directly or indirectly for or to patients (**for example**, patient education, creation of patient records, patient assessment).

patient record/medical record/clinical

record A written account of a variety of patient health information, such as assessment findings, treatment details, progress notes, and discharge summary. This record is created by health care professionals.

physiologic-based criteria Criteria centered on the branch of biology dealing with the functions of the living organism and its parts of the physical and chemical factors and processes involved.

plan A detailed method, formulated beforehand, that identifies needs, lists strategies to meet those needs, and sets goals and objectives. The format of the plan may include narratives, policies and procedures, protocols, practice guidelines, clinical paths, care maps, or a combination of these.

plan of care A plan that identifies the patient's care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. It is based on data gathered during patient assessment. The format of the plan in some organizations may be guided by specific policies and procedures, protocols, practice guidelines, clinical paths, or a combination of these. The plan of care may include prevention, care, treatment, habilitation, and rehabilitation. Also see plan.

point-of-care testing Analytical testing performed at sites outside the traditional laboratory

environment, usually at or near where care is delivered to individuals.

policy A statement of expectations, usually written, meant to influence or determine decisions and actions. Policies are the regulations, rules, or laws that inform procedures and processes.

practice guidelines *See* evidence-based (or scientific-based) guidelines; clinical practice guidelines.

practitioner Any person who has completed a course of study and is skilled in a field of health care. This includes a physician, dentist, nurse, pharmacist, respiratory therapist, among others. Practitioners are licensed by a government agency or certified by a professional organization. *Also see* independent practitioner.

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

preventive services Interventions to promote health and prevent disease. These include identification of and counseling on risk factors (for example, smoking, lack of physical activity), screening to detect disease (for example, breast cancer, sexually transmitted diseases), immunizations, and chemoprophylaxis (for example, hormone replacement therapy).

primary source verification Verification of an individual health care practitioner's reported qualifications by the original source or an approved agent of that source. Methods for conducting primary source verification of credentials include direct correspondence, documented telephone verification, secure electronic verification from the original qualification source, or reports from credentials verification organizations that meet JCI requirements.

principal site The site at which an academic medical center hospital provides the majority of medical specialty programs for postgraduate medical trainees (**for example**, residents or interns) and not just one specialty, as in a single-specialty hospital (**for example**, an ophthalmologic hospital, dental hospital, or orthopedic hospital). *See* General Eligibility Requirements in this manual.

privileging The process whereby a specific scope and content of patient care services (that is, clinical

privileges) are authorized for a health care practitioner by a health care organization, based on evaluation of the individual's credentials and performance.

procedure How a task is performed, usually including step-by-step instructions. Different from *process*, which defines the task and who performs it.

process A definition of a task that needs to be done and by whom. Different from *procedure*, which defines precisely how the task is performed.

program An organized, official system or plan guiding action toward a specific goal.

protocol A scientific medical treatment plan or study outline for a new or experimental procedure or treatment with the intent of measuring human applications (**for example**, management of diabetes mellitus type 2). Protocols frequently include components such as types of participants, scheduling, procedures used, types of medications and dosages, among others.

qualified individual An individual or staff member who can participate in one or all of the organization's care activities or services. Qualification is determined by the following: education, training, experience, competence, applicable licensure, laws or regulations, registration, or certification.

quality improvement An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of patients and others. Synonyms include continuous quality improvement, continuous improvement, organizationwide performance improvement, and total quality management.

quality of care The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Dimensions of performance include the following: patient perspective issues; safety of the care environment; and accessibility, appropriateness, continuity, effectiveness, efficacy, efficiency, and timeliness of care.

reappointment The process of reviewing the medical staff member's file to verify a continued licensure; that the medical staff member is not compromised by disciplinary actions of licensing and certification agencies; that the file contains

sufficient documentation for seeking new or expanded privileges or duties in the hospital; and that the medical staff member is physically and mentally able to provide patient care and treatment without supervision. *Also see* appointment.

recruitment Seeking—usually new—employees or other members of an organization.

reference (contract) laboratory A

laboratory owned and operated by an organization other than the hospital, with which the hospital contacts for testing.

referral The sending of an individual (1) from one clinician to another clinician or specialist or (2) from one setting or service to another or other resource, either for consultation or care that the referring source is not prepared or qualified to provide.

rehabilitation services The use of medical, social, educational, and vocational measures together for training or retraining individuals disabled by disease or injury. The goal is to enable patients to achieve their highest possible level of functional ability.

reliability The ability of the measure to accurately and consistently identify the events it was designed to identify across multiple health settings.

representative sample A sample in which each case in an initially identified population of cases has equal probability of being included in the sample. A representative sample is obtained if random sampling is used to select the sample cases.

resident See trainee, medical.

risk management program Clinical and administrative activities that organizations undertake to identify, to evaluate, and to reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.

root cause analysis A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event. *Also see* sentinel event.

rules and regulations Statements or directions specifying required decisions and actions. Penalties, legal or otherwise, are normally

assessed when rules and regulations are not followed.

safety The degree to which the organization's buildings, grounds, and equipment do not pose a hazard or risk to patients, staff, or visitors.

scope of practice The range of activities performed by a practitioner in a health care organization. The scope is determined by training, tradition, laws or regulations, or the organization.

scope of services The range of activities performed by governance, managerial, clinical, and support personnel.

screening criteria A set of standardized rules or tests applied to patient groups on which to base a preliminary judgment that further evaluation is warranted, such as the need for a nutritional evaluation based on nutritional screening.

security Protection from loss, destruction, tampering, or unauthorized access or use.

sedation *See* anesthesia and sedation.

sentinel event An unanticipated occurrence involving death or major permanent loss of function.

side effect Pharmacological effect of a drug, normally adverse, other than the one(s) for which the drug is prescribed.

specialty laboratory programs Programs that include laboratory disciplines, such as chemistry (including toxicology, therapeutic drug testing, and drugs of abuse testing), clinical cytogenetics immunogenetics, diagnostic immunology, embryology, hematology (including coagulation testing), histocompatibility, immunohematology, microbiology (including bacteriology, mycobacteriology, mycology, virology, and parasitology), molecular biology, pathology (including surgical pathology, cytopathology, and necropsy), and radiobioassay. (errata)

staff According to their roles and responsibilities, all people who provide care, treatment, and services in the organization (**for example**, medical staff and nursing staff), including those receiving pay (permanent, temporary, and part-time personnel, as well as contract employees), and health profession students.

clinical staff Those who provide direct patient care (physicians, dentists, nurses, among others).

nonclinical staff Those who provide indirect patient care (admissions, food service, among others).

standard A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality care, treatment, and service.

standards-based evaluation An assessment process that determines a health care organization's or practitioner's compliance with preestablished standards. *Also see* accreditation.

sterilization The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

student, medical An individual enrolled in a medical educational institution.

supply chain The steps in moving a finished product (drug, medical device, or medical supply) from its source (a manufacturer) to its customer (a hospital). Key considerations in the supply chain are the integrity of the product (**for example**, protection from heat, contamination, and other risks) and changes in accountability (multiple distribution channels, storage, customs, delivery, among others).

surgery Those procedures that investigate and/or treat diseases and disorders of the human body through cutting, removing, altering, or insertion of diagnostic/therapeutic scopes.

survivor risk factors Chances for surviving family members or other loved ones to experience difficulties with the death of a loved one.

symptom, primary First or most prominent indication of an illness, disease, or other disorder.

symptom, secondary An indication of illness, disease, or other disorder that appears after or because of a primary symptom.

therapeutic duplication One person using two drugs, usually unnecessarily, from the same therapeutic category at the same time.

time-out A pause, just prior to performing a surgical or other procedure, during which any

unanswered questions or confusion about patient, procedure, or site are resolved by the entire surgical or procedural team. Even when there is only one person doing the procedure, a brief pause to confirm the correct patient, procedure, and site is appropriate.

tracer methodology A process that JCI surveyors use during the on-site survey to analyze an organization's systems by following individual patients through the organization's health care process in the sequence experienced by the patients. Depending on the health care setting, this may require surveyors to visit multiple care units, departments, or areas within an organization or a single care unit to "trace" the care rendered to a patient.

patient tracer The process used by JCI to evaluate an individual patient's total care experience within a health care organization.

system tracer A session during the on-site survey devoted to evaluating high-priority safety and quality-of-care issues on a systemwide basis throughout the organization. Examples of such issues may include infection prevention and control, medication management, staffing effectiveness, and the use of data.

trainee, medical An individual training in medical service after graduation from a medical educational institution. For the purposes of JCI accreditation, *trainees* include interns, residents, and fellows.

transfer The formal shifting of responsibility for the care of a patient from (1) one care unit to another, (2) one clinical service to another, (3) one qualified practitioner to another, or (4) one organization to another.

urgent A classification of acuity used in triage systems to signify that the patient's condition is potentially life-threatening and requires timely assessment and possible intervention.

utility system Organizationwide systems and equipment that support the following: electrical distribution; emergency power; water; vertical and horizontal transport; heating, ventilating, and air-conditioning; plumbing, boiler, and steam; piped gases; vacuum systems; or communication systems, including data-exchange systems. May also include systems for life support; surveillance,

prevention, and control of infection; and environment support.

utilization The use, patterns of use, or rates of use of a specified health care service. Overuse occurswhen a health care service is provided under circumstances in which its potential for harm exceeds the possible benefits. Underuse is the failure to use a necessary health care service when it would have produced a favorable outcome for a patient. Misuse occurs when an appropriate service has been selected but a preventable complication occurs. All three reflect a problem in quality of health care. They can increase mortality risk and diminish quality of life. *Also see* utilization management.

utilization management The planning, organization, direction, and control of resources. How this relates to patient care by a health care organization is significant.

validity Ability to identify opportunities for improvement in the quality of care; demonstration that the measure used results in improvements in outcomes and/or quality of care.

variation The differences in results obtained in measuring the same event more than once. The sources of variation can be grouped into two major classes: common causes and special causes. Too much variation often leads to waste and loss, such as the occurrence of undesirable patient health outcomes and increased cost of health services.

verification The process of checking the validity and completeness of a clinical or other credential from the source that issued the credential.

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(Deletions in strikethrough. New text is underlined. Most recent changes in red. Clarifications in blue.)

Page 17, APR.10 (new text for clarity)

Requirement: APR.10

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

Rationale for APR.10

The integrity of the on-site evaluation process, as well as the integrity of the outcome, depend on the surveyor obtaining an unbiased, accurate understanding of his or her conversations with staff; and the hospital's staff communicating effectively in their language with the surveyor. To ensure this accurate, unbiased exchange, translation and interpretation is provided by individuals licensed and/or qualified to provide translation and interpretation services, with evidence of experience in health care translation and/or interpretation services. Individuals providing translation and interpretation services are not current or former employees of the hospital and do not have any conflicts of interest, such as immediate family members or employees of an affiliated hospital.

Individuals providing translation and interpretation services have not served in any consultation capacity to the hospital in relation to accreditation or accreditation preparation, with the possible exception of assistance in translating the documents required by JCI to be in English or providing translation and interpretation services at a previous survey.

Consequences of Noncompliance with APR.10

When translators are found to be unqualified due to lack of professional license <u>and/or other qualifications</u>, or a conflict of interest, the survey will be stopped until a suitable replacement can be found. The hospital is responsible for any additional costs related to the delay, including rescheduling of survey team members when necessary.

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

- Evidence of advanced education in English and the host hospital's primary language
- Evidence of translation and interpretation experience, preferably in the medical field
- Evidence of continuing education in translation and interpretation, preferably in the medical field
- Memberships in professional translation and interpretation associations
- Translation and interpretation proficiency testing results, when applicable
- Translation and interpretation certifications, when applicable
- Other relevant translation and interpretation credentials



(Deletions in strikethrough. New text is underlined. Most recent changes in red. Clarifications in blue.)

Page 84, AOP.6.8

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Standard AOP.6.8 requires the hospital to collect and review quality control results for all "outside" sources of diagnostic services. In this case, "outside" is considered to be the equivalent of "contracted," meaning the hospital is required to collect quality control data from any diagnostic imaging services that are contracted by the hospital, but not within the hospital facility. When the hospital simply provides a list of diagnostic services from which a patient can freely choose or refers a patient to a diagnostic service that is not part of the hospital and for which the hospital does not contract services, the hospital is not required to obtain quality control results.



(Deletions in strikethrough. New text is underlined. Most recent changes in red. Clarifications in blue.)

Page 97, COP chapter, Hospitals Providing Organ and/or Tissue Transplant Services

(reworded for clarity)

Note: The following standards are intended to be used during those times when patients and/or families request information about organ and tissue donation and/or when organ/tissue procurement is performed. For hospitals providing organ and/or tissue transplant services, Standards COP.8 through COP.9.3 apply are intended to be used by hospitals providing organ and/or tissue transplant services. Please contact the JCI Accreditation Office with inquiries.



(Deletions in strikethrough. New text is underlined. Most recent changes in red. Clarifications in blue.)

Page 219, SQE.11

(changed lettered list to bulleted list to indicate advisory text [bullets] versus requirements [lettered list])

Professional Growth

Medical staff members grow and mature as the organizations in which they practice evolve, introducing new patient groups, technologies, and clinical science. Each medical staff member, to varying degrees, will reflect growth and improvement in the following important dimensions of health care and professional practice:

- Patient care, including provision of patient care that is compassionate, appropriate, and effective for health promotion, disease prevention, treatment of disease, and care at the end of life. (Potential measures include frequency of preventive services and reports from patients and families.) (*Also see* PRF.3)
- b) Medical/clinical knowledge, including knowledge of established and evolving biomedical, clinical, epidemiologic, and social-behavioral sciences, as well as the application of knowledge to patient care and the education of others. (Potential measures include application of clinical practice guidelines, including the adaptation and revision of guidelines, participation in professional conferences, and publications.) (Also see GLD.11.2)
- Practice-based learning and improvement, including use of scientific evidence and methods to investigate, evaluate, and continuously improve patient care based on self-evaluation and lifelong learning. (Examples of potential measures include self-motivated clinical inquiry/research, acquiring new clinical privileges based on study and acquiring new skills, and full participation in meeting requirements of professional specialty requirements or continuing education requirements of licensure.)
- hInterpersonal and communication skills, including establishment and maintenance of effective exchange of information and collaboration with patients, their families, and other members of health care teams. (**Examples** of potential measures include participation in teaching rounds, team consultations, team leadership, and patient and family feedback.)
- Professionalism, including commitment to continuous professional development, ethical practice, an understanding and sensitivity to diversity, and a responsible attitude toward patients, their profession, and society. (Examples of potential measures include an opinion leader within the medical staff on clinical and professional issues, service on an ethics panel or discussions of ethical issues, keeping appointed schedules, and community participation.)
- System-based practices, including awareness of and responsiveness to the larger contexts and systems of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care. (**Examples** of potential measures include understanding the meaning of frequently used, hospitalwide systems, such as the medication system; and awareness of the implications of the overuse, underuse, and misuse of systems.)
- Stewardship of resources, including understanding of the need for stewardship of resources and practicing cost-conscious care, including avoiding the overuse and misuse of diagnostic tests and therapies that do not benefit patient care but add to health care costs. (Examples of potential measures include participation in key purchasing decisions within their practice area, participating in efforts to understand appropriate use of resources, and being aware of the cost to patients and payers of the services they provide.) (Also see GLD.7)



(Deletions in strikethrough. New text is underlined. Most recent changes in red. Clarifications in blue.)

Page 264, Glossary

(text inadvertently omitted from initial publication 1 September 2013)

deep sedation/analgesia A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous impaired ventilation may be inadequate. Cardiovascular function is usually maintained.

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



Errata and Interpretations, JCI Accreditation Standards for Hospitals, 5th Edition Issued 4 December 2013

(Deletions in strikethrough. New text is underlined. Most recent changes in red. Interpretations in blue.)

Page 3, Introduction (correcting a typo)

Accreditation Participation Requirements (APR)

The Accreditation Participation Requirements (APR) section, new to JCI in this edition, is composed of specific requirements for participation in the accreditation process and for maintaining an accreditation award. Hospitals must be compliant with the requirements in this section at all times during the accreditation process. However, APRs are not scored like standards during the on-site survey; hospitals are considered either compliant or not compliant with the APR. When a hospital is not compliant with a specific APR, the hospital will be required to become complainant or risk losing accreditation.



Errata and Interpretations, JCI Accreditation Standards for Hospitals, 5th Edition Issued 4 December 2013

(Deletions in strikethrough. New text is underlined. Most recent changes in red. Interpretations in blue.)

Page 272, Glossary (correcting a typo)

specialty laboratory programs Programs that include laboratory disciplines, such as chemistry (including toxicology, therapeutic drug testing, and drugs of abuse testing), clinical cytogenetics, immunogenetics, diagnostic immunology, embryology, hematology (including coagulation testing), histocompatibility, immunohematology, microbiology (including bacteriology, mycobacteriology, mycology, virology, and parasitology), molecular biology, pathology (including surgical pathology, cytopathology, and necropsy), and radiobioassay.