

Standards Sampler for Urgent Care Centers



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Introduction

The *Comprehensive Accreditation Manual for Ambulatory Care* (CAMAC) contains the set of standards that have been designed to evaluate a variety of ambulatory care settings, including ambulatory surgery centers, urgent care centers, and diagnostic imaging centers. The manual can also be used as a comprehensive self-assessment tool that you can use to prepare for a Joint Commission on-site survey.

To help familiarize you with the standards while you are in the early stages of exploring accreditation, The Joint Commission has prepared this resource, the *Standards Sampler for Urgent Care Centers*, which contains a few selected standards from each of the 15 standards chapters to illustrate the types of issues that accreditation addresses.

As you review the *Standards Sampler*, please note the structure of each standard.

The Standard itself is a statement that defines the performance expectations and/or structures or processes that must be in place in order for an organization to provide safe, high-quality care. A center is evaluated as either “compliant” or “not compliant” with a standard. Accreditation decisions are based on simple counts of the standards scored “not compliant.”

The Rationale is a statement that provides background, justification, or additional information about a standard. A standard’s rationale is not scored. In some instances, the rationale for a standard is self-evident. Therefore, not every standard has a written rationale.

Elements of performance (EPs) are specific performance expectations and/or structures or processes that must be in place. The scoring of EP compliance determines a center’s overall compliance with a standard. EPs are evaluated on the following scale:

- 0** - Insufficient compliance
- 1** - Partial compliance
- 2** - Satisfactory compliance
- NA** - Not applicable

Scoring

There are two categories of Elements of Performance:

Category A

These EPs relate to the presence or absence of the requirement(s) and are scored either yes (2) or no (0).

Category C

Category C EPs are frequency based and are scored 0, 1, or 2 based on the number of times your center does not meet the EP. Each event discovered by a surveyor(s) will be counted as a separate occurrence. The EP will be scored 2 if there are one or few occurrences of noncompliance; it will be scored 1 if there are two occurrences of noncompliance, and it will be scored 0 if there are three or more occurrences of noncompliance.

The Scoring Process

Accreditation decisions are based on a “criticality” model. This model is based on the premise that the level of potential risk to quality of care and patient safety—based on noncompliance with Joint Commission standards and EPs—is variable, with certain situations constituting more immediate risks than others. Thus the more immediate the risk is to quality of care and patient safety, the shorter the period of time that the organization will have to address any relevant standards they are not in compliance with.

Criticality is defined as *the immediacy of risk to patient safety or quality of care as a result of non-compliance with a Joint Commission requirement* (for example, an Element of Performance, National Patient Safety Goal, or Universal Protocol). The levels of criticality fall into the following four categories: 1) Immediate Threat to Health and Safety, 2) Situational Decision Rules, 3) Direct Impact Requirements, and 4) Indirect Impact Requirements.

1. Immediate Threat to Health and Safety

This category represents the most immediate risk and involve a recommendation for Preliminary Denial of Accreditation. While not linked to any specific standards or EPs, immediate threat to health or safety situations have or may potentially have serious adverse effects on patient health and safety. These issues must be resolved through the Evidence of Standards Compliance process **within 45 days**. Upon resolution of an Immediate Threat to Life Situation, the organization’s accreditation status will change from Preliminary Denial of Accreditation to Conditional Accreditation. A follow-up survey will then be conducted to validate the proper implementation of corrective actions.

2. Situational Decision Rules

These situations involve a recommendation for Preliminary Denial of Accreditation or Conditional Accreditation based on such issues as loss of facility licensure, provision of care by unlicensed individuals who require such a license, and failure to implement corrective action in response to identified *Life Safety Code* deficiencies. To

follow-up in these situations, organizations must demonstrate resolution of the situation through the Evidence of Standards Compliance (ESC) process **within 45 days**. A follow-up survey is then conducted to validate the proper implementation of corrective actions.

3. Direct Impact Requirements

A “Direct Impact” requirement (standard, elements of performance, National Patient Safety Goal, or Accreditation Participation Requirement) is a requirement that has a direct impact on quality of care or patient safety if noncompliance is likely to create an immediate risk to patient safety or quality of care. The immediate risk usually results because there are no or few processes—or no or few protective defenses—intervening between the noncompliance and the impact on the safety or quality of a patient’s care. These issues must be resolved through the Evidence of Standards Compliance process **within 45 days**.

All instances of identified partial compliance or insufficient compliance with elements of performance which are associated with the Direct Impact requirements above need to be resolved through the Evidence of Standards Compliance process **within 45 days**. The organization’s accreditation decision is awarded after successful submission of Evidence of Standards Compliance.

4. Indirect Impact Requirements

These requirements pose less immediate risk to patient care and safety than Direct Impact requirements, but noncompliance increases risk to patient safety and quality of care over time.

All instances of identified partial compliance and insufficient compliance with elements of performance under these Indirect Impact requirements must be resolved through the Evidence of Standards Compliance process **within 60 days**. As above, the organization’s accreditation decision is awarded after successful submission of Evidence of Standards Compliance.

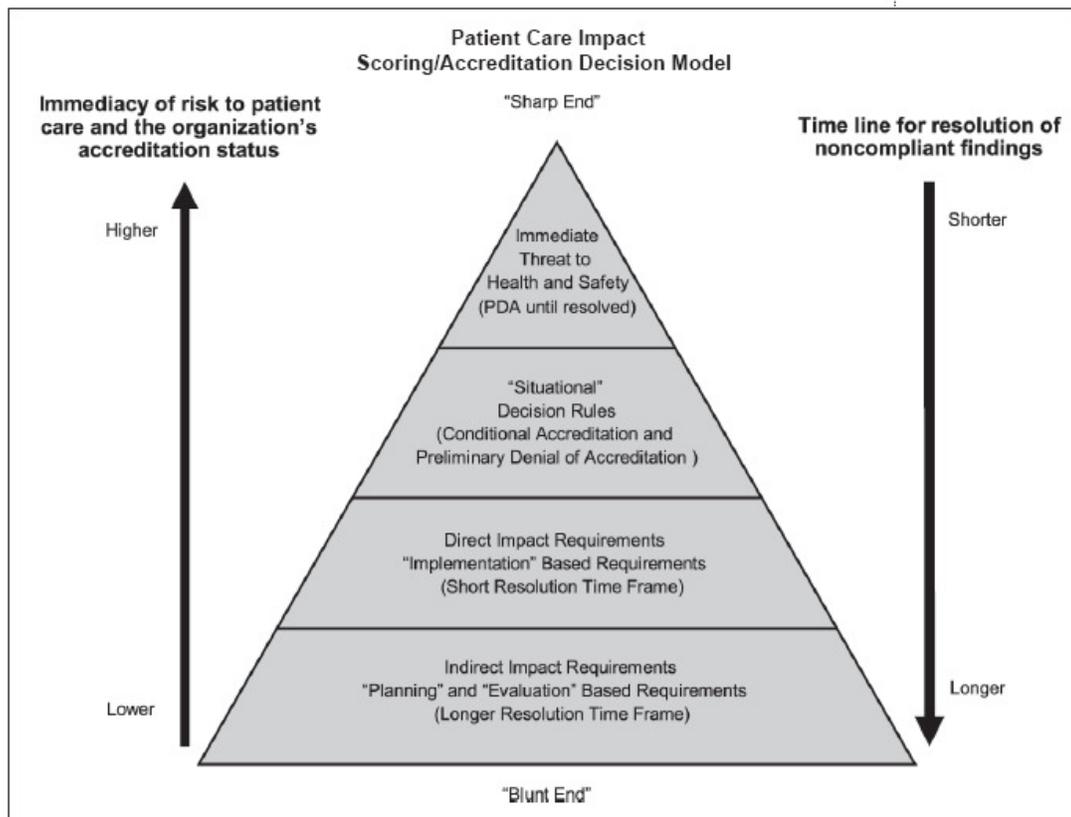


Figure 4. Accreditation based on impact on patient care.

Please share these examples of ambulatory care standards with your staff. You'll likely see that much of what is required for accreditation is already in place at your urgent care center. As a guide, The Joint Commission, in conjunction with the Urgent Care Association of America (UCAOA), has published an "applicability grid" to illustrate which standards/elements of performance apply in a typical urgent care clinic. See the resource at: http://www.ucaoa.org/accreditation_main.php.

The full text for all of these standards can be found in the *Comprehensive Accreditation Manual for Ambulatory Care (CAMAC)*.

Joint Commission Resources, a Joint Commission affiliate, publishes the ambulatory care standards in a variety of formats. You can review these options on the web at www.jcrinc.com or by phone to JCR's Customer Service Center at (877) 223-6866.

You may also take advantage of a complimentary Joint Commission resource called the Standards Interpretation Group, a help desk for answering specific standards-based questions. The phone number is (630) 792-5900 (Option 6 for Ambulatory Care settings); access a web-based question submission form at www.jointcommission.org.

For information about accrediting your urgent care center, contact The Joint Commission's Business Development unit at 630.792.5286, or visit www.jointcommission.org/UrgentCare

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Environment of Care (EC)

The goal of this chapter is to promote a safe, functional, and supportive environment within the organization so that quality and safety are preserved. The environment of care is made up of the following three basic elements:

- The building or space, including how it is arranged and special features that protect patients, visitors and staff
- Equipment used to support patient care or to safely operate the building or space
- People, including those who work within the organization, patients, and anyone else who enters the environment, all of whom have a role in minimizing risks

This chapter stresses the importance of managing risks in the environment of care, which are different from the risks associated with the provision of care, treatment, or services.

The standards are organized around the concepts of planning, implementing, and evaluating of results.

Important aspects of the environment addressed in the standards include the following:

- *Safety and security.* This section addresses risks in the physical environment, access to security sensitive areas, product recalls, and smoking.
- *Hazardous materials and waste.* This section addresses risks associated with hazardous chemicals, radioactive materials, hazardous energy sources, hazardous medications, and hazardous gases and vapors.
- *Fire safety.* This section addresses risks from fire, smoke, and other products of combustion; fire response plans; fire drills; and management of fire detection, alarm, and suppression equipment and systems.
- *Medical equipment.* This section addresses selection, testing, and maintenance of medical equipment and contingencies when equipment fails.
- *Utilities.* This section addresses inspection and testing of operating components, control of airborne contaminants, and management of disruptions.

Standard EC.02.01.01

The organization manages safety and security risks.

Rationale for EC.02.01.01

Safety and security risks are present in most health care environments. These risks affect all individuals in the organization – patients, visitors, and those who work in the organization. It is important to identify these risks in advance so that the organization can prevent or effectively respond to incidents. In some organizations, safety and security are treated as a single function, although others they are treated as separate functions.

Safety risks may arise from the structure of the physical environment, from the performance of everyday tasks, or from situations beyond the organization's control, such as the weather. Safety incidents are most often accidental.

On the other hand, security incidents are often intentional. Security protects individuals and property against harm or loss. Examples of security risks include workplace violence, theft, and unrestricted access to medications. Security incidents are caused by individuals from either outside or inside the organization.

Elements of Performance for EC.02.01.01

1. The organization identifies safety and security risks associated with the environment of care. Risks are identified from internal sources such as ongoing monitoring of the environment, results of root cause analyses, results of annual proactive risk assessments of high-risk processes, and from credible external sources such as Sentinel Event Alerts. (See also EC.04.01.01, EP 14; LD.04.04.05, EPs 7 and 8)

3. The organization takes action to minimize identified safety and security risks in the physical environment.

6. The organization manages safety risks related to entering and exiting the organization.

8. The organization controls access to and from areas it identifies as security sensitive.

11. The organization responds to product notices and recalls. (See also MM.05.01.17, EPs 1-4)

Standard EC.02.04.01

The organization manages medical equipment risks.

Elements of Performance for EC.02.04.01

1 The organization has a systematic approach to selecting and acquiring medical equipment.

2 The organization maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life support equipment) and equipment incident history. The organization evaluates new types of equipment before initial use to determine whether they should be included in the inventory. (See also EC.02.04.03, EPs 1 and 3)

3 The organization identifies the activities for maintaining, inspecting and testing for all medical equipment on the inventory. (See also EC.02.04.03, EPs 2 and 3)

Note: Organizations may use different maintenance strategies based on the type of equipment. Strategies must include defined intervals for inspecting, testing, and maintaining equipment on the inventory. Defined intervals are based on criteria such as manufacturers' recommendations, risk levels, and current organization experience. In addition, predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance may be selected to ensure reliable performance.

4 The organization identifies frequencies for inspecting, testing, and maintaining medical equipment on the inventory based on criteria such as manufacturers' recommendations, risk levels, or current organization experience. (See also EC.02.04.03, EPs 2 and 3)

5 The organization monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990.

6 The organization has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.

Standard EC.02.04.03

The organization inspects, tests, and maintains medical equipment.

Elements of Performance for EC.02.04.03

1 Before initial use of medical equipment on the medical equipment inventory, the organization performs safety, operational, and functional checks. (See also EC.02.04.01, EP 2)

2 The organization inspects, tests, and maintains all life support equipment. These activities are documented. (See also EC.02.04.01, EPs 3 and 4)

3 The organization inspects, tests, and maintains non-life support equipment identified on the medical equipment inventory. These activities are documented. (See also EC.02.04.01, EPs 2-4)

4 The organization conducts performance testing of and maintains all sterilizers. These activities are documented. (See also IC.02.02.01, EP 2)

Standard EC.02.06.01

The organization establishes and maintains a safe, functional environment.

Elements of Performance for EC.02.06.01

1 Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, or services provided.

7 For ambulatory surgery centers that elect to use The Joint Commission deemed status option: The organization provides separate waiting and postanesthesia recovery areas.

11 Lighting is suitable for care, treatment, or services.

13 The organization maintains ventilation, temperature, and humidity levels suitable for the care, treatment, or services provided.

20 Areas used by patients are clean.

23 The organization provides emergency access to all locked and occupied spaces.

Emergency Management (EM)

Emergencies can be threats to any health care organization. A single emergency can temporarily disrupt services; however, multiple emergencies that occur concurrently or sequentially can adversely impact patient safety and the organization's ability to provide care, treatment, or services for an extended length of time. Power failures, water and fuel shortages, flooding, and communication breakdowns are just a few of the hazards that can disrupt patient care and pose risks to staff and the organization.

The "Emergency Management" (EM) chapter is organized to allow organizations to plan to respond to the effects of potential emergencies that fall on a continuum from disruptive to disastrous.

The four phases of emergency management are mitigation, preparedness, response, and recovery. They occur over time; mitigation and preparedness generally occur before an emergency, and response and recovery occur during and after an emergency.

Organizations should identify the types of emergencies that could impact the organization's capacity to provide care, treatment, or services for its patients. This assessment is designed to assist organizations in gaining a realistic understanding of their vulnerabilities in order to help them mitigate and prepare to respond to emergencies and their impact. Organizations can plan for managing the following critical areas of their organizations so that they can respond effectively regardless of the cause(s) of an emergency:

- Communications
- Resources and assets
- Safety and security
- Staff responsibilities
- Utilities
- Patient clinical and support activities
- When organizations consider their capabilities in these areas, they are taking an approach to emergency management that supports a level of preparedness sufficient to address a range of emergencies.

Standard EM.02.01.01

The organization has an Emergency Management Plan.

Note: The organization's Emergency Management Plan is designed to coordinate its communications, resources and assets, safety and security, staff responsibilities, utilities, and patient clinical and support activities during an emergency (refer to Standards EM.02.02.01, EM.02.02.03, EM.02.02.05, EM.02.02.07, EM.02.02.09, and EM.02.02.11). Although emergencies have many causes, the effects on these areas of the organization and the required response effort may be similar. This "all hazards" approach supports a general response capability that is sufficiently nimble to address a range of emergencies of different duration, scale, and cause. For this reason, the Plan's response procedures address the prioritized emergencies, but are also adaptable to other emergencies that the organization may experience.

Rationale for EM.02.01.01

A successful response effort relies on a comprehensive and flexible Emergency Management Plan that guides decision-making regarding how the organization will respond to emergencies, including plans to continue to serve patients or to close in specified circumstances. The plan also supports decision-making at the onset of an emergency and as an emergency evolves. While the Emergency Management Plan can be formatted in a variety of ways, it must address response procedures that are adaptable in supporting key areas (such as communications and patient care) that might be affected by emergencies of different causes.

Elements of Performance for EM.02.01.01

1 The organization's leaders participate in the development of the Emergency Management Plan.

2 The organization has a written Emergency Management Plan that describes the response procedures to follow when emergencies occur. (See also EM.03.01.03, EP 5)

Note: The response procedures address the prioritized emergencies, but can also be adapted to other emergencies that the organization may experience. Response procedures could include the following:

- Maintaining or expanding services.
- Conserving resources.
- Curtailing services.
- Supplementing resources from outside the local community.
- Closing the organization to new patients.
- Staged evacuation.
- Total evacuation.

4 The organization has a written Emergency Management Plan that describes the recovery strategies, actions, and individual responsibilities necessary to restore the organization's care, treatment, or services after an emergency.

5 The Emergency Management Plan describes the processes for initiating and terminating the organization's response and recovery phases of the emergency, including under what circumstances these phases are activated.

Note: Mitigation, preparedness, response, and recovery are the four phases of emergency management. They occur over time; mitigation and preparedness generally occur before an emergency and response and recovery occur during and after the emergency.

6 The Emergency Management Plan identifies the individual(s) responsible for activating the response and recovery phases of the emergency response.

8 If the organization experiences an actual emergency, the organization implements its response procedures related to care, treatment, or services for its patients. (See also EM.02.02.03, EP 12)

Standard EM.02.02.03

As part of its Emergency Management Plan, the organization prepares for how it will manage resources and assets during emergencies.

Note: All organizations are required to respond to a patient's immediate care and safety needs if an emergency occurs with patients on site.

Rationale for EM.02.02.03

The organization that continues to provide care, treatment, or services to its patients during emergencies needs to determine how resources and assets (that is, supplies, equipment, and facilities) will be managed internally, and when necessary, solicited and acquired from external sources. The organization should also recognize the risk that some resources may not be available from planned sources, especially in emergencies of long duration or broad geographic scope, and that contingency plans will be necessary for critical supplies. This situation may occur when multiple organizations are vying for a limited supply from the same vendor.

Elements of Performance for EM.02.02.03

1 For organizations that plan to provide service during an emergency: The Emergency Management Plan describes how the organization will obtain and replenish medications and related supplies that will be required in response to an emergency.

2 For organizations that plan to provide service during an emergency: The Emergency Management Plan describes how the organization will obtain and replenish medical supplies that will be required in response to an emergency.

3 For organizations that plan to provide service during an emergency: The Emergency Management Plan describes how the organization will obtain and replenish non-medical supplies that will be required in response to an emergency.

12 For organizations that plan to provide service during an emergency: The organization implements the components of its Emergency Management Plan that require advance preparation to provide for resources and assets during an emergency. (See also EM.02.02.11, EP 1)

Standard EM.02.02.11

As part of its Emergency Management Plan, the organization prepares for how it will manage patients during emergencies.

Rationale for EM.02.02.11

The fundamental goal of emergency management planning is to protect life and prevent disability. The manner in which care, treatment or services are provided may vary by type of emergency. However, certain activities are so fundamental to patient safety (this can include decisions to modify or discontinue services, make referrals, or transport patients) that the organization should take a proactive approach in considering how they might be accomplished.

Elements of Performance for EM.02.02.11

1 The Emergency Management Plan describes how the organization will manage activities related to patient care, treatment, or services. (See also EM.02.02.03, EP 12)

Note: Activities related to care, treatment, or services might include scheduling, modifying, or discontinuing services; controlling information about patients; making referrals; transporting patients; and providing security.

3 The Emergency Management Plan describes how the organization will evacuate its occupied space.

11 The organization implements the components of its Emergency Management Plan that require advance preparation to manage patients during an emergency.

Standard EM.03.01.03

The organization evaluates the effectiveness of its Emergency Management Plan.

Rationale for EM.03.01.03

The organization conducts exercises to assess the Plan's appropriateness, adequacy, and the effectiveness of logistics, human resources, training, policies, procedures, and protocols. Exercises should stress the limits of the plan to support assessment of the organization's preparedness and performance. The design of the exercise should reflect likely disasters, but should test the organization's ability to respond to the effects of emergencies on their capabilities to provide care, treatment, and services.

Elements of Performance for EM.03.01.03

1 As an emergency response exercise, the organization activates its Emergency Management Plan twice a year at each site included in the Plan.

Note 1: If the organization activates its Plan in response to one or more actual emergencies, these emergencies can serve in place of emergency response exercises.

Note 2: Staff in freestanding buildings classified as a business occupancy (as defined by the Life Safety Code) that do not offer emergency services nor are community-designated as disaster-receiving stations need to conduct only one emergency management exercise annually.

Note 3: Tabletop sessions, though useful, are not acceptable substitutes for these exercises.
Footnote: The Life Safety Code is published by the National Fire Protection Association. Refer to NFPA 101-2000 for occupancy classifications.

2 For each site of the organization that offers emergency services or is a community-designated disaster receiving station, at least one of the organization's two emergency response exercises includes an influx of simulated patients.

Note: Tabletop sessions, though useful, cannot serve for this portion of the exercise.

5 Emergency response exercises incorporate likely disaster scenarios that allow the organization to evaluate its handling of communications, resources and assets, security, staff, utilities, and patients. (See also EM.02.01.01, EP 2)

13 Representatives from administrative, support, and clinical services participate in the evaluation of all emergency response exercises and all responses to actual emergencies.

14 The evaluation of all emergency response exercises and all responses to actual emergencies includes the identification of deficiencies and opportunities for improvement. This evaluation is documented.

16 The organization modifies its Emergency Management Plan based on its evaluations of emergency response exercises and responses to actual emergencies.

Note: When modifications requiring substantive resources cannot be accomplished by the next emergency response exercise, interim measures are put in place until final modifications can be made.

17 Subsequent emergency response exercises reflect modifications and interim measures as described in the modified Emergency Management Plan.

Human Resources (HR)

The contribution that human resources management makes to an organization's ability to provide safe, quality care cannot be overestimated.

The standards and elements of performance in this chapter address the organization's responsibility to establish and verify staff qualifications, orient staff, and provide staff with the training they need to support the care, treatment, or services the organization provides. Once staff is on the job, human resources must provide for the assessment of staff competence and performance.

This chapter also addresses the organization's responsibility to credential and privilege licensed independent practitioners and provide them with orientation and a fair hearing and appeal process.

Standard HR.01.02.07

The organization determines how staff function within the organization.

Elements of Performance for HR.01.02.07

1 All staff that provide patient care, treatment, or services possess a current license, certification, or registration, as required with law and regulation.

2 Staff who provide patient care, treatment, or services practice within the scope of their license, certification, or registration and as required by law and regulation. (See also HR.01.02.05, EPs 1 and 2)

5 Staff oversee the supervision of students when they provide patient care, treatment, or services as part of their training.

Standard HR.01.06.01

Staff are competent to perform their responsibilities.

Elements of Performance for HR.01.06.01

1 The organization defines the competencies it requires of its staff who provide patient care, treatment, or services.

3 An individual with the education background, experience, or knowledge related to the skills being reviewed assesses competence.

Note: When a suitable individual cannot be found to assess staff competence, the organization can utilize an outside individual for this task. Alternatively, the organization may consult the competency guidelines from an appropriate professional organization to make its assessment.

5 Staff competence is initially assessed and documented as part of orientation.

6 Staff competence is assessed and documented once every three years or more frequently as required by organization policy or in accordance with law and regulation.

15 The organization takes action when a staff member's competence does not meet expectations.

Standard HR.02.02.01

The organization provides orientation to licensed independent practitioners.

Elements of Performance for HR.02.02.01

1 The organization determines the key safety content of orientation provided to licensed independent practitioners.

Note: Key safety content may include specific processes and procedures related to the provision of care, the environment of care, and infection control.

2 The organization orients its licensed independent practitioners to key safety content before they provide care, treatment, or services. Completion of this orientation is documented.

3 The organization orients licensed independent practitioners on the following: Relevant policies and procedures. Completion of this orientation is documented.

4 The organization orients licensed independent practitioners on the following: Their specific responsibilities, including those related to infection prevention and control and assessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP 6 and RI.01.01.01, EP 8)

5 The organization orients licensed independent practitioners on the following: Sensitivity to cultural diversity based on their specific responsibilities. Completion of this orientation is documented.

Infection Prevention and Control (IC)

To help reduce the possibility of acquiring and transmitting an infection, ambulatory care centers should establish a systematic infection prevention and control program.

The processes outlined in this chapter are applicable to all infections or potential sources of infection that an ambulatory health care practitioner might encounter, including a sudden influx of potentially infectious patients.

These standards address activities of planning, implementation, and evaluation and are based on the following conditions necessary to establish and operate an effective infection prevention and control program. Every ambulatory care center, regardless of its size or the services it provides, should:

- Recognize that its infection prevention and control program plays a major role in its efforts to improve patient safety and quality of care
- Demonstrate leadership's commitment to infection prevention and control
- See that staff collaborate with each other when designing and implementing the infection prevention and control program
- Regularly assess its infection prevention and control program by using an approach that consists of surveillance, data collection, analysis, and trend identification
- Coordinate its program with the larger community
- Take into account that the potential exists for an infection outbreak so extensive that it overwhelms the ambulatory care center's resources

Standard IC.01.05.01

The organization plans for preventing and controlling infections.

Elements of Performance for IC.01.05.01

1 When developing infection prevention and control activities, the organization uses evidence-based national guidelines or, in the absence of such guidelines, expert consensus.

2 The organization plans infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection. These activities are documented.

3 The organization plans how it will evaluate its infection prevention and control activities. This method of evaluation is documented.

5 The organization describes, in writing, the method for investigating outbreaks of infectious disease within the organization. (See also IC.02.01.01, EP 5)

6 Everyone who works in the organization has responsibilities for preventing and controlling infection. (See also HR.01.04.01, EPs 2 and 4 and HR.02.02.01, EP 4)

7 The organization has a method for communicating responsibilities about preventing and controlling infection to licensed independent practitioners, staff, visitors, patients, and families. (See also IC.02.01.01, EP 7)

Note: Information may be in different forms of media, such as posters or pamphlets.

8 The organization identifies methods for reporting infection surveillance, prevention, and control information to external organizations. (See also IC.02.01.01, EPs 9-11)

Standard IC.02.02.01

The organization reduces the risk of infections associated with medical equipment, devices, and supplies.

Elements of Performance for IC.02.02.01

1 The organization implements infection prevention and control activities when doing the following: Cleaning and disinfecting medical equipment, devices, and supplies.

Note: Low-level disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions.

Footnote: For further information regarding cleaning and performing low-level disinfection of medical equipment, devices and supplies, refer to the Web site of the Centers for Disease Control and Prevention (CDC) at <http://www.cdc.gov/ncidod/dhqp/sterile.html> (Sterilization and Disinfection in Healthcare Settings).

2 The organization implements infection prevention and control activities when doing the following: Sterilizing medical equipment, devices, and supplies. (See also EC.02.04.03, EP 4)

Note: High-level disinfection is used for items such as respiratory equipment and specula. Sterilization is used for items implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes.

Footnote: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the Web site of the Centers for Disease Control and Prevention (CDC) at <http://www.cdc.gov/ncidod/dhqp/sterile.html> (Sterilization and Disinfection in Healthcare Settings).

3 The organization implements infection prevention and control activities when doing the following: Disposing of medical equipment, devices, and supplies.

4 The organization implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies.

5 When reprocessing single-use devices, the organization implements infection prevention and control activities that are consistent with regulatory and professional standards.

Standard IC.02.03.01

The organization works to prevent the transmission of infectious disease among patients, licensed independent practitioners, and staff.

Elements of Performance for IC.02.03.01

1 The organization makes screening for exposure and/or immunity to infectious disease available to licensed independent practitioners and staff who may come in contact with infections at the workplace.

2 When licensed independent practitioners or staff have, or are suspected of having, an infectious disease that puts others at risk, the organization provides them with or refers them for assessment, testing, immunization, prophylaxis/treatment, or counseling.

3 When licensed independent practitioners or staff have been occupationally exposed to an infectious disease, the organization provides them with or refers them for assessment, and potential testing, prophylaxis/treatment, or counseling.

4 When patients have been exposed to an infectious disease, the organization provides them with or refers them for assessment, and potential testing, prophylaxis/treatment, or counseling.

Information Management (IM)

Every episode of care generates health information that must be managed systematically by the organization. All data and information used by the organization is categorized, filed, and maintained. Health information should be accessed by authorized users who will use health

information to provide safe, quality care. Unauthorized access can be limited by the adoption of policies that address the privacy, security, and integrity of health information.

Planning is the initial focus of this chapter. A well planned system meets the internal and external information needs of the organization with efficiency and accuracy. Planning also provides for continuity in the event that the organization's operations are disrupted or fail. The organization also plans to protect the privacy, security, and integrity of the data and information it collects, which results in preserving confidentiality. The chapter concludes with a standard on maintaining accurate health information.

Requirements in this chapter apply to all types of information managed by the organization, unless the requirement specifically limits the type of information to health information.

Standard IM.02.01.01

The organization protects the privacy of health information.

Elements of Performance for IM.02.01.01

1 The organization has a written policy addressing the privacy of health information. (See also RI.01.01.01, EP 7)

Footnote: For ambulatory surgical centers that elect to use The Joint Commission deemed status option, this requirement is specified at 45 CFR 160 and 164.

2 The organization implements its policy on the privacy of health information. (See also RI.01.01.01, EP 7)

Footnote: For ambulatory surgical centers that elect to use The Joint Commission deemed status option, this requirement is specified at 45 CFR 160 and 164.

3 The organization uses health information only for purposes as required by law and regulation or as further limited by its policy on privacy. (See also MM.01.01.01, EP 1; RI.01.01.01, EP 7)

Footnote: For ambulatory surgical centers that elect to use The Joint Commission deemed status option, this requirement is specified at 45 CFR 160 and 164.

4 The organization discloses health information only as authorized by the patient or as otherwise consistent with law and regulation. (See also RI.01.01.01, EP 7)

Footnote: For ambulatory surgical centers that elect to use The Joint Commission deemed status option, this requirement is specified at 45 CFR 160 and 164.

5 The organization monitors compliance with its policy on the privacy of health information. (See also RI.01.01.01, EP 7)

Footnote: For ambulatory surgical centers that elect to use The Joint Commission deemed status option, this requirement is specified at 45 CFR 160 and 164.

Standard IM.02.02.01

The organization effectively manages the collection of health information.

Rationale for IM.02.02.01

Within the organization, health information can come from multiple sources. The use of standardized formats and terminology can help clarify information that is used by different individuals for various purposes. Capturing data in standardized language can lead to greater data integrity, and reliability, as well as an increased potential for ease of use by internal and external systems and users. The more consistent the organization's efforts are to capture accurate data in standardized language, the more likely the organization will be to rely on that data for patient-related purposes, including reimbursement, risk management, performance improvement, and infection surveillance.

Elements of Performance for IM.02.02.01

1 The organization uses uniform data sets to standardize data collection throughout the organization.

2 The organization has a written policy that includes the following:

- Terminology and definitions approved for use in the organization
- Abbreviations, acronyms, symbols and dose designations approved for use in the organization
- Abbreviations, acronyms, symbols, and dose designations prohibited from use in the organization, which include the following:
 - U,u
 - IU
 - Q.D., WD, q.d., qd
 - Q.O.D., QOD, q.o.d, qod
 - Trailing zero (X.0 mg)
 - MS
 - MSO4

Note: A trailing zero may be used only when required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report the size of lesion, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

Standard IM.02.02.03

The organization retrieves, disseminates, and transmits health information in useful formats.

Rationale for IM.02.02.03

The ease of use of health information between systems and users contributes to its potential usefulness within the organization and for external reporting purposes. Data stored in different formats cannot easily be converted to a new format or transferred to other organizations or providers. For example, immediate access to infection control data can impact patient safety within the organization and outside of the organization. As more organizations automate various processes and activities, these systems need to allow for transmitting and receiving critical data while maintaining data integrity.

Elements of Performance for IM.02.02.03

2 The organization's storage and retrieval systems make health information accessible when needed for patient care, treatment, or services. (See also IC.01.02.01, EP 1)

3 The organization disseminates data and information in useful formats within time frames defined by the organization and consistent with law and regulation.

Leadership (LD)

The safety and quality of care, treatment, or services depend on many factors including the following:

- A culture that fosters safety as a priority for everyone who works in the organization
- The planning and provision of services that meet the needs of patients
- The availability of resources—human, financial, and physical—for providing care, treatment, or services
- The existence of competent staff and other care providers
- Ongoing evaluation of and improvement in performance

Management of these important functions is the direct responsibility of leaders; they are, in effect, responsible for the care, treatment, or services that the organization provides to its patients.

This chapter is divided into four sections: *Leadership Structure*, *Leadership Relationships*, *Organization Culture and System Performance Expectations*, and *Operations*.

- *Leadership Structure* section identify and define the various leadership groups and their responsibilities.
- *Leadership Relationships* address the development of the organization's mission, vision, and goals and communication among leaders.
- *Organization Culture and System Performance Expectations* section focus on the framework for the organization's culture and systems. The standards also affect important systems within the organization (for example, data use, planning, communication, changing performance, staffing).
- *Operations* section address the functions that are important to patient safety and high-quality care, treatment, or services.

Standard LD.02.03.01

Leaders regularly communicate with each other on issues of safety and quality.

Rationale for LD.02.03.01

Leaders, who provide for safety and quality, must communicate with each other on matters affecting the organization and those it serves. The safety and quality of care, treatment, or services depend on open communication. Ideally, this will result in trust and mutual respect among those who work in the organization.

Elements of Performance for LD.02.03.01

1 Leaders discuss issues that affect the organization and the population it serves, including the following:

- Performance improvement activities.
- Reported safety and quality issues.
- Proposed solutions and their impact on the organization's resources.
- Reports on key quality measures and safety indicators.
- Safety and quality issues specific to the population served.
- Input from the population(s) served.

2 The organization establishes time frames for the discussion of issues that affect the organization and the population it serves.

Standard LD.03.02.01

The organization uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Rationale for LD.03.02.01

Data help organizations make the right decisions. When decisions are supported by data, organizations are more likely to move in directions that help them achieve their goals. Successful organizations measure and analyze their performance. When data are analyzed and turned into information, this process helps organizations see patterns and trends and understand the reasons for their performance. Many types of data are used to evaluate performance, including data on outcomes of care, performance on safety and quality initiatives, patient satisfaction, process variation, and staff perceptions.

Elements of Performance for LD.03.02.01

1 Leaders set expectations for using data and information to improve the safety and quality of care, treatment, or services.

2 Leaders are able to describe how data and information are used to create a culture of safety and quality.

3 The organization uses processes to support systematic data and information use.

4 Leaders provide the resources needed for data and information use, including staff, equipment, and information systems.

5 The organization uses data and information in decision-making that supports the safety and quality of care, treatment, or services. (See also PI.02.01.01, EP 8)

6 The organization uses data and information to identify and respond to internal and external changes in the environment.

7 Leaders evaluate how effectively data and information are used throughout the organization.

Standard LD.04.01.01

The organization complies with law and regulation.

Elements of Performance for LD.04.01.01

1 The organization is licensed, certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission.

Note: Each service location that performs laboratory testing (waived or non waived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations and applicable state law.
(See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)

2 The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.

3 Leaders act on or comply with reports or recommendations from external authorized agencies, such as accreditation, certification, or regulatory bodies.

Standard LD.04.03.01

The organization provides services that meet patient needs.

Elements of Performance for LD.04.03.01

1 The needs of the population served guide decisions about which services will be provided directly or through referral, consultation, contractual arrangements, or other agreements.

Standard LD.04.04.01

Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter)

Elements of Performance for LD.04.04.01

1 Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3)

2 Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPS 14-15)

3 Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.

4 Performance improvement occurs organization-wide.

Medication Management (MM)

A safe medication management system addresses an organization's medication processes, which in many organizations includes the following (as applicable):

- Planning
- Selection and procurement
- Storage
- Ordering
- Preparing and dispensing
- Administration
- Monitoring
- Evaluation

The “Medication Management” (MM) chapter addresses these critical processes, including those undertaken by the organization and those provided through contracted pharmacy services. However, the specifics of the medication management system used by the organization can vary depending on the care, treatment, or services it provides. Not all organizations will implement all of the medication processes.

In essence, a well-planned and implemented medication management system supports patient safety and improves the quality of care by doing the following:

- Reducing variation, errors, and misuse
- Using evidence-based practices to develop medication management processes
- Managing critical processes to promote safe medication management throughout the organization
- Standardizing equipment and handling processes, including those for sample medications, across the organization to improve the medication management system
- Monitoring the medication management process for efficiency, quality, and safety

Standard MM.01.01.01

The organization plans its medication management processes.

Rationale for MM.01.01.01

Medication management is often complicated, involving many people and processes. For this reason, the organization plans each part of the process with care so that safety and quality are maintained. This planning may involve the coordinated efforts of multiple services and disciplines.

Elements of Performance for MM.01.01.01

1 The organization has a written policy that describes that the following information is accessible to licensed independent practitioners and staff who participate in the management of the patient's medications:

- Age
- Sex
- Diagnoses
- Allergies
- Sensitivities
- Current medications
- Height and weight (when necessary)
- Pregnancy and lactation information (when necessary)
- Laboratory results (when necessary)
- Any additional information required by the organization
(See also IM.02.01.01, EP 3; RC.01.01.01, EP 13)

2 The organization implements its policy to make information about the patient accessible to licensed independent practitioners and staff who participate in the management of the patient's medications.

Note: This element of performance does not apply in emergency situations.

Standard MM.03.01.01

The organization safely stores medications.

Rationale for MM.03.01.01

Medication storage is designed to assist in maintaining medication integrity, promote the availability of medications when needed, minimize the risk of medication diversion, and reduce potential dispensing errors. Law and regulation and manufacturer guidelines further define the organization's approach to medication storage.

Elements of Performance for MM.03.01.01

2 The organization stores medications according to the manufacturer's recommendations.

3 The organization stores controlled (scheduled) medications to prevent diversion, in accordance with law and regulation.

5 The organization safely handles medications between receipt by licensed independent practitioners or staff and administration of the medications.

6 The organization prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulation.

7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.

8 The organization removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration.

9 The organization keeps concentrated electrolytes present in patient care areas only when patient safety necessitates their immediate use and precautions are used to prevent inadvertent administration. (See also MM.01.01.03, EP 2)

18 The organization periodically inspects all medication storage areas.

Standard MM.03.01.03

The organization safely manages any emergency medications.

Rationale for MM.03.01.03

Patient emergencies occur frequently in health care settings. The organization, therefore, needs to plan how it will address patient emergencies and what medications and supplies it will need. Although the processes may be different, the organization treats emergency medications with the same care for safety as it does medications in non-emergency settings.

Elements of Performance for MM.03.01.03

1 Organization leaders decide which, if any, emergency medications and their associated supplies will be readily accessible in patient care areas based on the population served.

2 Emergency medications and their associated supplies are readily accessible. (See also PC.03.01.01, EP 8)

3 Whenever possible, emergency medications are available in unit-dose, age-specific, and ready-to-administer forms.

6 When emergency medications or supplies are used, the organization replaces them as soon as possible to maintain a full stock.

Standard MM.03.01.05

The organization safely controls medications brought into the organization by patients, their families, or licensed independent practitioners.

Rationale for MM.03.01.05

A number of valid reasons exist for allowing the patient to use his or her own medications in an organization. The organization needs to control the use of these medications in order to protect the safety of the patient and the quality of care provided. Therefore, the organization needs to define its responsibilities for the safe use of these medications.

Elements of Performance for MM.03.01.05

1 The organization defines when medications brought into the organization by patients, their families, or licensed independent practitioners can be administered.

2 Before use or administration, of a medication brought into the organization by patients, his or her family, or licensed independent practitioner, the organization identifies the medication and visually evaluates the medication's integrity. (See also MM.05.01.07, EP 3 and MM.06.01.01, EP 4)

3 The organization informs the prescriber and patient if the medications brought into the organization by patients, their families, or licensed independent practitioners are not permitted.

National Patient Safety Goals (NPSG)

This chapter addresses the requirements of the 2010 National Patient Safety Goals (NPSGs). The purpose of The Joint Commission's NPSGs is to promote specific improvements in patient safety. The goals highlight problematic areas in health care and describe evidence- and expert-based consensus as solutions to these problems.

2010 goals are available directly on The Joint Commission's website at the following link: <http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>

NPSG.07.01.01

Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

Rationale for NPSG.07.01.01

According to the Centers for Disease Control and Prevention, each year, millions of people acquire an infection while receiving care, treatment, or services in a health care organization. Consequently, health care-associated infections (HAIs) are a patient safety issue affecting all types of health care organizations. One of the most important ways to address HAIs is by improving the hand hygiene of health care staff. Compliance with the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines will reduce the transmission of infectious agents by staff to patients, thereby decreasing the incidence of HAIs. To ensure compliance with this National Patient Safety Goal, an organization should assess its compliance with the CDC and/or WHO guidelines through a comprehensive program that provides a hand hygiene policy, fosters a culture of hand hygiene, and monitors compliance and provides feedback.

Elements of Performance for NPSG.07.01.01

1. Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)
2. Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)
3. Improve compliance with hand hygiene guidelines based on established goals.

Provision of Care, Treatment, and Services (PC)

The standards in the “Provision of Care, treatment, or services” (PC) chapter center around the integrated and cyclical process that allows care to be delivered according to patient needs and the organization’s scope of services.

The provision of care, treatment, or services is composed of four core components of the care process:

- Assessing patient needs
- Planning care, treatment, or services
- Providing care, treatment, or services
- Coordinating care, treatment, or services

Within these core processes, care activities include the following:

- Providing access to levels of care and/or disciplines necessary to meet the patient's needs
- Interventions based on the plan of care, including the education or instruction of patients regarding their care, treatment, or services
- Coordinating care to promote continuity when patients are referred, discharged, or transferred

The standards are organized to relate to the patient’s experience from entry into the organization to discharge or transfer, and address the following:

- Accepting the patient for care, treatment, or services
- Assessing and reassessing the patient
- Planning the patient’s care
- Providing the patient with care, treatment, or services
- Coordinating the patient’s care, treatment, or services
- Providing the patient with education
- Planning the patient’s operative or other high-risk procedures, including those that require the administration of moderate or deep sedation
- Meeting the patient’s need for continuing care, treatment, or services after discharge or transfer.

Standard PC.01.01.01

The organization accepts the patient for care, treatment, or services based on its ability to meet the patient's needs.

Elements of Performance for PC.01.01.01

7 The organization accepts a patient for care, treatment, or services based on whether its scope of services can meet the patient's needs. (See also LD.01.03.01, EP 3)

Standard PC.01.02.07

The organization assesses and manages the pain of patients who have pain.

Elements of Performance for PC.01.02.07

1 When warranted by the patient's condition, the organization either conducts or refers the patient for a comprehensive pain assessment. (See also PC.01.02.01, EP 2 and RI.01.01.01, EP 8)

2 The organization uses methods to assess pain that are consistent with the patient's age, condition, and ability to understand.

3 The organization reassesses and responds to the patient's pain, based on its reassessment criteria.

4 The organization either treats the patient's pain or refers the patient for treatment.

Standard PC.01.02.15

The organization provides for diagnostic testing.

Elements of Performance for PC.01.02.15

1 Diagnostic testing and procedures are performed as ordered.

2 Diagnostic testing and procedures are performed within time frames defined by the organization.

3 When a test report requires clinical interpretation, information necessary to interpret the results is provided with the request for the test.

Standard PC.02.01.09

The organization plans for and responds to life-threatening emergencies.

Elements of Performance for PC.02.01.09

1 The organization has written policies and procedures for responding to life-threatening emergencies.

3 The organization responds to life-threatening emergencies according to its policies and procedures.

4 For ambulatory surgery centers that elect to use The Joint Commission deemed status option: Staff trained in emergency equipment use and cardiopulmonary resuscitation are available whenever a patient is in the ambulatory surgery center. (See also HR.01.01.01, EP 13)

Standard PC.02.02.01

The organization coordinates the patient's care, treatment, or services based on the patient's needs.

Elements of Performance for PC.02.02.01

1 The organization has a process to receive or share patient information when the patient is referred to other internal or external providers of care, treatment, or services. (See also PC.04.02.01, EP 1)

2 The organization's process for hand-off communication provides for the opportunity for discussion between the giver and receiver of patient information.

Note: Such information may include the patient's condition, care, treatment, medications, services, and any recent or anticipated changes to any of these.

10 When the organization uses external resources to meet the patient's needs, it participates in coordinating the patient's care, treatment, or services.

17 The organization coordinates care, treatment, or services within a time frame that meets the patient's needs.

Standard PC.04.01.05

Before the organization discharges or transfers a patient, it informs and educates the patient about his or her follow-up care, treatment, and services.

Elements of Performance for PC.04.01.05

1 When the organization determines the patient's discharge or transfer needs, it promptly shares this information with the patient.

7 The organization educates the patient about how to obtain any continuing care, treatment, or services that he or she will need.

8 The organization provides written discharge instructions in a manner that the patient and/or the patient's family or care-giver can understand.
(See also RI.01.01.03, EP 1)

Performance Improvement (PI)

All organizations want better patient outcomes and, therefore, are concerned about improving the safety and quality of the care they provide. The best way to achieve better care is by first measuring the performance of processes that support care and then by using that data to make improvements. The standards in this chapter stress the importance of using data to inform positive change.

Collecting data is the foundation of performance improvement. The Joint Commission has identified important processes that should always be measured because they involve risk and can harm patients.

Regardless of how much data the organization collects, data are not useful if they are not analyzed. Analysis identifies trends, patterns, and performance levels that suggest opportunities for improvement. The organization can then make improvements based on the analysis.

The standards in this chapter address the fundamental principles of performance improvement: collecting data, analyzing them, and taking action to improve.

Standard PI.02.01.01

The organization compiles and analyzes data.

Elements of Performance for PI.02.01.01

- 1 The organization compiles data in usable formats.
- 2 The organization identifies the frequency for data analysis.
- 4 The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.
- 5 The organization compares data with external sources, when available.
- 8 The organization uses the results of data analysis to identify improvement opportunities. (See also LD.03.02.01, EP 5 and PI.03.01.01, EP 1)

Standard PI.03.01.01

The organization improves performance.

Elements of Performance for PI.03.01.01

- 1 Leaders prioritize the identified improvement opportunities. (See also PI.02.01.01, EP 8)
- 2 The organization takes action on improvement priorities.

- 3 The organization evaluates actions to confirm they resulted in improvements.
- 4 The organization takes action when it does not achieve or sustain planned improvements.

Record of Care, Treatment, and Services (RC)

The “Record of Care, Treatment, and Services” (RC) chapter contains a wealth of information about the components of a complete clinical record. The record of care functions not only as a historical record of a patient’s episode(s) of care, but also as a method of communication between practitioners and staff that can facilitate the continuity of care and aid in clinical decision-making.

In many organizations, patient care is episodic. The organization may only see the patient once or twice, depending on the patient’s need and the organization’s scope of services.

Within this chapter, those responsible for compiling the clinical record can find a comprehensive set of requirements for its contents. The separate components of a complete clinical record are listed and arranged within common groups (demographic, clinical, and additional information). This chapter also contains documentation requirements for screenings, assessments, and reassessments; pre- and postoperative procedures; the administration of moderate or deep sedation or anesthesia; restraint and seclusion; the clinical procedures themselves; and discharge. Standards provide policies and procedures that guide the compilation, completion, authentication, retention, and release of records.

Standard RC.01.03.01

Documentation in the clinical record is entered in a timely manner.

Elements of Performance for RC.01.03.01

- 1 The organization has a written policy that requires timely entry of information into the clinical record. (See also PC.01.02.03, EP 1)
- 2 The organization defines the time frame for completion of the clinical record.
- 3 The organization implements its policy requiring timely entry of information into the patient’s clinical record. (See also PC.01.02.03, EP 2)

Standard RC.01.04.01

The organization audits its clinical records.

Elements of Performance for RC.01.04.01

1 According to a time frame it defines, the organization reviews its clinical records to confirm that the required information is present, accurate, legible, authenticated, and completed on time.

Standard RC.02.03.07

Qualified staff receive and record verbal orders.

Elements of Performance for RC.02.03.07

1 The organization identifies in writing the staff who are authorized to receive and record verbal orders, in accordance with law and regulation.

2 Only authorized staff receive and record verbal orders.

3 Documentation of verbal orders includes the date and the names of individuals who gave, received, recorded, and implemented the order.

4 Verbal orders are authenticated within the time frame specified by law and regulation.

Rights and Responsibilities of the Individual (RI)

When the organization recognizes and respects patient rights, it is providing an important aspect of care that has been shown to encourage patients to become more informed and involved in their care. Recognizing and respecting patient rights directly impact the provision of care. Care, treatment, or services should also be carefully planned and provided with regard to the patient's personal values, beliefs, and preferences.

Recognizing and respecting patient rights are, however, only part of the story. Patients also have the obligation to take on certain responsibilities. The organization defines these responsibilities and then relays them to the patient.

The standards in this chapter address the following processes and activities as they relate to patient rights:

- Informing patients of their rights
- Helping patients understand and exercise their rights
- Respecting patients' values, beliefs, and preferences
- Informing patients of their responsibilities regarding their care, treatment, or services

Standard RI.01.01.03

The organization respects the patient's right to receive information in a manner he or she understands.

Elements of Performance for RI.01.01.03

1 The organization provides information in a manner tailored to the patient's age, language, and ability to understand. (See also RI.01.01.01, EPs 3 and 5, and PC.04.01.05, EP 8)

2 The organization provides interpreting and translation services, as necessary. (See also RI.01.01.01, EP 3)

3 The organization communicates with the patient who has vision, speech, hearing, or cognitive impairments in a manner that meets the patient's needs. (See also RI.01.01.01, EP 3)

Standard RI.01.04.01

The organization respects the patient's right to receive information about the individual(s) responsible for his or her care, treatment, or services.

Elements of Performance for RI.01.04.01

1 The organization informs the patient of the name of the physician or other practitioner who has primary responsibility for his or her care, treatment, or services.

2 The organization informs the patient of the name of the physician(s) or other practitioner(s) who will provide his or her care, treatment, or services.

Standard RI.01.07.01

The patient and his or her family have the right to have complaints reviewed by the organization.

Elements of Performance for RI.01.07.01

1 The organization establishes a complaint resolution process.

2 The organization informs the patient and his or her family about the complaint resolution process.

4 The organization reviews and, when possible, resolves complaints from the patient and his or her family.

Waived Testing (WT)

A laboratory test is an activity that evaluates a substance(s) removed from a human body and translates the evaluation into a result.

Test results that are used to assess a patient condition or make a clinical decision about a patient are governed by the federal regulations known as the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). CLIA '88 classifies testing into four complexity levels: high complexity, moderate complexity, provider performed microscopy (PPM procedures, a subset of moderate complexity), and waived testing. The high, moderate, and PPM levels, otherwise called nonwaived testing, have specific and detailed requirements regarding personnel qualifications, quality assurance, quality control, and other systems. Waived testing, on the other hand, has few requirements and is less stringent than the requirements for nonwaived testing.

When a patient performs a test on him- or herself (for example, whole blood glucose testing by a patient on his or her own meter cleared by the FDA for home use), the action is not regulated. Only testing performed by staff on patients is an activity regulated by CLIA '88. The Joint Commission standards apply to staff using instruments owned by staff, owned by the organization, or owned by the patient in performing waived laboratory tests.

Note: The Joint Commission requirements for laboratories or sites that perform non-waived testing are located in the “Quality Control” (QC) chapter of *The Comprehensive Manual for Laboratory and Point-of-Care Testing*.

Standard WT.02.01.01

The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate identifies the staff responsible for performing and supervising waived testing.

Note 1: Responsible staff may be employees of the organization, contracted staff, or employees of a contracted service.

Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names.

Elements of Performance for WT.02.01.01

1 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or a qualified designee identifies in writing the staff responsible for performing waived testing.

2 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or a qualified designee identifies in writing the staff responsible for supervising waived testing.

Standard WT.04.01.01

The organization performs quality control checks for waived testing on each procedure.

Note: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.

Elements of Performance for WT.04.01.01

1 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate establishes a written quality control plan for waived testing that specifies the method(s) for controlling procedures for quality, establishes timetables, and explains the rationale for choice of procedures and timetables. (See also LD.04.01.01, EP 1)

2 The documented quality control rationale for waived testing is based on the following:

- How the test is used.
- Reagent stability.
- Manufacturers' recommendations.
- The organization's experience with the test.
- Currently accepted guidelines.

3 For non instrument-based waived testing, quality control checks are performed at the frequency and number of levels recommended by the manufacturer and as defined by the organization's policies. (See also WT.01.01.01, EP 6)

Note: If these elements are not defined by the manufacturer, the organization defines the frequency and number of levels for quality control.

4 For instrument-based waived testing, quality control checks are performed each day on each instrument used for patient testing or per manufacturer's instructions, if more stringent. (See also WT.01.01.01, EP 6)

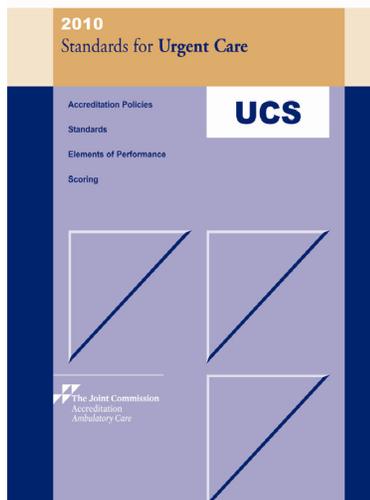
Note: Quality control checks are not required on an individual instrument on days when it is not used for patient testing.

5 For instrument-based waived testing, quality control checks require two levels of control, if commercially available. (See also WT.01.01.01, EP 6)

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