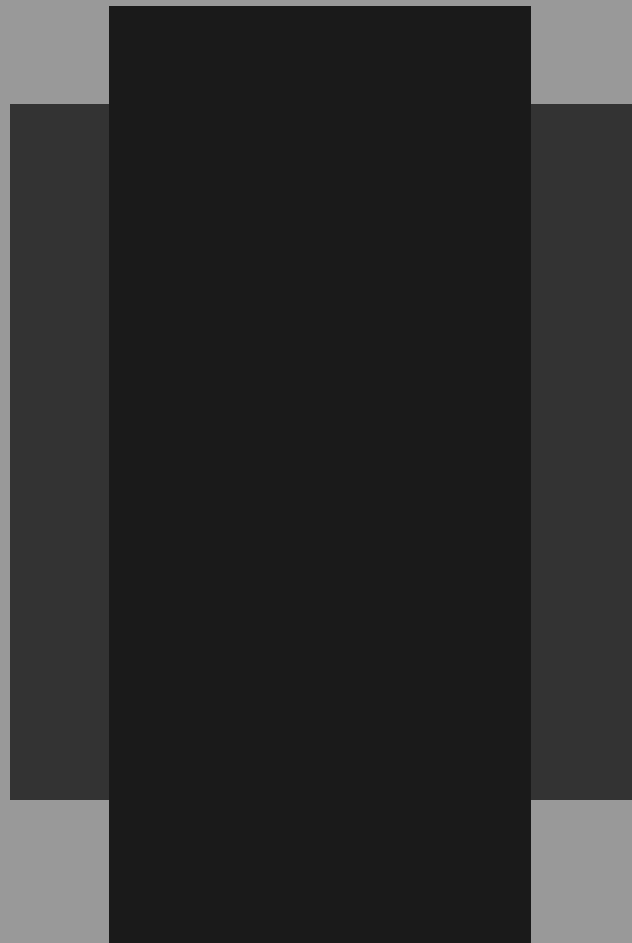


# Standards Sampler for Office-Based Surgery



# Standards Sampler for Office-Based Surgery (OBS)

## Introduction

The *Comprehensive Accreditation Manual for Office-Based Surgery (CAMOBS)* contains the set of standards that have been designed specifically to evaluate office-based surgery organizations. 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 Office-Based Surgery*. The *Standards Sampler* 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 practice 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 practice’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 practice 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.

### **1A. 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.

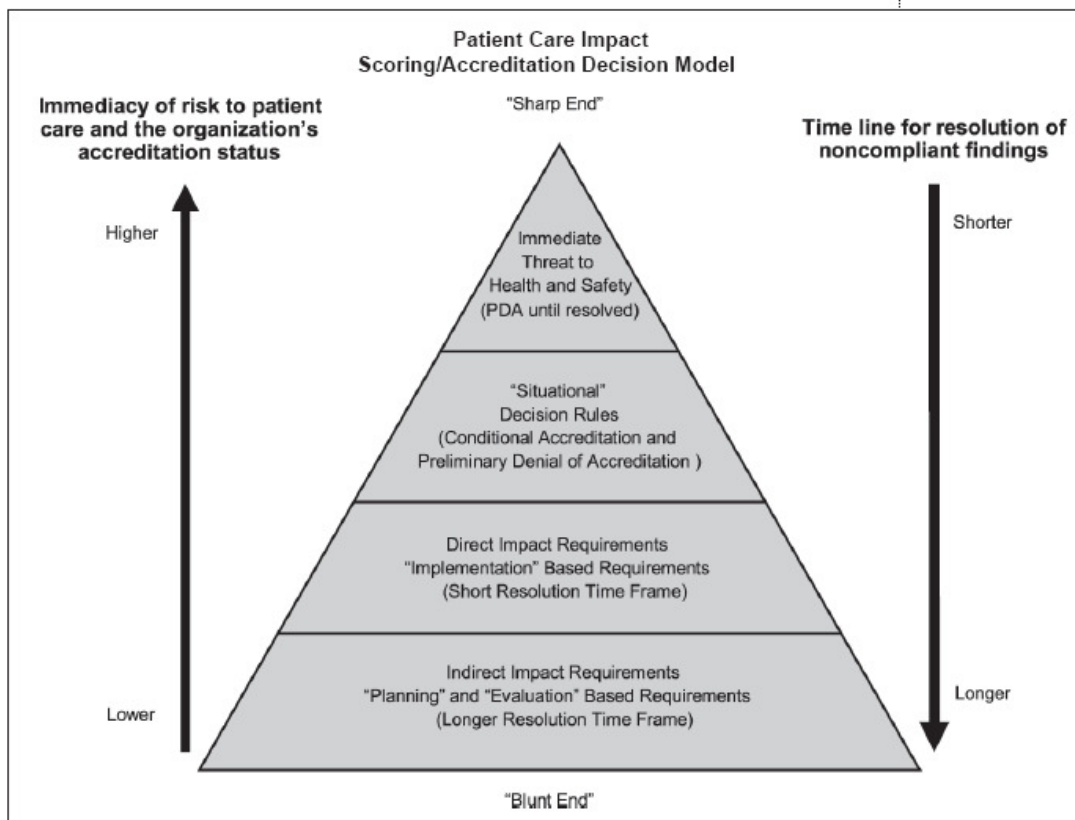


Figure 4. Accreditation based on impact on patient care.

Please share these examples of office-based surgery standards with your staff. You'll likely see that much of what is required for accreditation is already in place in your practice.

The full text for all of these standards can be found in the *Comprehensive Accreditation Manual for Office-Based Surgery (CAMOBS)*.

Joint Commission Resources, a Joint Commission affiliate, publishes the office-based surgery standards in a variety of formats. You can review these options on the web at [www.jcrinc.com](http://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 Office-Based Surgery settings); access a web-based question submission form at [www.jointcommission.org](http://www.jointcommission.org).

For information about accrediting your OBS practice, contact The Joint Commission's Business Development unit at 630.792.5286, or visit [www.jointcommission.org/OBS](http://www.jointcommission.org/OBS).

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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 office 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 office 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 in 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.02.02.01**

The organization manages risks related to hazardous materials and waste.

### **Elements of Performance for EC.02.02.01**

3. The organization has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures.
4. The organization implements its procedures in response to hazardous material and waste spills or exposures.
5. The organization minimizes risks associated with selecting, handling, storing, transporting, using, and disposing hazardous chemicals.
6. The organization minimizes risks associated with selecting, handling, storing, transporting, using, and disposing radioactive materials.
7. The organization minimizes risks associated the selection and use of hazardous energy sources.  
*Note:* Hazardous energy is produced by both ionizing equipment (for example, radiation and x-ray equipment) and nonionizing equipment (for example, lasers and MRIs).
8. The organization minimizes risks associated with disposing hazardous medications. (See also MM.01.01.03, EPs 1-3)
9. The organization minimizes risks associated with selecting, handling, storing, transporting, using, and disposing hazardous gases and vapors.  
*Note:* Hazardous gases and vapors include, but are not limited to, glutaraldehyde, ethylene oxide, vapors generated while using cauterizing equipment and lasers, and gases such as nitrous oxide.

10. The organization monitors levels of hazardous gases and vapors to determine that they are in safe range.

*Note:* Law and regulation determine the frequency of monitoring hazardous gases and vapors as well as acceptable ranges.

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### **Standard EC.02.03.03**

The [organization] conducts fire drills.

#### **Rationale for EC.02.03.03**

The organization's plan for fire response is an important part of achieving a fire-safe environment. It is important that this response be evaluated in drill scenarios or actual fire situations in order to assess performance of staff and fire safety equipment. Testing the fire response plan should involve realistic situations, although actual evacuation of patients during the drills is not required.

#### **Elements of Performance for EC.02.03.03**

1. The organization conducts quarterly fire drills in each building defined as an ambulatory health care occupancy by the Life Safety Code. (See also LS.01.02.01, EP 11; LS.03.01.70; EP6)

*Note 1:* Evacuation of patients during drills is not required.

*Note 2:* In leased or rented facilities, drills need be conducted only in areas of the building that the organization occupies.

2. The organization conducts fire drills every 12 months from the date of the last drill in each area that is defined as a business occupancy by the Life Safety Code and in which care, treatment, or services are provided- or quarterly for ambulatory surgical centers seeking accreditation for Medicare certification.

*Note 1:* In leased or rented facilities, drills need to be conducted only in areas of the building that the organization occupies.

*Note 2:* In sites that are used on average 70 hours or less per month, the organization may choose either to review the fire response plan or to conduct a fire drill every 12 months. This note does not apply to ambulatory surgical centers that elect to use The Joint Commission deemed status option

5. The organization critiques fire drills. (See also EC.02.03.01, EP 10)

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### **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.

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.

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

20. Areas used by patients are clean.

## **Emergency Management (EM)**

Emergencies can be threats to any OBS 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.

### **Standard EM.02.01.01**

The organization has an Emergency Management Plan.

*Note:* The organization's Emergency Management Plan (EMP) is designed to coordinate its communications, resources and assets, safety and security, and patient clinical and support activities during an emergency (refer to EM.02.02.01, EM.02.02.03, EM.02.02.05, 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 way, 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**

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, EP5)

*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
- Staged Evacuation
- Total Evacuation

8. If the organization experiences an actual emergency, the organization implements its response procedures related to care, treatment, or services for its patients.

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### **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.

### **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, particularly 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**

12. The organization implements the components of its Emergency Management Plan that require advance preparation to provide for resources and assets during an emergency.

## **Human Resources (HR)**

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.01.02.05**

The organization verifies staff qualifications.

### **Elements of Performance for HR.01.02.05**

1. When law or regulation requires care providers to be currently licensed, certified, or registered to organization their professions, the organization both verifies these credentials with the primary source and documents this verification when a provider is hired and when his or her credentials are renewed. (See also HR.01.02.07, EP 2)

*Note 1:* It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented.

*Note 2:* A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source.

*Note 3:* An external organization (for example, a credentials verification organization (CVO)) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.

2. When the organization requires licensure, registration, or certification not required by law and regulation, the organization both verifies these credentials and documents this verification at time of hire and when credentials are renewed. (See also HR.01.02.07, EP 2)

6. The organization uses the following information from HR.01.02.05, Elements of Performance 1 and 2, to make decisions about staff job responsibilities:

- Required licensure, certification, or registration verification
- Required credentials verification

7. Before providing care, treatment, or services, the organization confirms that nonemployees who are brought into the organization by a licensed independent practitioner to provide care, treatment, or services have the same qualifications and competencies required of employed individuals performing the same or similar services at the organization.

*Note 1:* This confirmation can be accomplished either through the organization's regular process or with the licensed independent practitioner who brought in the individual.

*Note 2:* When the care, treatment, or services provided by the nonemployee are not currently performed by anyone employed by the organization, organization leaders consult the appropriate professional organization guidelines for the required credentials and competencies.

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## **Standard HR.01.04.01**

The organization provides orientation to staff.

### **Elements of Performance for HR.01.04.01**

1. The organization determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3)

*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 staff to the key safety content before staff provides care, treatment, or services. Completion of this orientation is documented.

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

4. The organization orients staff on the following: Their specific job duties, including those related to infection prevention and control and accessing and managing pain. Completion of this orientation is documented. (See also IC.01.05.01, EP6; IC.02.01.01, EP 7; RI.01.01.01, EP8)

### **Standard HR.01.06.01**

Staff are competent to perform their responsibilities.

#### **Elements of Performance for HR.01.06.01**

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.
- 

### **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, EP6; RI.01.01.01, EP8)

## **Infection Prevention and Control (IC)**

To help reduce the possibility of acquiring and transmitting an infection, OBS organizations 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.

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 OBS organization, 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

### **Standard IC.01.02.01**

Organization leaders allocate needed resources for infection prevention and control activities.

#### **Elements of Performance for IC.01.02.01**

1. The organization provides access to information needed to support infection prevention and control activities. (See also IM.02.02.03, EP 2)
  2. The organization provides for laboratory resources when needed to support infection prevention and control activities. (See also IC.01.05.01, EP 2; IC.02.01.01, EPs 2 and 3; LD.03.03.01, EP 4)
- 

### **Standard IC.01.03.01**

The organization identifies risks for acquiring and transmitting infections.

#### **Elements of Performance for IC.01.03.01**

1. The organization identifies infection risks based on the following: Its geographic location, community, and population served.
  2. The organization identifies infection risks based on the following: The care, treatment, or services it provides.
  3. The organization identifies infection risks based on the following: The analysis of its infection surveillance and control data. (See also TS.03.03.01, EP 2)
  5. The organization prioritizes the identified risks for acquiring and transmitting infections. These prioritized risks are documented.
- 

### **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.

7. The organization has a method for communicating responsibilities about preventing and controlling infection to licensed independent practitioners, staff, visitors, patients, and families. Information for visitors, patients, and families includes hand and respiratory hygiene practices. (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.

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### **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: Performing low-level disinfection of medical supplies and devices.

*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: performing intermediate and high-level disinfection and sterilization of 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 such as 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.

### **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.

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### **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) (See page 63)
  2. The organization implements its policy on the privacy of health information. (See also RI.01.01.01, EP 7) (See page 63)
- 

### **Standard IM.02.01.03**

The organization maintains the security and integrity of health information.

#### **Elements of Performance for IM.02.01.03**

1. The organization has a written policy addressing the security of health information, including access, use, and disclosure.
2. The organization has a written policy addressing the integrity of health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.
3. The organization has a written policy addressing the intentional destruction of health information.
4. The organization defines when and by whom the removal of health information is permitted. Note: Removal refers to those actions that place health information outside the organization's control.
6. The organization protects health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.
7. The organization controls the intentional destruction of health information.

## **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 practice
- 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 practice provides to its patients.

This chapter is divided into four sections:

- *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 practice’s culture and systems. The standards also affect important systems within the practice (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.

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### **Standard LD.01.03.01**

Governance is ultimately accountable for the safety and quality of care, treatment, or services.

#### **Rationale for LD.01.03.01**

Governance’s ultimate responsibility for safety and quality derives from their legal responsibility and operational authority for organization performance. In this context, organization leaders provide for internal structures and resources, including staff, that support safety and quality.

#### **Elements of Performance for LD.01.03.01**

1. Governance defines in writing its responsibilities.
3. Governance approves the organization's written scope of services. (See also PC.01.01.01, EP 7)

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### **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.
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### **Standard LD.03.06.01**

Those who work in the organization are focused on improving safety and quality.

### **Rationale for LD.03.06.01**

The safety and quality of care, treatment, or services are highly dependent on the people who work in the organization. The mission, scope, and complexity of services define the design of work processes and the skills and number of individuals needed. In a successful [organization], work processes and the environment make safety and quality paramount. This standard, therefore, applies to all those who work in or for the organization, including staff and licensed independent practitioners.

### **Elements of Performance for LD.03.06.01**

1. Leaders design work processes to focus individuals on safety and quality issues.
2. Leaders are able to describe how those who work in the organization support a culture of safety and quality.
3. Leaders provide for a sufficient number and mix of individuals to support safe, quality care, treatment, or services. (See also IC.01.01.01., EP 3)
4. Those who work in the organization are competent to complete their assigned responsibilities.

5. Those who work in the organization adapt to changes in the environment.
  6. Leaders evaluate the effectiveness of those who work in the organization to promote safety and quality.
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### **Standard LD.04.02.03**

Ethical principles guide the organization's business organizations.

### **Elements of Performance for LD.04.02.03**

4. Marketing materials accurately represent the organization and address the care, treatment, or services that the organization provides either directly or by contractual arrangement.
  5. Care, treatment, or services are provided based on patient needs, regardless of compensation or financial risk-sharing with those who work in the organization, including staff and licensed independent practitioners.
  7. Patients receive information about charges for which they will be responsible.
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### **Standard LD.04.04.01**

Leaders establish priorities for performance improvement. (See also 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 4, 6-7, and 14-15)
3. Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.

## **Life Safety (LS)**

This chapter applies only to sites of care that are considered ambulatory health care occupancies. The National Fire Protection Agency's (NFPA) *Life Safety Code (101-2000)* defines an ambulatory health care occupancy as a building or part of a building in which anesthesia or outpatient services are provided to four or more outpatients at the same time, making them incapable of saving themselves in emergencies.

### **Standard LS.01.01.01**

The organization designs and manages the physical environment to comply with the Life Safety Code.

*Note:* This standard applies to sites of care where four or more patients at the same time are provided either anesthesia or outpatient services that render patients incapable of saving themselves in the event of an emergency in the organization.

#### **Elements of Performance for LS.01.01.01**

1. The organization assigns an individual(s) to assess compliance with the Life Safety Code, complete the electronic Statement of Conditions (e-SOC), and manage the resolution of deficiencies.

2. The organization maintains a current electronic Statement of Conditions (e-SOC).

*Note:* The (e-SOC) is available to each organization through The Joint Commission Connect extranet site.

3. When the organization plans to resolve a deficiency through a Plan for Improvement (PFI), the organization meets the time frames identified in the PFI accepted by The Joint Commission. (See also LS.01.02.01, EPs 1,2,4-14)

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### **Standard LS.03.01.70**

The organization provides and maintains operating features that conform to fire and smoke prevention requirements.

*Note 1:* This standard applies to sites of care where four or more patients at the same time are provided either anesthesia or outpatient services that render patients incapable of saving themselves in an emergency in the organization.

*Note 3:* In leased facilities, the elements of performance of this standard apply only to the space in which the accredited organization is located; all exits from the space to the outside at grade level; and any Life Safety Code building systems that support the space (for example, fire alarm system, automatic sprinkler system).

#### **Elements of Performance for LS.03.01.70**

1. The organization prohibits all combustibles decorations that are not flame retardant. (For full text and any exceptions, refer to NFPA 101-2000: 20/21.7.5.4)

2. Soiled linen and trash receptacles larger than 32 gallons (including recycling containers) are located in a room protected as a hazardous area. (For full text and any exceptions, refer to NFPA 101-2000: 20/21.7.5.5)

3. The organization prohibits portable space heaters in smoke compartments containing patient treatment and sleeping areas. (For full text and any exceptions, refer to NFPA 101-2000: 20/21.7.8)

4. The organization does not allow unvented fuel-fired heaters. (For full text and any exceptions, refer to NFPA 101-2000: 20/21.5.2.2)

5. All heating appliances are provided with safety features to stop the flow of fuel and turn off the appliance during times of excessive temperatures or ignition failure. (For full text and any exceptions, refer to NFPA 101-2000: 20/21.5.2.2)

6. The organization meets all other Life Safety Code operating feature requirements related to NFPA 101-2000: 20/21.7. (See also EC.02.03.03, EP 1)

## **Medication Management (MM)**

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

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

The specifics of the medication management system used by the OBS 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 organizations 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

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### **Standard MM.01.01.03**

The organization safely manages high-alert and hazardous medications.

#### **Rationale for MM.01.01.03**

High-alert medications are those medications involved in a high percentage of errors and/or sentinel events, as well as medications that carry a higher risk for abuse or other adverse outcomes. Lists of high-alert medications are available from such organizations as the Institute for Safe Medication Organizations (ISMP). (<http://ismp.org/Tools/highalert/medication.pdf>). Examples of high-alert medications include investigational medications, controlled medications, medications not on the approved Food and Drug Administration (FDA) list, medications with a narrow therapeutic range, psychotherapeutic medications, and look-alike/sound-alike medications.

Hazardous medications are those in which studies in animals or humans indicate that exposures to them have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs.

Lists of hazardous medications are available from organizations such as the National Institute for Occupational Safety and Health (NIOSH) (<http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html#o>).

For safe management, the organization needs to develop its own list(s) of high-alert drugs based on its unique utilization patterns of medications and its own internal data about medication errors and sentinel events. It is up to the organization to determine whether medications that are new to the market or new to the organization are high alert or hazardous.

### **Elements of Performance for MM.01.01.03**

1. The organization identifies, in writing, its high-alert medications. (See also EC.02.02.01, EP 8)

Footnote: For a list of high-alert medications, see [www.ismp.org/](http://www.ismp.org/). For a list of hazardous medications, see <http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html#o>.

2. The organization has a process for managing high-alert medications. (See also EC.02.02.01, EP 8; MM.03.01.01, EP 9)

3. The organization implements its process for managing high-alert medications. (See also EC.02.02.01, EPs 1 and 8)

4. The organization minimizes risks associated with managing hazardous medications. (See also EC.02.02.01, EP 8)

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### **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 manufacturers' 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 manufacturers' 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 medications.

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)

### **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 nonemergency settings.

#### **Elements of Performance for MM.03.01.03**

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

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

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### **Standard MM.06.01.01**

The organization safely administers medications.

#### **Elements of Performance for MM.06.01.01**

1. The organization defines, in writing, licensed independent practitioners and the clinical staff disciplines that are authorized to administer medication, with or without supervision, in accordance with law and regulation.

2. Only authorized licensed independent practitioners and clinical staff administer medications.

*Note:* This does not prohibit self-administration of medications by patients when indicated.

3. Before administration, the individual administering the medication does the following: Verifies that the medication selected matches the medication order and product label.

4. Before administration, the individual administering the medication does the following: Visually inspects the medication for particulates, discoloration, or other loss of integrity. (See also MM.03.01.05, EP 2; MM.05.01.07, EP 3)

5. Before administration, the individual administering the medication does the following: Verifies the medication has not expired.

6. Before administration, the individual administering the medication does the following: Verifies that no contraindications exist.

### **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/>

## **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.

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### **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.02.01.09**

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

#### **Elements of Performance for PC.02.01.09**

5. In the event of a patient emergency, at least two staff members are on site at all times when a patient is undergoing a procedure(s) and until the patient is discharged. (See also PC.03.01.01, EPs 3 and 4)
  6. Staff members have been trained in the roles they play during medical emergencies.
  7. Staff members know when and how to use emergency medical services and other community resources to help in a medical emergency.
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### **Standard PC.03.01.05**

The organization monitors the patient during operative or other high-risk procedures and/or during the administration of moderate or deep sedation or anesthesia.

#### **Elements of Performance for PC.03.01.05**

1. During operative or other high risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously. (See also RC.02.01.03, EP 8)
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### **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**

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 caregiver 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.

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### **Standard PI.01.01.01**

The organization collects data to monitor its performance.

#### **Elements of Performance for PI.01.01.01**

1. The leaders set priorities for data collection. (See also LD.04.04.01, EP 1)
  2. The organization identifies the frequency for data collection.
  3. The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.04.04.01, EP 1)
  4. The organization collects data on the following: Operative or other procedures that place patients at risk of disability or death. (See also LD.04.04.01, EP 2)
  5. The organization collects data on the following: All significant discrepancies between preoperative and postoperative diagnoses, including pathologic diagnoses.
  6. The organization collects data on the following: Adverse events related to using moderate or deep sedation or anesthesia. (See also LD.04.04.01, EP 2)
  7. The organization collects data on the following: The use of blood and blood components. (See also LD.04.04.01, EP 2)
  14. The organization collects data on the following: Significant medication errors. (See also LD.04.04.01, EP 2; MM.08.01.01, EP 1)
  15. The organization collects data on the following: Significant adverse drug reactions. (See also LD.04.04.01, EP 2; MM.08.01.01, EP 1)
  16. The organization collects data on the following: Patient perception of the safety and quality of care, treatment, or services.
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### **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.

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.

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### **Standard RC.01.01.01**

The organization maintains complete and accurate clinical records.

#### **Elements of Performance for RC.01.01.01**

1. The organization defines the components of a complete clinical record.
5. The clinical record contains the information needed to support the patient’s diagnosis and condition.
7. The clinical record contains information that documents the course and result of the patient's care, treatment, or services.
8. The clinical record contains information about the patient’s care, treatment, or services that promotes continuity of care among providers.
11. All entries in the clinical record are dated.
12. The organization tracks the location of all components of the clinical record.
13. The organization assembles or makes available in a summary in the clinical record all information required to provide patient care, treatment, or services. (See also MM.01.01.01, EP 1)
14. When needed to provide care, summaries of treatment and other documents provided by the organization are forwarded to other care providers.

### **Standard RC.01.03.01**

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

#### **Elements of Performance for RC.01.03.01**

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)

### **Rights and Responsibilities of the Individual (RI)**

When the OBS practice 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.

#### **Standard RI.01.01.01**

The organization respects patient rights.

#### **Elements of Performance for RI.01.01.01**

6. The organization respects the patient's cultural and personal values, beliefs, and preferences.
7. The organization respects the patient's right to privacy. (See also IM.02.01.01, EPs 1 and 2)  
*Note:* This element of performance (EP) addresses a patient's personal privacy. For EPs addressing the privacy of a patient's health information, please see IM.02.01.01.

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#### **Standard RI.01.03.01**

The organization honors the patient's right to give or withhold informed consent.

#### **Rationale for RI.01.03.01**

Obtaining informed consent presents an opportunity to establish a mutual understanding between the patient and the licensed independent practitioner or other licensed practitioners with privileges about the care, treatment, or services that the patient will receive. Informed consent is not merely a signed document. It is a process that considers patient needs and preferences, compliance with law and regulation, and patient education. Utilizing the informed consent process helps the patient to participate fully in decisions about his or her care, treatment, or services.

### **Elements of Performance for RI.01.03.01**

7. The informed consent process includes a discussion about the patient's proposed care, treatment, and services.
  9. The informed consent process includes a discussion about potential benefits, including potential problems that might occur during recuperation.
  11. The informed consent process includes a discussion about reasonable alternatives to the patient's proposed care, treatment, or services. The discussion encompasses risks, benefits, and side effects related to the alternatives, and the risks related to not receiving the proposed care, treatment, or services.
  13. Informed consent is obtained in accordance with the organization's policy and processes. (See also RC.02.01.01, EP 4)
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### **Standard RI.02.01.01**

The organization informs the patient about his or her responsibilities related to his or her care, treatment, or services.

### **Elements of Performance for RI.02.01.01**

2. The organization informs the patient about his or her responsibilities.
- Note:* Information about patient responsibilities can be shared verbally, in writing, or both.

## **Transplant Safety (TS)**

The standards in this chapter focus on the development and implementation of policies and procedures for safe tissue transplantation.

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### **Standard TS.03.03.01**

The organization investigates adverse events related to tissue use or donor infections.

### **Elements of Performance for TS.03.03.01**

1. The organization has a written procedure to investigate tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue.
2. The organization investigates tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue. (See also IC.01.03.01, EP 3)
3. As soon as the organization becomes aware of a post-transplant infection or other adverse event related to the use of tissue, it reports the infection or adverse event to the tissue supplier.
4. The organization sequesters tissue whose integrity may have been compromised or that is reported by the tissue supplier as a suspected cause of infection.

5. The organization identifies and informs tissue recipients of infection risk when donors are subsequently found to have human immunodeficiency virus (HIV), human T-lymphotropic virus-I/II (HTLV-I/II), viral hepatitis, or other infectious agents known to be transmitted through tissue.

## **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.

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### **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.

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### **Standard WT.04.01.01**

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

### **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 2)

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 manufacturers' 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)