

# Prepublication Requirements

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## Standards and Elements of Performance Deletions Related to EP Review Phase III

APPLICABLE TO OFFICE-BASED SURGERY ORGANIZATIONS

Effective July 1, 2017

### Environment of Care Chapter

#### EC.02.04.01

The practice manages medical equipment risks.

##### Elements of Performance for EC.02.04.01

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

**Rationale:** Issue that should be left to the discretion of the organization

#### EC.02.05.07

The practice inspects, tests, and maintains emergency power systems.

Note: This standard does not require practices to have the types of emergency power equipment discussed below. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.

##### Elements of Performance for EC.02.05.07

9. If a required emergency power system test fails, the practice implements measures to protect patients, visitors, and staff until necessary repairs or corrections are completed.

**Rationale:** Part of regular operations/processes

Key:  indicates that documentation is required;  indicates an identified risk area

10. If a required emergency power system test fails, the practice performs a retest after making the necessary repairs or corrections.

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**Rationale: Part of regular operations/processes**

### EC.03.01.01

Staff and licensed independent practitioners are familiar with their roles and responsibilities relative to the environment of care.

#### Elements of Performance for EC.03.01.01

1. Staff and licensed independent practitioners can describe or demonstrate methods for eliminating and minimizing physical risks in the environment of care. (See also HR.01.04.01, EP 1)

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**Rationale: Should be left to organization discretion**

3. Staff and licensed independent practitioners can describe or demonstrate how to report environment of care risks. (See also HR.01.04.01, EP 1)

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**Rationale: Should be left to organization discretion**

### EC.04.01.01

The practice collects information to monitor conditions in the environment.

#### Elements of Performance for EC.04.01.01

14. The practice monitors environmental deficiencies, hazards, and unsafe practices.

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**Rationale: Should be left to organization discretion**

## Human Resources Chapter

### HR.01.02.05

The practice verifies staff qualifications.

#### Elements of Performance for HR.01.02.05

6. The practice 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

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**Rationale: Issue should be left to organization discretion**

## Infection Prevention and Control Chapter

### IC.01.05.01

The practice plans for preventing and controlling infections.

#### Elements of Performance for IC.01.05.01

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



**Rationale: Process should be left to the discretion of the organization**

7. The practice 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.



**Rationale: Duplicative of IC.02.01.01, EP 7**

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



**Rationale: Duplicative of IC.02.01.01, EP 9**

## Leadership Chapter

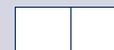
### LD.01.07.01

Individual leaders have the knowledge needed for their roles in the practice or they seek guidance to fulfill their roles.

**Rationale: Issue should be left to the discretion of the organization. Applies to all EPs within this standard.**

#### Elements of Performance for LD.01.07.01

2. Leaders are oriented to all of the following:
- The practice's mission and vision
  - The practice's safety and quality goals
  - The practice's structure and the decision-making process
  - The development of the budget as well as the interpretation of the practice's financial statements
  - The population(s) served by the practice and any issues related to that population(s)
  - The individual and interdependent responsibilities and accountabilities of leaders as they relate to supporting the mission of the practice and to providing safe and quality care
  - Applicable law and regulation



3. Leaders have access to information and training in areas where they need additional skills or expertise.

### LD.02.03.01

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

#### Elements of Performance for LD.02.03.01

1. Leaders discuss issues that affect the practice and the population(s) it serves, including the following:
- Performance improvement activities
  - Reported safety and quality issues
  - Proposed solutions and their impact on the practice'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

**Rationale: Leave to organization discretion. Also implicit in other requirements such as LD.04.04.05**

2. The practice establishes time frames for the discussion of issues that affect the practice and the population(s) it serves.

**Rationale: Leave to organization discretion**

### LD.03.01.01

Leaders create and maintain a culture of safety and quality throughout the practice.

#### Elements of Performance for LD.03.01.01

3. Leaders provide opportunities for all individuals who work in the practice to participate in safety and quality initiatives.

**Rationale: Process should be left to the discretion of the organization**

6. Leaders provide education that focuses on safety and quality for all individuals.

**Rationale: Process should be left to the discretion of the organization**

7. Leaders establish a team approach among all staff at all levels.

**Rationale: Process should be left to the discretion of the organization**

8. All individuals who work in the practice, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality. (See also LD.04.04.05, EP 6)

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**Rationale: Process should be left to the discretion of the organization**

9. Literature and advisories relevant to patient safety are available to all individuals who work in the practice.

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**Rationale: Process should be left to the discretion of the organization**

10. Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the practice.

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**Rationale: Process should be left to the discretion of the organization**

### LD.04.01.05

The practice is effectively managed.

#### Elements of Performance for LD.04.01.05

1. Leaders oversee operations.

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**Rationale: Duplicative of current LD.04.01.05, EPs 2, 3, 4, 5**

### LD.04.01.11

The practice makes space and equipment available as needed for the provision of care, treatment, or services.

#### Elements of Performance for LD.04.01.11

2. The arrangement and allocation of space supports safe, efficient, and effective care, treatment, or services.

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**Rationale: Duplicative of current LD.04.01.11, EP 3**

### LD.04.02.03

Ethical principles guide the practice's business practices.

#### Elements of Performance for LD.04.02.03

4. Marketing materials accurately represent the practice and address the care, treatment, or services that the practice provides either directly or by contractual arrangement.

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**Rationale: Part of regular operations/processes**

### LD.04.03.07

Patients with comparable needs receive the same standard of care, treatment, or services throughout the practice.

#### Elements of Performance for LD.04.03.07

2. Care, treatment, or services are consistent with the practice’s mission, vision, and goals.

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**Rationale: Issue should be left to the discretion of the organization**

### LD.04.04.03

New or modified services or processes are well designed.

#### Elements of Performance for LD.04.04.03

6. The practice tests and analyzes its design of new or modified services or processes to determine whether the proposed design or modification is an improvement. (See also LD.04.04.05, EPs 6 and 11)

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Note: A proactive risk assessment is one of several ways to address the proposed design or modification in terms of potential risk to patients. For suggested components, refer to the Proactive Risk Assessment section at the beginning of this chapter.

**Rationale: Process should be left to the discretion of the organization**

## Provision of Care, Treatment, and Services Chapter

### PC.01.02.01

The practice assesses and reassesses its patients.

#### Elements of Performance for PC.01.02.01

23. During patient assessments and reassessments, the practice gathers the data and information it requires.

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**Rationale: Part of clinical care process; also covered at PC.01.02.01, EP 1**

### PC.01.02.09

The practice assesses the patient who may be a victim of possible abuse and neglect.

#### Elements of Performance for PC.01.02.09

5. The practice either assesses the patient who meets criteria for possible abuse and neglect or refers the patient to a public or private community agency for assessment.

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**Rationale: Implicit in other EPs in this standard**

### PC.01.02.15

The practice provides for diagnostic testing.

#### Elements of Performance for PC.01.02.15

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| 1. Diagnostic testing and procedures are performed as ordered. | <input type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Part of clinical care process**

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| 3. When a test report requires clinical interpretation, information necessary to interpret the results is provided with the request for the test. | <input type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Part of clinical care process**

### PC.03.01.01

The practice plans operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.

#### Elements of Performance for PC.03.01.01

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| 1. Individuals administering moderate or deep sedation and anesthesia are qualified and have credentials to manage and rescue patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. (See also HR.02.01.03, EPs 3–6) | <input checked="" type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Addressed in other standards such as HR.01.02.05, HR.01.02.07, and HR.02.01.03**

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| 8. For operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia: the practice has resuscitation equipment available. (See also MM.03.01.03, EP 2) | <input checked="" type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Duplicative of PC.02.01.11, EP 2**

### PC.03.01.03

The practice provides the patient with care before initiating operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.

#### Elements of Performance for PC.03.01.03

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| 2. Before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered: The practice assesses the patient's anticipated needs in order to plan for the postprocedure care. | <input type="checkbox"/> <input type="checkbox"/> |
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**Rationale: Part of the clinical care process determined by the organization**

3. Before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered: The practice provides the patient with preprocedural treatment and services, according to his or her plan for care.

**Rationale: Part of the clinical care process determined by the organization**

7. Before administering moderate or deep sedation or anesthesia, a licensed independent practitioner plans or concurs with the plan for sedation or anesthesia.

**Rationale: Part of the clinical care process determined by the organization; also covered at PC.01.03.01, EP 1**

### PC.04.01.01

The practice has a process that addresses the patient's need for continuing care, treatment, or services after discharge or transfer.

#### Elements of Performance for PC.04.01.01

3. The practice describes the mechanisms for external transfer of the patient.

**Rationale: Duplicative of PC.04.01.01, EP 2**

4. The practice agrees with the receiving organization about each of their roles to keep the patient safe during transfer.

**Rationale: Duplicative of PC.04.01.01, EP 2**

## Performance Improvement Chapter

### PI.02.01.01

The practice compiles and analyzes data.

#### Elements of Performance for PI.02.01.01

1. The practice compiles data in usable formats.

**Rationale: Issue should be left to organization discretion**

2. The practice identifies the frequency for data analysis.

**Rationale: Issue should be left to organization discretion**

5. The practice compares data with external sources, when available.

**Rationale: Issue should be left to organization discretion**

### PI.03.01.01

The practice 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)

**Rationale: Issue should be left to organization discretion**

3. The practice evaluates actions to confirm that they resulted in improvements.

**Rationale: Issue should be left to organization discretion**

## Record of Care, Treatment, and Services Chapter

### RC.01.01.01

The practice maintains complete and accurate clinical records.

#### Elements of Performance for RC.01.01.01

12. The practice tracks the location of all components of the clinical record.

**Rationale: Operational issue that should be left to organization discretion**

13. The practice 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)

**Rationale: Part of regular operations/process that should be determined by the organization**

## Rights and Responsibilities of the Individual Chapter

### RI.01.03.05

The practice protects the patient and respects his or her rights during research, investigation, and clinical trials.

#### Elements of Performance for RI.01.03.05

1. The practice reviews all research protocols and weighs the risks and benefits to the patient participating in the research.

**Rationale: Part of clinical care; process should be left to the discretion of the organization. Implicit in other EPs in this standard**

## Transplant Safety Chapter

### TS.03.01.01

The practice uses standardized procedures for managing tissues.

#### Elements of Performance for TS.03.01.01

4. The practice coordinates its acquisition, receipt, storage, and issuance of tissues throughout the practice.

**Rationale: Part of regular operations that should be left to the discretion of the organization**

11. The practice complies with state and/or federal regulations when it acts as a tissue supplier. \*

Note: The US Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.

Footnote \*: Please refer to the following website:  
<http://www.fda.gov/cber/tissue/tisreg.htm>.

**Rationale: Covered by law and regulation or other external requirements**

## Waived Testing Chapter

### WT.01.01.01

Policies and procedures for waived tests are established, current, approved, and readily available.

#### Elements of Performance for WT.01.01.01

5. Current and complete policies and procedures are available for use during testing to the person performing the waived test.

**Rationale: Part of regular operations that should be left to the discretion of the organization**

6. Written policies, procedures, and manufacturers' instructions for waived testing are followed. (See also WT.04.01.01, EPs 3–5)

Note: Manufacturers' recommendations and suggestions are surveyed as requirements.

**Rationale: Part of regular operations that should be left to the discretion of the organization; covered by law and regulation or other external requirements; also covered at WT.01.01.01, EPs 1 and 2**

7. The criteria for confirmatory testing are followed as specified in the waived testing written procedures.

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**Rationale: Part of regular operations that should be left to the discretion of the organization**

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8. Clinical use of results is consistent with the practice's policies and the manufacturers' recommendations for waived tests.

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**Rationale: Part of regular operations that should be left to the discretion of the organization; covered by law and regulation or other external requirements**

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