

# Patient Safety Systems (PS)

## Introduction

The quality of care and the safety of patients are core values of The Joint Commission accreditation process. This is a commitment The Joint Commission has made to patients, families, health care practitioners, staff, and health care organization leaders. This chapter exemplifies that commitment.

The intent of this “Patient Safety Systems” (PS) chapter is to provide health care organizations with a proactive approach to designing or redesigning a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with the Joint Commission’s mission and its standards.

The Joint Commission partners with accredited health care organizations to improve health care systems to protect patients. The first obligation of health care is to “do no harm.” Therefore, this chapter is focused on the following three guiding principles:

1. Aligning existing Joint Commission standards with daily work in order to engage patients and staff throughout the health care system, at all times, on reducing harm.
2. Assisting health care organizations with advancing knowledge, skills, and competence of staff and patients by recommending methods that will improve quality and safety processes.
3. Encouraging and recommending proactive quality and patient safety methods that will increase accountability, trust, and knowledge while reducing the impact of fear and blame.

Quality\* and safety are inextricably linked. *Quality* in health care is the degree to which its processes and results meet or exceed the needs and desires of the people it serves.<sup>1,2</sup> Those needs and desires include safety.

The components of a quality management system should include the following:

- Ensuring reliable processes

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\* The Institute of Medicine defines quality as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. **Source:** Committee to Design a Strategy for Quality Review and Assurance in Medicare, Institute of Medicine. *Medicare: A Strategy for Quality Assurance*, vol. 1. Lohr KN, editor. Washington, DC: The National Academies Press, 1990.

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- Decreasing variation and defects (waste)
- Focusing on achieving better outcomes
- Using evidence to ensure that a service is satisfactory

Patient safety emerges as a central aim of quality. *Patient safety*, as defined by the World Health Organization, is the prevention of errors and adverse effects to patients that are associated with health care. Safety is what patients, families, staff, and the public expect from Joint Commission–accredited organizations. While patient safety events may not be completely eliminated, harm to patients can be reduced, and the goal is always zero harm. This chapter describes and provides approaches and methods that may be adapted by a health care organization that aims to increase the reliability of its complex systems while making visible and removing the risk of patient harm. Joint Commission–accredited organizations should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families, and staff.<sup>1,2</sup>

The ultimate purpose of The Joint Commission’s accreditation process is to enhance quality of care and patient safety. Each requirement or standard, the survey process, the Sentinel Event Policy, and other Joint Commission initiatives are designed to help organizations reduce variation, reduce risk, and improve quality. Hospitals should have an integrated approach to patient safety so that high levels of safe patient care can be provided for every patient in every care setting and service.

Hospitals are complex environments that depend on strong leadership to support an integrated patient safety system that includes the following:

- Safety culture
- Validated methods to improve processes and systems
- Standardized ways for interdisciplinary teams to communicate and collaborate
- Safely integrated technologies

In an integrated patient safety system, staff and leaders work together to eliminate complacency, promote collective mindfulness, treat each other with respect and compassion, and learn from their patient safety events, including close calls and other system failures that have not yet led to patient harm.

## What Does This Chapter Contain?

The “Patient Safety Systems” (PS) chapter is intended to help inform and educate hospitals about the importance and structure of an integrated patient safety system.

**While this chapter does not include new accreditation requirements, it describes how**

**existing requirements can be applied to achieve improved patient safety.** It is also intended to help all health care workers understand the relationship between Joint Commission accreditation and patient safety.

This chapter does the following:

- Describes an integrated patient safety system
- Discusses how hospitals can develop into learning organizations
- Explains how hospitals can continually evaluate the status and progress of their patient safety systems
- Describes how hospitals can work to prevent or respond to patient safety events (Sidebar 1, below, defines key terminology)
- Serves as a framework to guide hospital leaders as they work to improve patient safety in their hospitals
- Contains a list of standards and requirements related to patient safety systems (which will be scored as usual in their original chapters)
- Contains references that were used in the development of this chapter

This chapter refers to a number of Joint Commission standards. Standards cited in this chapter are formatted with the standard number in boldface type (for example, “Standard **RI.01.01.01**”) and are accompanied by language that summarizes the standard. For the full text of a standard and its element(s) of performance (EP), please see the Appendix beginning on page PS-23.

## Sidebar 1. Key Terms to Understand

- *Patient safety event*: An event, incident, or condition that could have resulted or did result in harm to a patient.
- *Adverse event*: A patient safety event that resulted in harm to a patient.
- *Sentinel event*<sup>†</sup>: A subcategory of Adverse Events, a Sentinel Event is a patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in any of the following:
  - Death
  - Permanent harm
  - Severe temporary harm

<sup>†</sup>For a list of specific patient safety events that are also considered sentinel events, see page SE-1 in the “Sentinel Events” (SE) chapter of this manual.

- **Close call** (or “near miss,” “no harm,” or “good catch”): A patient safety event that did not cause harm as defined by the term *sentinel event*.
- **Hazardous** (or “unsafe”) *condition(s)*: A circumstance (other than a patient’s own disease process or condition) that increases the probability of an adverse event.

**Note:** *It is impossible to determine if there are practical prevention or mitigation countermeasures available without first doing an event analysis. An event analysis will identify systems-level vulnerabilities and weaknesses and the possible remedial or corrective actions that can be implemented.*

## Becoming a Learning Organization

The need for sustainable improvement in patient safety and the quality of care has never been greater. One of the fundamental steps to achieving and sustaining this improvement is to become a learning organization. A *learning organization* is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.<sup>3</sup> Learning organizations uphold five principles: team learning, shared visions and goals, a shared mental model (that is, similar ways of thinking), individual commitment to lifelong learning, and systems thinking.<sup>3</sup> In a learning organization, patient safety events are seen as opportunities for learning and improvement.<sup>4</sup> Therefore, leaders in learning organizations adopt a transparent, nonpunitive approach to reporting so that the organization can *report to learn* and can collectively learn from patient safety events. In order to become a learning organization, a hospital must have a fair and just safety culture, a strong reporting system, and a commitment to put that data to work by driving improvement. Each of these require the support and encouragement of hospital leaders.

Leaders, staff, licensed independent practitioners, and patients in a learning organization realize that *every* patient safety event (from **close calls** to events that cause major harm to patients) must be reported.<sup>4-8</sup> When patient safety events are continuously reported, experts within the hospital can define the problem, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the hospital.<sup>4-8</sup> In a learning organization, the hospital provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting.

# The Role of Hospital Leaders in Patient Safety

Hospital leaders provide the foundation for an effective patient safety system by doing the following:<sup>9</sup>

- Promoting learning
- Motivating staff to uphold a fair and just safety culture
- Providing a transparent environment in which quality measures and patient harms are freely shared with staff
- Modeling professional behavior
- Removing intimidating behavior that might prevent safe behaviors
- Providing the resources and training necessary to take on improvement initiatives

For these reasons, many of the standards that are focused on the hospital's patient safety system appear in the Joint Commission's Leadership (LD) standards, including Standard **LD.04.04.05** (which focuses on having an organizationwide, integrated patient safety program within performance improvement activities).

Without the support of hospital leaders, hospitalwide changes and improvement initiatives are difficult to achieve. Leadership engagement in patient safety and quality initiatives is imperative because 75% to 80% of all initiatives that require people to change their behaviors fail in the absence of leadership managing the change.<sup>4</sup> Thus, leadership should take on a long-term commitment to transform the hospital.<sup>10</sup>

## Safety Culture

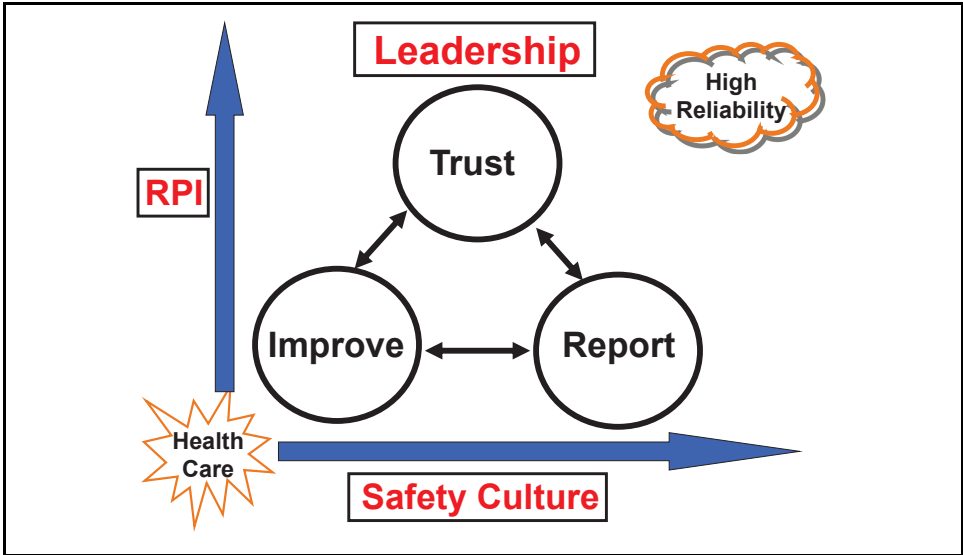
A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for hospitals striving to become learning organizations. In a strong safety culture, the hospital has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of hospital leaders is to establish and maintain a strong safety culture within their hospital. The Joint Commission's standards address safety culture in Standard **LD.03.01.01**, which requires leaders to create and maintain a culture of safety and quality throughout the hospital.

The *safety culture* of a hospital is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety. Hospitals that have a robust safety culture are characterized by communications founded on mutual trust, by shared

perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.<sup>11</sup> Organizations will have varying levels of safety culture, but all should be working toward a safety culture that has the following qualities:

- Staff and leaders that value transparency, accountability, and mutual respect.<sup>4</sup>
- Safety as everyone's first priority.<sup>4</sup>
- Behaviors that undermine a culture of safety are not acceptable, and thus should be reported to organizational leadership by staff, patients, and families for the purpose of fostering risk reduction.<sup>4,10,12</sup>
- Collective mindfulness is present, wherein staff realize that systems always have the potential to fail and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed.<sup>10</sup> Staff do not view close calls as evidence that the system prevented an error but rather as evidence that the system needs to be further improved to prevent any defects.<sup>10,13</sup>
- Staff who do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events.<sup>6</sup> Staff know that their leaders will focus not on blaming providers involved in errors but on the systems issues that contributed to or enabled the patient safety event.<sup>6,14</sup>
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the hospital fosters a cycle of trust, reporting, and improvement.<sup>10,15</sup> In hospitals that have a strong safety culture, health care providers trust their coworkers and leaders to support them when they identify and report a patient safety event.<sup>10</sup> When trust is established, staff are more likely to report patient safety events, and hospitals can use these reports to inform their improvement efforts. In the trust-report-improve cycle, leaders foster trust, which enables staff to report, which enables the hospital to improve.<sup>10</sup> In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself.<sup>10</sup> (*See Figure 1 on page PS-7.*)



**Figure 1.** *The Trust-Report-Improve Cycle*

In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.

Leaders need to ensure that intimidating or unprofessional behaviors within the hospital are addressed, so as not to inhibit others from reporting safety concerns.<sup>16</sup> Leaders should both educate staff and hold them accountable for professional behavior. This includes the adoption and promotion of a code of conduct that defines acceptable behavior as well as behaviors that undermine a culture of safety. The Joint Commission's Standard **LD.03.01.01**, EP 4, requires that leaders develop such a code.

Intimidating and disrespectful behaviors disrupt the culture of safety and prevent collaboration, communication, and teamwork, which is required for safe and highly reliable patient care.<sup>17</sup> Disrespect is not limited to outbursts of anger that humiliate a member of the health care team; it can manifest in many forms, including the following:<sup>4,12,17</sup>

- Inappropriate words (profane, insulting, intimidating, demeaning, humiliating, or abusive language)
- Shaming others for negative outcomes
- Unjustified negative comments or complaints about another provider's care
- Refusal to comply with known and generally accepted practice standards, the refusal of which may prevent other providers from delivering quality care

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- Not working collaboratively or cooperatively with other members of the interdisciplinary team
- Creating rigid or inflexible barriers to requests for assistance or cooperation
- Not returning pages or calls promptly

These issues are still occurring in hospitals nationwide. Of 4,884 respondents to a 2013 survey by the Institute for Safe Medication Practices (ISMP), 73% reported encountering negative comments about colleagues or leaders during the previous year. In addition, 68% reported condescending language or demeaning comments or insults; while 77% of respondents said they had encountered reluctance or refusal to answer questions or return calls.<sup>18</sup> Further, 69% report that they had encountered impatience with questions or the hanging up of the phone.

Nearly 50% of the respondents indicated that intimidating behaviors had affected the way they handle medication order clarifications or questions, including assuming that an order was correct in order to avoid interaction with an intimidating coworker.<sup>18</sup> Moreover, 11% said they were aware of a medication error during the previous year in which behavior that undermines a culture of safety was a contributing factor. The respondents included nurses, physicians, pharmacists, and quality/risk management personnel.

Only 50% of respondents indicated that their organizations had clearly defined an effective process for handling disagreements with the safety of an order. This is down from 60% of respondents to a similar ISMP survey conducted in 2003, which suggests that this problem is worsening.<sup>18</sup> While these data are specific to medication safety, their lessons are broadly applicable: Behaviors that undermine a culture of safety have an adverse effect on quality and patient safety.

## **A Fair and Just Safety Culture**

A fair and just safety culture is needed for staff to trust that they can report patient safety events without being treated punitively.<sup>2,8</sup> In order to accomplish this, hospitals should provide and encourage the use of a standardized reporting process for staff to report patient safety events. This is also built into the Joint Commission's standards at **Standard LD.04.04.05, EP 6**, which requires leaders to provide and encourage the use of systems for blame-free reporting of a system or process failure or the results of proactive risk assessments. Reporting enables both proactive and reactive risk reduction. *Proactive risk reduction* solves problems before patients are harmed, and *reactive risk reduction* attempts to prevent the recurrence of problems that have already caused patient harm.<sup>10,15</sup>

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A fair and just culture takes into account that individuals are human, fallible, and capable of mistakes, and that they work in systems that are often flawed. In the most basic terms, a fair and just culture holds individuals accountable for their actions but does not punish individuals for issues attributed to flawed systems or processes.<sup>14,18,19</sup> Refer to Standard **LD.04.01.05**, EP 4, which requires that staff are held accountable for their responsibilities.

It is important to note that for some actions for which an individual is accountable, the individual should be held culpable and some disciplinary action may then be necessary. (See Sidebar 2, below, for a discussion of tools that can help leaders determine a fair and just response to a patient safety event.) However, staff should never be punished or ostracized for **reporting** the event, close call, hazardous condition, or concern.

## Sidebar 2. Assessing Staff Accountability

The aim of a safety culture is not a “blame-free” culture but one that balances learning with accountability. To achieve this, it is essential that leaders assess errors and patterns of behavior in a manner that is applied consistently, with the goal of eliminating behaviors that undermine a culture of safety. There has to exist within the hospital a clear, equitable, and transparent process for recognizing and separating the blameless errors that fallible humans make daily from the unsafe or reckless acts that are blameworthy.<sup>1-3</sup>

There are a number of sources for information (some of which are listed immediately below) that provide rationales, tools, and techniques that will assist an organization in creating a formal decision process to determine what events should be considered blameworthy and require individually directed action in addition to systems-level corrective actions. The use of a formal process will reinforce the culture of safety and demonstrate the organization’s commitment to transparency and fairness.

Reaching answers to these questions requires an initial investigation into the patient safety event to identify contributing factors. The use of the Incident Decision Tree (adapted by the United Kingdom’s National Patient Safety Agency from James Reason’s culpability matrix) or other formal decision process can help make determinations of culpability more transparent and fair.<sup>5</sup>

### References

1. The Joint Commission. Behaviors that undermine a culture of safety. *Sentinel Event Alert*, No. 40, Jul 9, 2009. Accessed Sep 3, 2013. [http://www.jointcommission.org/sentinel\\_event\\_alert\\_issue\\_40\\_behaviors\\_that\\_undermine\\_a\\_culture\\_of\\_safety/](http://www.jointcommission.org/sentinel_event_alert_issue_40_behaviors_that_undermine_a_culture_of_safety/)

2. The Joint Commission. Leadership committed to safety. *Sentinel Event Alert*. Aug 27, 2009. Accessed Sep 8, 2013. [http://www.jointcommission.org/sentinel\\_event\\_alert\\_issue\\_43\\_leadership\\_committed\\_to\\_safety](http://www.jointcommission.org/sentinel_event_alert_issue_43_leadership_committed_to_safety)
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7. Bagian JP, et al. Developing and deploying a patient safety program in a large health care delivery system: You can't fix what you don't know about. *Jt Com J Qual Patient Saf*. 2001 Oct;27(10):522–532.
8. National Patient Safety Foundation. RCA<sup>2</sup>: Improving Root Cause Analyses and Actions to Prevent Harm. Jun 16, 2015. Accessed Jun 23, 2015. <http://www.npsf.org/?page=RCA2>

## Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When hospitals adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the hospital begins reporting to learn—and to learn collectively from adverse events, close calls, and hazardous conditions. This section focuses on data from reported patient safety events. Hospitals should note that this is but one type of data among many that should be collected and used to drive improvement.

When there is continuous reporting for adverse events, close calls, and hazardous conditions, the hospital can analyze the patient safety events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the organization.<sup>20–24</sup>

In addition to those mentioned earlier in this chapter, a number of standards relate to the reporting of safety information, including Performance Improvement (PI) Standard **PI.01.01.01**, which requires hospitals to collect data to monitor their performance, and Standard **LD.03.02.01**, which requires hospitals to use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Hospitals can engage frontline staff in internal reporting in a number of ways, including the following:

- Create a nonpunitive approach to patient safety event reporting

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- Educate staff on identifying patient safety events that should be reported
- Provide timely feedback regarding actions taken on patient safety events

## Effective Use of Data

### Collecting Data

When hospitals collect data or measure staff compliance with evidence-based care processes or patient outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient safety.<sup>25</sup> The effective use of data enables hospitals to identify problems, prioritize issues, develop solutions, and track to determine success.<sup>9</sup> Objective data can be used to support decisions, influence people to change their behaviors, and to comply with evidence-based care guidelines.<sup>9,26</sup>

The Joint Commission and the Centers for Medicare & Medicaid Services (CMS) both require hospitals to collect and use data related to certain patient care outcomes and patient harms. Some key Joint Commission standards related to data collection and use require hospitals to do the following:

- Collect information to monitor conditions in the environment (Standard **EC.04.01.01**)
- Identify risks for acquiring and transmitting infections (Standard **IC.01.03.01**)
- Use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality (Standard **LD.03.02.01**)
- Have an organizationwide, integrated patient safety program within their performance improvement activities (Standard **LD.04.04.05**)
- Evaluate the effectiveness of their medication management system (Standard **MM.08.01.01**)
- Report (if using Joint Commission accreditation for deemed status purposes) deaths associated with the use of restraint and seclusion (Standard **PC.03.05.19**)
- Collect data to monitor their performance (Standard **PI.01.01.01**)
- Improve performance on an ongoing basis (Standard **PI.03.01.01**)

### Analyzing Data

Effective data analysis can enable a hospital to “diagnose” problems within its system similar to the way one would diagnose a patient’s illness based on symptoms, health history, and other factors. Turning data into information is a critical competency of a learning organization and of effective management of change. When the right data are collected and appropriate analytic techniques are applied, it enables the hospital to

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monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the hospital not only understand the current performance of hospital systems but also can help it predict its performance going forward.<sup>23</sup>

Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps a hospital determine what has occurred in a system and provides clues as to why the system responded as it did.<sup>23</sup> Table 1, following, describes and compares examples of these tools. Please note that several types of SPC charts exist; this discussion focuses on the XmR chart, which is the most commonly used.

**Table 1. Defining and Comparing Analytical Tools**

Tool	When to Use	Example
Run Chart <sup>1</sup>	<ul style="list-style-type: none"> <li>When the hospital needs to identify variation within a system</li> <li>When the hospital needs a simple and straightforward analysis of a system</li> <li>As a precursor to an SPC chart</li> </ul>	
Statistical Process Control Chart	<ul style="list-style-type: none"> <li>When the hospital needs to identify variation within a system and find indicators of why the variation occurred</li> <li>When the hospital needs a more detailed and in-depth analysis of a system</li> </ul>	
Capability Chart <sup>2</sup>	<ul style="list-style-type: none"> <li>When the hospital needs to determine whether a process will function as expected, according to requirements or specifications</li> </ul>	

In the example above, the curve at the top of the chart indicates a process that is only partly capable of meeting requirements. The curve at the bottom of the chart shows a process that is fully capable.

**Sources:**

- Agency for Healthcare Research and Quality. Advanced Methods in Delivery System Research—Planning, Executing, Analyzing, and Reporting Research on Delivery System Improvement. Webinar #2: Statistical Process Control. Jul 2013. Accessed Aug 21, 2015. <http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/webinar02/index.html>. (Example 2, above).
- George ML, et al. *The Lean Six Sigma Pocket Toolkit: A Quick Reference Guide to Nearly 100 Tools for Improving Process Quality, Speed, and Complexity*. New York: McGraw-Hill, 2005. Used with permission.

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## Using Data to Drive Improvement

After data has been turned into information, leadership should ensure the following (per the requirements shown):<sup>27–29</sup>

- Information is presented in a clear manner (Standard **LD.03.04.01**, EP 3)
- Information is shared with the appropriate groups throughout the organization (from the front line to the board) (Standards **LD.03.04.01**, **LD.04.04.05**)
- Opportunities for improvement and actions to be taken are clearly articulated (Standards **LD.03.05.01**, EP 4; **LD.04.04.01**)
- Leadership provides staff with time, resources, and opportunities for participating in improvement efforts as part of daily work (Standard **LD.03.01.01**, EP 3)
- Improvements are celebrated or recognized

## A Proactive Approach to Preventing Harm

Proactive risk reduction prevents harm before it reaches the patient. By engaging in proactive risk reduction, a hospital can correct process problems in order to reduce the likelihood of experiencing adverse events.

In a proactive risk assessment the hospital evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. A proactive risk assessment increases understanding within the organization about the complexities of process design and management—and what could happen if the process fails.

When conducting a proactive risk assessment, organizations should prioritize high-risk, high-volume areas. Areas of risk are identified from internal sources such as ongoing monitoring of the environment, results of previous proactive risk assessments, from results of data collection activities. Risk assessment tools should be accessed from credible external sources such as a *Sentinel Event Alert*, nationally recognized risk assessment tools, and peer review literature. Benefits of a proactive approach to patient safety includes increased likelihood of the following:

- Identification of actionable common causes
- Avoidance of unintended consequences
- Identification of commonalities across departments/services/units
- Identification of system solutions

Hazardous (or unsafe) conditions provide an opportunity for a hospital to take a proactive approach to reduce harm. Hospitals also benefit from identifying hazardous conditions while designing any new process that could impact patient safety. A

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hazardous condition is defined as any circumstance that increases the probability of a patient safety event. A hazardous condition may be the result of a human error or violation, may be a design flaw in a system or process, or may arise in a system or process in changing circumstances.<sup>‡</sup> A proactive approach to such conditions should include an analysis of the systems and processes in which the hazardous condition is found, with a focus on conditions that preceded the hazardous condition. (See Sidebar 3, below.)

A proactive approach to hazardous conditions should include an analysis of the related systems and processes, including the following aspects:<sup>30</sup>

- **Preconditions.** Examples include hazardous (or unsafe) conditions in the environment of care (such as noise, clutter, wet floors and so forth), inadequate staffing levels, an operator who is impaired or inadequately trained.
- **Supervisory influences.** Examples include inadequate supervision, planned inappropriate operations, failure to address a known problem, authorization of activities that are known to be hazardous.
- **Organizational influences.** Examples include inadequate staffing, inadequate policies, lack of strategic risk assessment.

The Joint Commission addresses proactive risk assessments at Standard **LD.04.04.05**, EP 10, which requires hospitals to select one high-risk process and conduct a proactive risk assessment at least every 18 months.

Hospitals should recognize that this standard represents a minimum requirement. Hospitals working to become learning organizations are encouraged to exceed this requirement by constantly working to proactively identify risk.

### Sidebar 3. Strategies for an Effective Risk Assessment

Although several methods could be used to conduct a proactive risk assessment, the following steps comprise one approach:

- Describe the chosen process (for example, through the use of a flowchart).

<sup>‡</sup>Human errors are typically skills based, decision based, or knowledge based; whereas violations could be either routine or exceptional (intentional or negligent). *Routine violations* tend to include habitual “bending of the rules,” often enabled by management. A routine violation may break established rules or policies, and yet be a common practice within an organization. An *exceptional violation* is a willful behavior outside the norm that is not condoned by management, engaged in by others, and not part of the individual’s usual behavior. **Source:** Diller T, et al. The human factors analysis classification system (HFACS) applied to health care. *Am J Med Qual.* 2014 May–Jun;29(3)181–190.

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- Identify ways in which the process could break down or fail to perform its desired function, which are often referred to as “failure modes.”
- Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- Prioritize the potential process breakdowns or failures.
- Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
- Design or redesign the process and/or underlying systems to minimize the risk of the effects on patients.
- Test and implement the newly designed or redesigned process.
- Monitor the effectiveness of the newly designed or redesigned process.

## Tools for Conducting a Proactive Risk Assessment

A number of tools are available to help organizations conduct a proactive risk assessment. One of the best known of these tools is the Failure Modes and Effects Analysis (FMEA). An FMEA is used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them. The FMEA asks “What if?” to explore what could happen if a failure occurs at particular steps in a process.<sup>31</sup>

Hospitals have other tools they can consider using in their proactive risk assessment. Some examples include the following:

- Institute for Safe Medication Practices Medication Safety Risk Assessment: This tool is designed to help reduce medication errors. Visit <https://www.ismp.org/selfassessments/default.asp> for more information.
- Contingency diagram: The contingency diagram uses brainstorming to generate a list of problems that could arise from a process. Visit <http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/contingency-diagram> for more information.
- Potential problem analysis (PPA) is a systematic method for determining what could go wrong in a plan under development. The problem causes are rated according to their likelihood of occurrence and the severity of their consequences. Visit <http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/potential-problem-analysis> for more information.
- Process decision program chart (PDPC) provides a systematic means of finding errors with a plan while it is being created. After potential issues are found, preventive measures are developed, allowing the problems to either be avoided or a

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contingency plan to be in place should the error occur. Visit <http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/process-decision-program-chart>.

## Encouraging Patient Activation

To achieve the best outcomes, patients and families must be more actively engaged in decisions about their health care and must have broader access to information and support. Patient activation is inextricably intertwined with patient safety. Activated patients are less likely to experience harm and unnecessary hospital readmissions. Patients who are less activated suffer poorer health outcomes and are less likely to follow their provider's advice.<sup>32,33</sup>

A patient-centered approach to care can help hospitals assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the hospital. This includes adopting the following principles:<sup>34</sup>

- Patient safety guides all decision making.
- Patients and families are partners at every level of care.
- Patient- and family-centered care is verifiable, rewarded, and celebrated.
- The licensed independent practitioner responsible for the patient's care, or his or her designee, discloses to the patient and family any unanticipated outcomes of care, treatment, and services.
- Though Joint Commission standards do not require apology, evidence suggests that patients benefit—and are less likely to pursue litigation—when physicians disclose harm, express sympathy, and apologize.
- Staffing levels are sufficient, and staff has the necessary tools and skills.
- The hospital has a focus on measurement, learning, and improvement.
- Staff and licensed independent practitioners must be fully engaged in patient- and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Hospitals can adopt a number of strategies to support and improve patient activation, including promoting culture change, adopting transitional care models, and leveraging health information technology capabilities.<sup>34</sup>

A number of Joint Commission standards address patient rights and provide an excellent starting point for hospitals seeking to improve patient activation. These standards require that hospitals do the following:

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- Respect, protect, and promote patient rights (Standard **RI.01.01.01**)
- Respect the patient's right to receive information in a manner he or she understands (Standard **RI.01.01.03**)
- Respect the patient's right to participate in decisions about his or her care, treatment, and services (Standard **RI.01.02.01**)
- Honor the patient's right to give or withhold informed consent (Standard **RI.01.03.01**)
- Address patient decisions about care, treatment, and services received at the end of life (Standard **RI.01.05.01**)
- Inform the patient about his or her responsibilities related to his or her care, treatment, and services (Standard **RI.02.01.01**)

## Beyond Accreditation: The Joint Commission Is Your Patient Safety Partner

To assist hospitals on their journey toward creating highly reliable patient safety systems, The Joint Commission provides many resources, including the following:

- *Office of Quality and Patient Safety*: An internal Joint Commission department that offers hospitals guidance and support when they experience a sentinel event. Organizations can call the Sentinel Event Hotline (630-792-3700) to clarify whether a patient safety event is considered to be a sentinel event (and therefore reviewable) or to discuss any aspect of the Sentinel Event Policy. The Office of Quality and Patient Safety assesses the thoroughness and credibility of a hospital's comprehensive systematic analysis as well as the action plan to help the hospital prevent the hazardous or unsafe conditions from occurring again.
- *Joint Commission Center for Transforming Healthcare*: A Joint Commission not-for-profit affiliate that offers highly effective, durable solutions to health care's most critical safety and quality problems to help hospitals transform into high reliability organizations. For specific quality and patient problems, the Center's Targeted Solutions Tool® (TST®) guides health care organizations through a step-by-step process to measure their organization's performance, identify barriers to excellence, and direct them to proven solutions. To date, a TST has been developed for each of the following: hand hygiene, hand-off communications, and wrong-site surgery. For more information, visit <http://www.centerfortransforminghealthcare.org>.
- *Standards Interpretation Group*: An internal Joint Commission department that helps organizations with their questions about Joint Commission standards. First, organizations can see if other organizations have asked the same question by

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accessing the Standards FAQs at [http://www.jointcommission.org/standards\\_information/jcfaq.aspx](http://www.jointcommission.org/standards_information/jcfaq.aspx). Thereafter, organizations can submit questions about standards to the Standards Interpretation Group by completing an online form at <https://web.jointcommission.org/sigsubmission/sigonlineform.aspx>.

- *National Patient Safety Goals*: The Joint Commission's yearly patient safety requirements based on data obtained from the Joint Commission's Sentinel Event Database and recommended by a panel of patient safety experts. (For a list of the current National Patient Safety Goals, go to [http://www.jointcommission.org/standards\\_information/npsgs](http://www.jointcommission.org/standards_information/npsgs).)
- *Sentinel Event Alert*: The Joint Commission's periodic alerts with timely information about similar, frequently reported sentinel events, including root causes, applicable Joint Commission requirements, and suggested actions to prevent a particular sentinel event. (For archives of previously published *Sentinel Event Alert*, go to [http://www.jointcommission.org/sentinel\\_event](http://www.jointcommission.org/sentinel_event).)
- *Quick Safety*: Quick Safety is a monthly newsletter that outlines an incident, topic, or trend in health care that could compromise patient safety. [http://www.jointcommission.org/quick\\_safety.aspx?archieve=y](http://www.jointcommission.org/quick_safety.aspx?archieve=y)
- *Core Measure Solution Exchange*<sup>®</sup>: Available for accredited or certified organizations through the *Joint Commission Connect*<sup>™</sup> extranet, organizations can search a database of over two hundred success stories from accredited hospitals that have attained excellent performance on core measures, including accountability measures.
- *Joint Commission Resources*: A Joint Commission not-for-profit affiliate that produces books and periodicals, holds conferences, provides consulting services, and develops software products (including AMP<sup>®</sup>, Tracers with AMP<sup>®</sup>, E-dition<sup>®</sup>, ECM Plus<sup>®</sup>, CMSAccess<sup>®</sup>, and JCAccess<sup>®</sup>) for accreditation and survey readiness. (For more information, visit <http://www.jcrinc.com>.)
- *Webinars and podcasts*: The Joint Commission and its affiliate, Joint Commission Resources, offer free webinars and podcasts on various accreditation and patient safety topics.
- *Speak Up*<sup>™</sup> program: The Joint Commission's campaign to educate patients about health care processes and potential safety issues and encourage them to speak up whenever they have questions or concerns about their safety. (For more information and patient education resources, go to <http://www.jointcommission.org/speakup>.)
- *Standards BoosterPaks*<sup>™</sup>: Available for accredited or certified organizations through *Joint Commission Connect*, organizations can access BoosterPaks that provide detailed information about a single standard or topic area that has been associated with a high volume of inquiries or noncompliance scores. Recent standards

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BoosterPak topics have included credentialing and privileging in nonhospital settings, waived testing, restraint and seclusion, management of hazardous waste, environment of care (including Standards **EC.04.01.01**, **EC.04.01.03**, and **EC.04.01.05**), and sample collection.

- *Leading Practice Library*. Available for accredited or certified organizations through *Joint Commission Connect*, organizations can access an online library of solutions to help improve safety. The searchable documents in the library are actual solutions that have been successfully implemented by hospitals and reviewed by Joint Commission standards experts.
- *Joint Commission web portals*: Through The Joint Commission website, organizations can access web portals with a repository of resources from The Joint Commission, the Joint Commission Center for Transforming Healthcare, Joint Commission Resources, and Joint Commission International on the following topics:
  - Transitions of care: <http://www.jointcommission.org/toc.aspx>
  - High reliability: <http://www.jointcommission.org/highreliability.aspx>
  - Infection prevention and health care–associated infections (HAI): <http://www.jointcommission.org/hai.aspx>
  - Emergency management: [http://www.jointcommission.org/emergency\\_management.aspx](http://www.jointcommission.org/emergency_management.aspx)

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## Appendix. Key Patient Safety Requirements

A number of Joint Commission standards have been discussed in the “Patient Safety Systems” (PS) chapter. However, many Joint Commission requirements address issues related to the design and management of patient safety systems, including the following examples:

### Accreditation Participation Requirements (APR)

#### Standard APR.09.01.01

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

**Note:** *Methods of notice may include, but are not limited to, distribution of information about The Joint Commission, including contact information in published materials such as brochures and/or posting this information on the hospital’s website.*

#### Elements of Performance for APR.09.01.01

- A 1.** The hospital informs the public it serves about how to contact its management to report concerns about patient safety and quality of care.
- A 2.** The hospital informs the public it serves about how to contact The Joint Commission to report concerns about patient safety and quality of care.

#### Standard APR.09.02.01

Any individual who provides care, treatment, and services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the hospital.

#### Elements of Performance for APR.09.02.01

- A 1.** The hospital educates its staff, medical staff, and other individuals who provide care, treatment, and services that concerns about the safety or quality of care provided in the organization may be reported to The Joint Commission.

- A 2.** The hospital informs its staff and medical staff that it will take no disciplinary or punitive action because an employee, physician, or other individual who provides care, treatment, and services reports safety or quality-of-care concerns to The Joint Commission.
- A 3.** The hospital takes no disciplinary or punitive action against employees, physicians, or other individuals who provide care, treatment, and services when they report safety or quality-of-care concerns to The Joint Commission.

## **Environment of Care (EC)**

### **Standard EC.04.01.01**

The hospital collects information to monitor conditions in the environment.

#### **Elements of Performance for EC.04.01.01**

- A 1.** The hospital establishes a process(es) for continually monitoring, internally reporting, and investigating the following: **R**
- Injuries to patients or others within the hospital's facilities
  - Occupational illnesses and staff injuries
  - Incidents of damage to its property or the property of others
  - Security incidents involving patients, staff, or others within its facilities
  - Hazardous materials and waste spills and exposures
  - Fire safety management problems, deficiencies, and failures
  - Medical or laboratory equipment management problems, failures, and use errors
  - Utility systems management problems, failures, or use errors

**Note 1:** *All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.*

**Note 2:** *Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve care, treatment, or services, or to prevent similar incidents, are not lost as a result of following the legal process.*

Based on its process(es), the hospital reports and investigates the following:



- C** 3. Injuries to patients or others in the hospital's facilities. (See also EC.04.01.03, EP 1) **M**
- C** 4. Occupational illnesses and staff injuries. (See also EC.04.01.03, EP 1) **M**
- C** 5. Incidents of damage to its property or the property of others. (See also EC.04.01.03, EP 1) **M**
- C** 6. Security incidents involving patients, staff, or others within its facilities. (See also EC.04.01.03, EP 1) **M**
- C** 8. Hazardous materials and waste spills and exposures. (See also EC.04.01.03, EP 1) **M**
- C** 9. Fire safety management problems, deficiencies, and failures. (See also EC.04.01.03, EP 1) **M**
- C** 10. Medical/laboratory equipment management problems, failures, and use errors. (See also EC.04.01.03, EP 1) **M**
- C** 11. Utility systems management problems, failures, or use errors. (See also EC.04.01.03, EP 1) **M**
- A** 12. The hospital conducts environmental tours every six months in patient care areas to evaluate the effectiveness of previously implemented activities intended to minimize or eliminate environment of care risks. (See also EC.04.01.03, EP 1)
- C** 13. The hospital conducts annual environmental tours in nonpatient care areas to evaluate the effectiveness of previously implemented activities intended to minimize or eliminate risks in the environment. (See also EC.04.01.03, EP 1) **M**
- A** 14. The hospital uses its tours to identify environmental deficiencies, hazards, and unsafe practices. (See also EC.02.01.01, EP 1; EC.04.01.03, EP 1) **R**
- A** 15. Every 12 months, the hospital evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness. (See also EC.01.01.01, EPs 3-8; EC.04.01.03, EP 1) **3 R**

## Human Resources (HR)

### Standard HR.01.05.03

Staff participate in ongoing education and training.

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## Elements of Performance for HR.01.05.03

- C** 7. **Ⓧ** Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented. **M**
- C** 8. **Ⓧ** Staff participate in education and training on fall reduction activities. Staff participation is documented. **M**
- C** 13. **Ⓧ** The hospital provides education and training that addresses how to identify early warning signs of a change in a patient's condition and how to respond to a deteriorating patient, including how and when to contact responsible clinicians. Education is provided to staff and licensed independent practitioners who may request assistance and those who may respond to those requests. Participation in this education is documented. **M** **△**<sub>3</sub>

## Infection Prevention and Control (IC)

### Standard IC.01.03.01

The hospital identifies risks for acquiring and transmitting infections.

### Elements of Performance for IC.01.03.01

The hospital identifies risks for acquiring and transmitting infections based on the following:

- A** 1. Its geographic location, community, and population served. (*See also* NPSG.07.03.01, EP 1)
- A** 2. The care, treatment, and services it provides. (*See also* NPSG.07.03.01, EP 1)
- A** 3. The analysis of surveillance activities and other infection control data. (*See also* NPSG.07.03.01, EP 1; TS.03.03.01, EP 2)
- A** 4. The hospital reviews and identifies its risks at least annually and whenever significant changes occur with input from, at a minimum, infection control personnel, medical staff, nursing, and leadership. (*See also* NPSG.07.03.01, EP 1)

- A 5.** © The hospital prioritizes the identified risks for acquiring and transmitting infections. These prioritized risks are documented. (*See also* NPSG.07.03.01, EP 1)

## Leadership (LD)

### Standard LD.02.01.01

The mission, vision, and goals of the hospital support the safety and quality of care, treatment, and services.

#### Elements of Performance for LD.02.01.01

- A 1.** The governing body, senior managers, and leaders of the organized medical staff work together to create the hospital's mission, vision, and goals. (*See also* NR.01.01.01, EP 2)
- A 2.** The hospital's mission, vision, and goals guide the actions of leaders.
- A 3.** Leaders communicate the mission, vision, and goals to staff and the population(s) the hospital serves.

### Standard LD.02.03.01

The governing body, senior managers, and leaders of the organized medical staff regularly communicate with one another on issues of safety and quality.

#### Elements of Performance for LD.02.03.01

- A 1.** Leaders discuss issues that affect the hospital and the population(s) it serves, including the following:
- Performance improvement activities
  - Reported safety and quality issues
  - Proposed solutions and their impact on the hospital'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
- (*See also* NR.01.01.01, EP 3)
- A 2.** The hospital establishes time frames for the discussion of issues that affect the hospital and the population(s) it serves.

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## **Standard LD.02.04.01**

The hospital manages conflict between leadership groups to protect the quality and safety of care.

### **Elements of Performance for LD.02.04.01**

- A 1.** Senior managers and leaders of the organized medical staff work with the governing body to develop an ongoing process for managing conflict among leadership groups.
- A 2.** The governing body approves the process for managing conflict among leadership groups.
- A 4.** The conflict management process includes the following:
  - Meeting with the involved parties as early as possible to identify the conflict
  - Gathering information regarding the conflict
  - Working with the parties to manage and, when possible, resolve the conflict
  - Protecting the safety and quality of care
- A 5.** The hospital implements the process when a conflict arises that, if not managed, could adversely affect patient safety or quality of care.

## **Standard LD.03.01.01**

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

### **Elements of Performance for LD.03.01.01**

- A 1.** Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.
- A 2.** Leaders prioritize and implement changes identified by the evaluation.
- A 3.** Leaders provide opportunities for all individuals who work in the hospital to participate in safety and quality initiatives.
- A 4.** ⓓ Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
- A 5.** Leaders create and implement a process for managing behaviors that undermine a culture of safety. ⚠<sub>3</sub>
- A 6.** Leaders provide education that focuses on safety and quality for all individuals.
- A 7.** Leaders establish a team approach among all staff at all levels.

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- A 8.** All individuals who work in the hospital, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality. (*See also* LD.04.04.05, EP 6)
- A 9.** Literature and advisories relevant to patient safety are available to all individuals who work in the hospital.
- A 10.** Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the hospital.

### **Standard LD.03.02.01**

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

#### **Elements of Performance for LD.03.02.01**


- A 1.** Leaders set expectations for using data and information to improve the safety and quality of care, treatment, and services.
- A 3.** The hospital uses processes to support systematic data and information use.
- A 4.** Leaders provide the resources needed for data and information use, including staff, equipment, and information systems.
- A 5.** The hospital uses data and information in decision making that supports the safety and quality of care, treatment, and services. (*See also* NR.02.01.01, EPs 3 and 6; PI.02.01.01, EP 8)
- A 6.** The hospital uses data and information to identify and respond to internal and external changes in the environment.
- A 7.** Leaders evaluate how effectively data and information are used throughout the hospital.

### **Standard LD.03.03.01**

Leaders use hospitalwide planning to establish structures and processes that focus on safety and quality.

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

- A 1.** Planning activities focus on improving patient safety and health care quality.

- A 3.** Planning is systematic, and it involves designated individuals and information sources.
- A 4.** Leaders provide the resources needed to support the safety and quality of care, treatment, and services. 
- A 5.** Safety and quality planning is hospitalwide.
- A 6.** Planning activities adapt to changes in the environment.
- A 7.** Leaders evaluate the effectiveness of planning activities.

### **Standard LD.03.04.01**

The hospital communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.

#### **Elements of Performance for LD.03.04.01**

- A 1.** Communication processes foster the safety of the patient and the quality of care.
- A 3.** Communication is designed to meet the needs of internal and external users.
- A 4.** Leaders provide the resources required for communication, based on the needs of patients, the community, physicians, staff, and management.
- A 5.** Communication supports safety and quality throughout the hospital. (*See also* LD.04.04.05, EPs 6 and 12)
- A 6.** When changes in the environment occur, the hospital communicates those changes effectively.
- A 7.** Leaders evaluate the effectiveness of communication methods.

### **Standard LD.03.05.01**

Leaders implement changes in existing processes to improve the performance of the hospital.

#### **Elements of Performance for LD.03.05.01**

- A 1.** Structures for managing change and performance improvements exist that foster the safety of the patient and the quality of care, treatment, and services.
- A 3.** The hospital has a systematic approach to change and performance improvement.



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- A 4.** Leaders provide the resources required for performance improvement and change management, including sufficient staff, access to information, and training.
- A 5.** The management of change and performance improvement supports both safety and quality throughout the hospital.
- A 6.** The hospital's internal structures can adapt to changes in the environment.
- A 7.** Leaders evaluate the effectiveness of processes for the management of change and performance improvement. (*See also* PI.02.01.01, EP 13)

### Standard **LD.03.06.01**

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



#### Elements of Performance for LD.03.06.01

- A 1.** Leaders design work processes to focus individuals on safety and quality issues.
  - A 3.** Leaders provide for a sufficient number and mix of individuals to support safe, quality care, treatment, and services. (*See also* IC.01.01.01, EP 3) 
- Note:** *The number and mix of individuals is appropriate to the scope and complexity of the services offered.*
- A 4.** Those who work in the hospital are competent to complete their assigned responsibilities. 
  - A 5.** Those who work in the hospital adapt to changes in the environment.
  - A 6.** Leaders evaluate the effectiveness of those who work in the hospital to promote safety and quality.

### Standard **LD.04.01.01**

The hospital complies with law and regulation.

#### Elements of Performance for LD.04.01.01

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

**Note:** *Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate<sup>§</sup> as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state law. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)*

- A 2.** The hospital provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.
- A 3.** Leaders act on or comply with reports or recommendations from external authorized agencies, such as accreditation, certification, or regulatory bodies.
- A 16.** For psychiatric hospitals that use Joint Commission accreditation for deemed status purposes:
- The psychiatric hospital is primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons.
  - The psychiatric hospital meets the hospital conditions of participation specified in 42 CFR 482.1 through 482.23, and 42 CFR 482.25 through 482.57.
  - The psychiatric hospital maintains clinical records on all patients to determine the degree and intensity of treatments, as specified in 42 CFR 482.61.
  - The psychiatric hospital meets the staffing requirements specified in 42 CFR 482.62.
- A 17. For hospitals that use Joint Commission accreditation for deemed status purposes:** The hospital has a utilization review plan consistent with 42 CFR 482.30 that provides for review of services furnished by the hospital and the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

**Note 1:** *The hospital does not need to have a utilization review plan if either a Quality Improvement Organization (QIO) has assumed binding review for the hospital or the Centers for Medicare & Medicaid Services (CMS) has determined that the utilization review procedures established by the state under title XIX of the Social*

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<sup>§</sup> For more information on how to obtain a CLIA certificate, see [http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_International\\_Laboratories.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html).

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*Security Act are superior to the procedures required in this section, and has required hospitals in that state to meet the utilization review plan requirements under 42 CFR 456.50 through 42 CFR 456.245.*

**Note 2:** *For guidance regarding the requirements at 42 CFR 482.30, refer to the “Medicare Requirements for Hospitals” appendix.*

- A 18. For hospitals that use Joint Commission accreditation for deemed status purposes:** Utilization review activities are implemented by the hospital in accordance with the plan.

**Note 1:** *The hospital does not need to implement utilization review activities itself if either a Quality Improvement Organization (QIO) has assumed binding review for the hospital or the Centers for Medicare & Medicaid Services (CMS) has determined that the utilization review procedures established by the state under title XIX of the Social Security Act are superior to the procedures required in this section, and has required hospitals in that state to meet the utilization review plan requirements under 42 CFR 456.50 through 42 CFR 456.245.*

**Note 2:** *For guidance regarding the requirements at 42 CFR 482.30, refer to the “Medicare Requirements for Hospitals” appendix.*

## Standard LD.04.01.05

The hospital effectively manages its programs, services, sites, or departments.

### Elements of Performance for LD.04.01.05

- A 4.** Staff are held accountable for their responsibilities.

## 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

- A 1.** Leaders set priorities for performance improvement activities and patient health outcomes. (*See also* PI.01.01.01, EPs 1 and 3)
- A 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, 6-8, 11-12, and 14-15)

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- A 3.** Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.
- A 4.** Performance improvement occurs hospitalwide.
- A 5. For hospitals that elect The Joint Commission Primary Care Medical Home option:** Ongoing performance improvement occurs hospitalwide for the purpose of demonstrably improving the quality and safety of care, treatment, or services.
- A 6. For hospitals that elect The Joint Commission Primary Care Medical Home option:** The interdisciplinary team actively participates in performance improvement activities.
- A 24. For hospitals that elect The Joint Commission Primary Care Medical Home option:** Leaders involve patients in performance improvement activities.
- Note: Patient involvement may include activities such as participating on a quality committee or providing feedback on safety and quality issues.*
- A 25.** Senior hospital leadership directs implementation of selected hospitalwide improvements in emergency management based on the following:
- Review of the annual emergency management planning reviews (*See also* EM.03.01.01, EP 4)
  - Review of the evaluations of all emergency response exercises and all responses to actual emergencies (*See also* EM.03.01.03, EP 15)
  - Determination of which emergency management improvements will be prioritized for implementation, recognizing that some emergency management improvements might be a lower priority and not taken up in the near term

## **Standard LD.04.04.05**

The hospital has an organizationwide, integrated patient safety program within its performance improvement activities.

### **Elements of Performance for LD.04.04.05**

- A 1.** The leaders implement a hospitalwide patient safety program.
- A 2.** One or more qualified individuals or an interdisciplinary group manages the safety program.

- A 3.** The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as near misses, close calls, or good catches) to hazardous conditions and sentinel events.
- A 4.** All departments, programs, and services within the hospital participate in the safety program.
- A 5.** As part of the safety program, the leaders create procedures for responding to system or process failures.

**Note:** Responses might include continuing to provide care, treatment, and services to those affected, containing the risk to others, and preserving factual information for subsequent analysis.

- A 6.** The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.01.01, EP 8; LD.03.04.01, EP 5; LD.04.04.03, EP 3; PI.01.01.01, EP 8)

**Note:** This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for their blameworthy errors.

- A 7.** The leaders define patient safety event and communicate this definition throughout the organization.

**Note:** At a minimum, the organization's definition includes those events subject to review in the "Sentinel Events" (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of a serious adverse outcome or result in an adverse event, often referred to as a close call or near miss.

- A 8.** The hospital conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Events" (SE) chapter of this manual. 3
- A 9.** The leaders make support systems available for staff who have been involved in an adverse or sentinel event.

**Note:** *Support systems recognize that conscientious health care workers who are involved in sentinel events are themselves victims of the event and require support. Support systems provide staff with additional help and support as well as additional resources through the human resources function or an employee assistance program. Support systems also focus on the process rather than blaming the involved individuals.*

- A 10.** At least every 18 months, the hospital selects one high-risk process and conducts a proactive risk assessment. (*See also* LD.04.04.03, EP 3)

**Note:** *For suggested components, refer to the Proactive Risk Assessment section at the beginning of this chapter.*

- A 11.** To improve safety and to reduce the risk of medical errors, the hospital analyzes and uses information about system or process failures and the results of proactive risk assessments. (*See also* LD.04.04.03, EP 3)

- A 12.** The leaders disseminate lessons learned from comprehensive systematic analyses (for example, root cause analyses), system or process failures, and the results of proactive risk assessments to all staff who provide services for the specific situation. (*See also* LD.03.04.01, EP 5)

- A 13.** © At least once a year, the leaders provide governance with written reports on the following:
- All system or process failures
  - The number and type of sentinel events
  - Whether the patients and the families were informed of the event
  - All actions taken to improve safety, both proactively and in response to actual occurrences
  - **For hospitals that use Joint Commission accreditation for deemed status purposes:** The determined number of distinct improvement projects to be conducted annually
  - All results of the analyses related to the adequacy of staffing (*See also* PI.02.01.01, EP 14)

- A 14.** The leaders encourage external reporting of significant adverse events, including voluntary reporting programs in addition to mandatory programs.

**Note:** *Examples of voluntary programs include The Joint Commission Sentinel Event Database and the US Food and Drug Administration (FDA) MedWatch. Mandatory programs are often state initiated.*

## Medication Management (MM)

### Standard MM.07.01.03

The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

#### Elements of Performance for MM.07.01.03

- C** 3. The hospital complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors. **M**

**Note:** *This element of performance is also applicable to sample medications.*

### Standard MM.08.01.01

The hospital evaluates the effectiveness of its medication management system.

**Note:** *This evaluation includes reconciling medication information. (Refer to NPSG.03.06.01 for more information)*

#### Elements of Performance for MM.08.01.01

- A** 1. The hospital collects data on the performance of its medication management system. *(See also PI.01.01.01, EPs 14 and 15)*

**Note:** *This element of performance is also applicable to sample medications.*
- A** 2. The hospital analyzes data on its medication management system.
 

**Note:** *This element of performance is also applicable to sample medications.*
- A** 3. The hospital compares data over time to identify risk points, levels of performance, patterns, trends, and variations of its medication management system.
 

**Note:** *This element of performance is also applicable to sample medications.*
- A** 4. The hospital reviews the literature and other external sources for new technologies and best practices.
- A** 5. Based on analysis of its data, as well as review of the literature for new technologies and best practices, the hospital identifies opportunities for improvement in its medication management system.

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**A 6.** The hospital takes action on improvement opportunities identified as priorities for its medication management system. (Refer to PI.03.01.01, EP 2)

**Note:** *This element of performance is also applicable to sample medications.*

**A 7.** The hospital evaluates its actions to confirm that they resulted in improvements for its medication management system.

**A 8.** The hospital takes additional action when planned improvements for its medication management processes are either not achieved or not sustained.

## **Medical Staff (MS)**

### **Standard MS.08.01.01**

The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance.

#### **Elements of Performance for MS.08.01.01**

**A 1.** A period of focused professional practice evaluation is implemented for all initially requested privileges.

**A 2.** Ⓣ The organized medical staff develops criteria to be used for evaluating the performance of practitioners when issues affecting the provision of safe, high quality patient care are identified.

**A 3.** Ⓣ The performance monitoring process is clearly defined and includes each of the following elements:

- Criteria for conducting performance monitoring
- Method for establishing a monitoring plan specific to the requested privilege
- Method for determining the duration of performance monitoring
- Circumstances under which monitoring by an external source is required

**A 4.** Focused professional practice evaluation is consistently implemented in accordance with the criteria and requirements defined by the organized medical staff.

**A 5.** Ⓣ The triggers that indicate the need for performance monitoring are clearly defined.

**Note:** *Triggers can be single incidents or evidence of a clinical practice trend.*

- A 6.** The decision to assign a period of performance monitoring to further assess current competence is based on the evaluation of a practitioner’s current clinical competence, practice behavior, and ability to perform the requested privilege.

**Note:** *Other existing privileges in good standing should not be affected by this decision.*

- A 7.** Ⓓ Criteria are developed that determine the type of monitoring to be conducted.
- A 8.** Ⓓ The measures employed to resolve performance issues are clearly defined.
- A 9.** The measures employed to resolve performance issues are consistently implemented.

### **Standard MS.09.01.01**

The organized medical staff, pursuant to the medical staff bylaws, evaluates and acts on reported concerns regarding a privileged practitioner’s clinical practice and/or competence.

#### **Elements of Performance for MS.09.01.01**

- A 1.** Ⓓ The hospital, based on recommendations by the organized medical staff and approval by the governing body, has a clearly defined process for collecting, investigating, and addressing clinical practice concerns. (*See also* RI.01.07.01, EPs 1, 2, 4, 6, 7, and 10)
- A 2.** Reported concerns regarding a privileged practitioner’s professional practice are uniformly investigated and addressed, as defined by the hospital and applicable law.

## **Nursing (NR)**

### **Standard NR.01.01.01**

The nurse executive directs the delivery of nursing care, treatment, and services.

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

- A 2.** The nurse executive has the authority to speak on behalf of nursing to the same extent that other hospital leaders speak for their respective disciplines, departments, or service lines. (*See also* LD.01.02.01, EP 1 and LD.02.01.01, EP 1)

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## **Standard NR.02.01.01**

The nurse executive directs the hospital's nursing services.

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

- A 3.** The nurse executive coordinates: The development of an effective, ongoing program to measure, analyze, and improve the quality of nursing care, treatment, and services. (*See also* LD.03.02.01, EP 5)
- A 5.** The nurse executive directs: The implementation of hospitalwide programs, policies, and procedures that address how nursing care needs of the patient population are assessed, met, and evaluated. (*See also* LD.04.04.07, EP 1)  
  
*Note: Examples of patient populations include pediatric, diabetic, and geriatric patients.*
- A 6.** The nurse executive directs: The implementation of an effective, ongoing program to measure, analyze, and improve the quality of nursing care, treatment, and services. (*See also* LD.03.02.01, EP 5)

## **Standard NR.02.02.01**

The nurse executive establishes guidelines for the delivery of nursing care, treatment, and services.

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

- A 5.** Ⓣ The nurse executive, registered nurses, and other designated nursing staff write: Standards to measure, assess, and improve patient outcomes.

## **Provision of Care, Treatment, and Services (PC)**

### **Standard PC.03.05.19**

**For hospitals that use Joint Commission accreditation for deemed status purposes:** The hospital reports deaths associated with the use of restraint and seclusion.



## Elements of Performance for PC.03.05.19

### A 1. For hospitals that use Joint Commission accreditation for deemed status

**purposes:** The hospital reports the following information to the Centers for Medicare & Medicaid Services (CMS) regarding deaths related to restraint or seclusion (this requirement does not apply to deaths related to the use of soft wrist restraints; for more information, refer to EP 3 in this standard):

- Each death that occurs while a patient is in restraint or seclusion
- Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion
- Each death known to the hospital that occurs within one week after restraint or seclusion was used when it is reasonable to assume that the use of the restraint or seclusion contributed directly or indirectly to the patient's death. The types of restraints included in this reporting requirement are all restraints except soft wrist restraints.

**Note:** *In this element of performance “reasonable to assume” includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time or deaths related to chest compression, restriction of breathing, or asphyxiation.*

### A 2. © For hospitals that use Joint Commission accreditation for deemed status

**purposes:** The deaths addressed in PC.03.05.19, EP 1, are reported to the Centers for Medicare & Medicaid Services (CMS) by telephone, by facsimile, or electronically no later than the close of the next business day following knowledge of the patient's death. The date and time that the patient's death was reported is documented in the patient's medical record.

### A 3. © For hospitals that use Joint Commission accreditation for deemed status

**purposes:** When no seclusion has been used and when the only restraints used on the patient are wrist restraints composed solely of soft, non-rigid, cloth-like material, the hospital does the following:

- Records in a log or other system any death that occurs while a patient is in restraint. The information is recorded within seven days of the date of death of the patient.
- Records in a log or other system any death that occurs within 24 hours after a patient has been removed from such restraints. The information is recorded within seven days of the date of death of the patient.
- Documents in the patient record the date and time that the death was recorded in the log or other system

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- Documents in the log or other system the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner responsible for the care of the patient, medical record number, and primary diagnosis(es)<sup>||</sup>
- Makes the information in the log or other system available to CMS, either electronically or in writing, immediately upon request

## Performance Improvement (PI)

### Standard PI.01.01.01

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The hospital collects data to monitor its performance.

#### Elements of Performance for PI.01.01.01

- A** 1. The leaders set priorities for data collection. (*See also* LD.04.04.01, EP 1)
- A** 2. The leaders identify the frequency for data collection.

**Note:** *For hospitals that use Joint Commission accreditation for deemed status purposes: The leaders that specify the frequency and detail of data collection is the governing body.*

The hospital collects data on the following:

- A** 3. Performance improvement priorities identified by leaders. (*See also* LD.04.04.01, EP 1)
- A** 4. Operative or other procedures that place patients at risk of disability or death. (*See also* LD.04.04.01, EP 2; MS.05.01.01, EP 6)
- A** 5. All significant discrepancies between preoperative and postoperative diagnoses, including pathologic diagnoses.
- A** 6. Adverse events related to using moderate or deep sedation or anesthesia. (*See also* LD.04.04.01, EP 2)
- A** 7. The use of blood and blood components. (*See also* LD.04.04.01, EP 2)

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<sup>||</sup> For law and regulation guidance pertaining to those responsible for the care of the patient, refer to 42 CFR 482.12(c).

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- A 8.** All reported and confirmed transfusion reactions. (*See also* LD.04.04.01, EP 2; LD.04.04.05, EP 6)
- A 11.** The results of resuscitation. (*See also* LD.04.04.01, EP 2)
- A 12.** Behavior management and treatment. (*See also* LD.04.04.01, EP 2)
- A 14.** Significant medication errors. (*See also* LD.04.04.01, EP 2; MM.08.01.01, EP 1)
- A 15.** Significant adverse drug reactions. (*See also* LD.04.04.01, EP 2; MM.08.01.01, EP 1)
- A 16.** Patient perception of the safety and quality of care, treatment, or services.
- A 30.** The hospital considers collecting data on the following:
  - Staff opinions and needs
  - Staff perceptions of risk to individuals
  - Staff suggestions for improving patient safety
  - Staff willingness to report adverse events
- A 38.** The hospital evaluates the effectiveness of all fall reduction activities including assessment, interventions, and education.
 

**Note:** *Examples of outcome indicators to use in the evaluation include number of falls and number and severity of fall-related injuries.*
- A 39.** The hospital collects data on the effectiveness of its response to change or deterioration in a patient's condition.
 

**Note:** *Measures may include length of stay, response time for responding to changes in vital signs, cardiopulmonary arrest, respiratory arrest, and mortality rates before and after implementation of an early intervention plan.*

**For hospitals that elect The Joint Commission Primary Care Medical Home option:** The primary care medical home collects data on the following:

- A 40.** Disease management outcomes.
- A 41.** Patient access to care within time frames established by the hospital.
- A 42.** **For hospitals that elect The Joint Commission Primary Care Medical Home option:** The primary care medical home collects data on the following:
  - Patient experience and satisfaction related to access to care, treatment, or services, and communication

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- Patient perception of the comprehensiveness of care, treatment, or services
- Patient perception of the coordination of care, treatment, or services
- Patient perception of the continuity of care, treatment, or services

(Refer to PI.01.01.01, EP 16)

- A** 46. The hospital collects data on patient thermal injuries that occur during magnetic resonance imaging exams.
- A** 47. The hospital collects data on the following:
- Incidents where ferromagnetic objects unintentionally entered the magnetic resonance imaging (MRI) scanner room
  - Injuries resulting from the presence of ferromagnetic objects in the MRI scanner room

### **Standard PI.02.01.01**

The hospital compiles and analyzes data.

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

- C** 1. The hospital compiles data in usable formats. **M**
- A** 2. The hospital identifies the frequency for data analysis.
- C** 3. The hospital uses statistical tools and techniques to analyze and display data.
- A** 4. The hospital analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.
- A** 5. The hospital compares data with external sources, when available.
- A** 6. The hospital reviews and analyzes incidents where the radiation dose index (computed tomography dose index [CTDI<sub>vol</sub>], dose length product [DLP], or size-specific dose estimate [SSDE]) from diagnostic CT examinations exceeded expected dose index ranges identified in imaging protocols. These incidents are then compared to external benchmarks.

**Note 1:** *While the CTDI<sub>vol</sub>, DLP, and SSDE are useful indicators for monitoring radiation dose indices from the CT machine, they do not represent the patient's radiation dose.*

**Note 2:** *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

- A 7.** The hospital analyzes its organ procurement conversion rate data as provided by the organ procurement organization (OPO). (See also TS.01.01.01, EP 1)

**Note:** *Conversion rate is defined as the number of actual organ donors over the number of eligible donors defined by the OPO, expressed as a percentage.*

- A 8.** The hospital uses the results of data analysis to identify improvement opportunities. (See also LD.03.02.01, EP 5; PI.03.01.01, EP 1)
- A 12.** When the hospital identifies undesirable patterns, trends, or variations in its performance related to the safety or quality of care (for example, as identified in the analysis of data or a single undesirable event), it includes the adequacy of staffing, including nurse staffing, in its analysis of possible causes.

**Note 1:** *Adequacy of staffing includes the number, skill mix, and competency of all staff. In their analysis, hospitals may also wish to examine issues such as processes related to work flow; competency assessment; credentialing; supervision of staff; and orientation, training, and education.*

**Note 2:** *Hospitals may find value in using the staffing effectiveness indicators (which include National Quality Forum Nursing Sensitive Measures) to help identify potential staffing issues. (Refer to the “Staffing Effectiveness Indicators” (SEI) chapter)*

- A 13.** When analysis reveals a problem with the adequacy of staffing, the leaders responsible for the hospitalwide patient safety program (as addressed at LD.04.04.05, EP 1) are informed, in a manner determined by the safety program, of the results of this analysis and actions taken to resolve the identified problem(s). (See also LD.03.05.01, EP 7)
- A 14.** © At least once a year, the leaders responsible for the hospitalwide patient safety program review a written report on the results of any analyses related to the adequacy of staffing and any actions taken to resolve identified problems. (See also LD.04.04.05, EP 13)

## **Standard PI.03.01.01**

The hospital improves performance on an ongoing basis.

### **Elements of Performance for PI.03.01.01**

- A** 1. Leaders prioritize the identified improvement opportunities. (*See also* PI.02.01.01, EP 8; MS.05.01.01, EPs 1-11)
- A** 2. The hospital takes action on improvement priorities. (*See also* MS.05.01.01, EPs 1-11)
- A** 3. The hospital evaluates actions to confirm that they resulted in improvements. (*See also* MS.05.01.01, EPs 1-11)
- A** 4. The hospital takes action when it does not achieve or sustain planned improvements. (*See also* MS.05.01.01, EPs 1-11)
- A** 11. **For hospitals that elect The Joint Commission Primary Care Medical Home option:** The primary care medical home uses the data it collects on the patient's perception of the safety and quality of care, treatment, or services to improve its performance. This data includes the following:
  - Patient experience and satisfaction related to access to care, treatment, or services and communication
  - Patient perception of the comprehensiveness of care, treatment, or services
  - Patient perception of the coordination of care, treatment, or services
  - Patient perception of the continuity of care, treatment, or services

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

### **Standard RI.01.01.01**

The hospital respects, protects, and promotes patient rights.

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

- A** 1. © The hospital has written policies on patient rights.

**Note: For hospitals that use Joint Commission accreditation for deemed status purposes:** *The hospital's written policies address procedures regarding patient visitation rights, including any clinically necessary or reasonable restrictions or limitations.*

- A 2.** The hospital informs the patient of his or her rights. (See also RI.01.01.03, EPs 1-3)

**Note 1: For hospitals that use Joint Commission accreditation for deemed status purposes:** *The hospital informs the patient (or support person, where appropriate) of his or her visitation rights. Visitation rights include the right to receive the visitors designated by the patient, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend. Also included is the right to withdraw or deny such consent at any time.*

**Note 2: For hospitals that use Joint Commission accreditation for deemed status purposes:** *The hospital makes sure that each patient, or his or her family, is informed of the patient's rights in advance of furnishing or discontinuing patient care whenever possible.*

- C 4.** The hospital treats the patient in a dignified and respectful manner that supports his or her dignity. **M**
- C 5.** The hospital respects the patient's right to and need for effective communication. (See also RI.01.01.03, EP 1) **M R**
- C 6.** The hospital respects the patient's cultural and personal values, beliefs, and preferences. **M R**
- C 7.** The hospital respects the patient's right to privacy. (See also IM.02.01.01, EPs 1-5) **M**

**Note 1:** *This element of performance (EP) addresses a patient's personal privacy. For EPs addressing the privacy of a patient's health information, please refer to Standard IM.02.01.01.*

**Note 2: For hospitals that use Joint Commission accreditation for deemed status purposes and have swing beds:** *The resident's right to privacy includes privacy and confidentiality of his or her personal records and written communications, including the right to send and receive mail promptly.*

- A 8.** The hospital respects the patient's right to pain management. (See also HR.01.04.01, EP 4; PC.01.02.07, EP 1; MS.03.01.03, EP 2)

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**C** 9. The hospital accommodates the patient's right to religious and other spiritual services. **M** **R**

**A** 10. The hospital allows the patient to access, request amendment to, and obtain information on disclosures of his or her health information, in accordance with law and regulation.

**A** 28. The hospital allows a family member, friend, or other individual to be present with the patient for emotional support during the course of stay.

**Note:** *The hospital allows for the presence of a support individual of the patient's choice, unless the individual's presence infringes on others' rights, safety, or is medically or therapeutically contraindicated. The individual may or may not be the patient's surrogate decision-maker or legally authorized representative. (For more information on surrogate or family involvement in patient care, treatment, and services, refer to RI.01.02.01, EPs 6-8.)*

**A** 29. The hospital prohibits discrimination based on age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, and gender identity or expression. **R**

### **Standard RI.01.01.03**

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

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

**C** 1. The hospital provides information in a manner tailored to the patient's age, language, and ability to understand. (See also PC.02.01.21, EP 2; PC.04.01.05, EP 8; RI.01.01.01, EPs 2 and 5) **M** **3** **R**

**C** 2. The hospital provides language interpreting and translation services. (See also HR.01.02.01, EP 1; PC.02.01.21, EP 2; RI.01.01.01, EPs 2 and 5) **M** **3** **R**

**Note:** *Language interpreting options may include hospital-employed language interpreters, contract interpreting services, or trained bilingual staff. These options may be provided in person or via telephone or video. The hospital determines which translated documents and languages are needed based on its patient population.*

**C** 3. The hospital provides information to the patient who has vision, speech, hearing, or cognitive impairments in a manner that meets the patient's needs. (See also PC.02.01.21, EP 2; RI.01.01.01, EPs 2 and 5) **M** **3** **R**

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**Standard RI.01.02.01**

The hospital respects the patient's right to participate in decisions about his or her care, treatment, and services.

**Note:** *For hospitals that use Joint Commission accreditation for deemed status purposes: This right is not to be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.*

**Elements of Performance for RI.01.02.01**

- A 1.** The hospital involves the patient in making decisions about his or her care, treatment, and services, including the right to have his or her family and physician promptly notified of his or her admission to the hospital. **△** **R**
- A 2.** **Ⓣ** The hospital provides the patient with written information about the right to refuse care, treatment, and services.
- A 3.** The hospital respects the patient's right to refuse care, treatment, and services, in accordance with law and regulation. **△** **R**
- A 6.** When a patient is unable to make decisions about his or her care, treatment, and services, the hospital involves a surrogate decision-maker in making these decisions. (See also RI.01.03.01, EP 6) **△** **R**
- A 7.** When a surrogate decision-maker is responsible for making care, treatment, and services decisions, the hospital respects the surrogate decision-maker's right to refuse care, treatment, and services on the patient's behalf, in accordance with law and regulation. **△** **R**
- A 8.** The hospital involves the patient's family in care, treatment, and services decisions to the extent permitted by the patient or surrogate decision-maker, in accordance with law and regulation. **R**
- A 20.** The hospital provides the patient or surrogate decision-maker with the information about the outcomes of care, treatment, and services that the patient needs in order to participate in current and future health care decisions. **R**
- A 21.** The hospital informs the patient or surrogate decision-maker about unanticipated outcomes of care, treatment, and services that relate to sentinel events as defined by The Joint Commission. (Refer to the Glossary for a definition of sentinel event.) **R**

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- A 22.** The licensed independent practitioner responsible for managing the patient's care, treatment, and services, or his or her designee, informs the patient about unanticipated outcomes of care, treatment, and services related to sentinel events when the patient is not already aware of the occurrence or when further discussion is needed. **R**

**Note:** *In settings where there is no licensed independent practitioner, the staff member responsible for managing the care of the patient is responsible for sharing information about such outcomes.*

- A 31. For hospitals that elect The Joint Commission Primary Care Medical Home option:** The primary care medical home respects the patient's right to make decisions about the management of his or her care.

- A 32. For hospitals that elect The Joint Commission Primary Care Medical Home option:** The primary care medical home respects the patient's right and provides the patient the opportunity to do the following:

- Obtain care from other clinicians of the patient's choosing within the primary care medical home
- Seek a second opinion from a clinician of the patient's choosing
- Seek specialty care

**Note:** *This element of performance does not imply financial responsibility for any activities associated with these rights. (Refer to LD.04.02.03, EP 7)*

## Standard **RI.01.03.01**

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

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

- A 1.** Ⓣ The hospital has a written policy on informed consent.
- A 2.** The hospital's written policy identifies the specific care, treatment, and services that require informed consent, in accordance with law and regulation.
- A 3.** The hospital's written policy describes circumstances that would allow for exceptions to obtaining informed consent.
- A 4.** The hospital's written policy describes the process used to obtain informed consent.

- A 5.** The hospital’s written policy describes how informed consent is documented in the patient record.
- Note:** *Documentation may be recorded in a form, in progress notes, or elsewhere in the record.*
- A 6.** The hospital’s written policy describes when a surrogate decision-maker may give informed consent. (*See also* RI.01.02.01, EP 6)
- A 7.** The informed consent process includes a discussion about the patient’s proposed care, treatment, and services. △
- A 9.** The informed consent process includes a discussion about potential benefits, risks, and side effects of the patient’s proposed care, treatment, and services; the likelihood of the patient achieving his or her goals; and any potential problems that might occur during recuperation. △
- A 11.** The informed consent process includes a discussion about reasonable alternatives to the patient’s proposed care, treatment, and services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment, and services. △
- A 12.** The informed consent process includes a discussion about any circumstances under which information about the patient must be disclosed or reported.
- Note:** *Such circumstances may include requirements for disclosure of information regarding cases of HIV, tuberculosis, viral meningitis, and other diseases that are reported to organizations such as health departments or the Centers for Disease Control and Prevention.*
- C 13.** Informed consent is obtained in accordance with the hospital’s policy and processes and, except in emergencies, prior to surgery. (*See also* RC.02.01.01, EP 4) M

## Standard RI.01.05.01

The hospital addresses patient decisions about care, treatment, and services received at the end of life.

### Elements of Performance for RI.01.05.01

- A** 1. Ⓓ The hospital has written policies on advance directives, forgoing or withdrawing life-sustaining treatment, and withholding resuscitative services, in accordance with law and regulation.
- A** 4. **For outpatient hospital settings:** The hospital's written advance directive policies specify whether the hospital will honor advance directives.
- Note:** *It is up to the hospital to determine in which of its outpatient settings, if any, it will honor advance directives.*
- C** 5. The hospital implements its advance directive policies. **M** **3**
- C** 6. Ⓓ The hospital provides patients with written information about advance directives, forgoing or withdrawing life-sustaining treatment, and withholding resuscitative services. **M**
- C** 8. Upon admission, the hospital provides the patient with information on the extent to which the hospital is able, unable, or unwilling to honor advance directives. **M**
- C** 9. Ⓓ The hospital documents whether or not the patient has an advance directive. **M**
- C** 10. Upon request, the hospital refers the patient to resources for assistance in formulating advance directives. **M**
- C** 11. Staff and licensed independent practitioners who are involved in the patient's care, treatment, and services are aware of whether or not the patient has an advance directive. (See also RC.02.01.01, EP 4) **M**
- A** 12. The hospital honors the patient's right to formulate or review and revise his or her advance directives.
- A** 13. The hospital honors advance directives, in accordance with law and regulation and the hospital's capabilities. **3**
- C** 15. Ⓓ The hospital documents the patient's wishes concerning organ donation when he or she makes such wishes known to the hospital or when required by the hospital's policy, in accordance with law and regulation. **M**

Shading indicates a change effective January 1, 2016, unless otherwise noted in the What's New.

- C** 16. The hospital honors the patient's wishes concerning organ donation within the limits of the hospital's capability and in accordance with law and regulation. **M**
- A** 17. The existence or lack of an advance directive does not determine the patient's right to access care, treatment, and services.
- C** 19. **For outpatient hospital settings:** The hospital communicates its policy on advance directives upon request or when warranted by the care, treatment, and services provided. **M**
- C** 20. **For outpatient hospital settings:** Upon request, the hospital refers patients to resources for assistance with formulating advance directives. **M**
- A** 21. **For hospitals that use Joint Commission accreditation for deemed status purposes:** The hospital defines how it obtains and documents permission to perform an autopsy.

### Standard **RI.02.01.01**

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

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

- A** 1. **Ⓓ** The hospital has a written policy that defines patient responsibilities, including but not limited to the following:
  - Providing information that facilitates their care, treatment, and services
  - Asking questions or acknowledging when he or she does not understand the treatment course or care decision
  - Following instructions, policies, rules, and regulations in place to support quality care for patients and a safe environment for all individuals in the hospital
  - Supporting mutual consideration and respect by maintaining civil language and conduct in interactions with staff and licensed independent practitioners
  - Meeting financial commitments
- C** 2. The hospital informs the patient about his or her responsibilities in accordance with its policy. **M**

**Note:** *Information about patient responsibilities can be shared verbally, in writing, or both.*

