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 organization leaders 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 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.[1,2] Those needs and desires include safety.

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

- Ensuring reliable processes

[*] 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.

- 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 an organization that aims to increase the reliability of its complex systems while making risk of patient harm apparent and removing that risk. Joint Commission–accredited organizations should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families, and staff.[1,2]

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. Organizations 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.

Organizations 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 organizations about the importance and structure of an integrated patient safety system. **This chapter describes how existing requirements can be applied to achieve improved**

patient safety; it does not contain any new requirements. 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 organizations can develop into learning organizations
- Explains how organizations can continually evaluate the status and progress of their patient safety systems
- Describes how organizations can work to prevent or respond to patient safety events (Sidebar 1, below, defines key terminology)
- Serves as a framework to guide organization leaders as they work to improve patient safety in their organizations
- 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:*[†] 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

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[†]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.

Sidebar 1. *(continued)*

- ❑ Severe temporary harm
- ■ *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.[3] 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.[3] In a learning organization, patient safety events are seen as opportunities for learning and improvement.[4] 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, an organization 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 organization 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.[4-8] When patient safety events are continuously reported, experts within the organization can define the problem, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the

organization.[4-8] In a learning organization, the organization provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting.

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The Role of Ambulatory Health Care Organization Leaders in Patient Safety

Organization leaders provide the foundation for an effective patient safety system by doing the following:[9]

- 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 organization'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 organization leaders, organizationwide 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.[4] Thus, leadership should take on a long-term commitment to transform the organization.[10]

Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for organizations striving to become learning organizations. In a strong safety culture, the organization has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of leaders is to establish and maintain a strong safety culture within their organization. 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 organization.

The *safety culture* of an organization 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. Organizations 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.[11] 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.[4]
- Safety as everyone's first priority.[4]
- 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.[4,10,12]
- 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.[10] 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.[10,13]
- 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.[6] 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.[6,14]
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the organization fosters a cycle of trust, reporting, and improvement.[10,15] In organizations 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.[10] When trust is established, staff are more likely to report patient safety events, and organizations 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 organization to improve.[10] In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself.[10] (*See* Figure 1. The Trust-Report-Improve Cycle with Robust Process Improvement® (RPI®).)

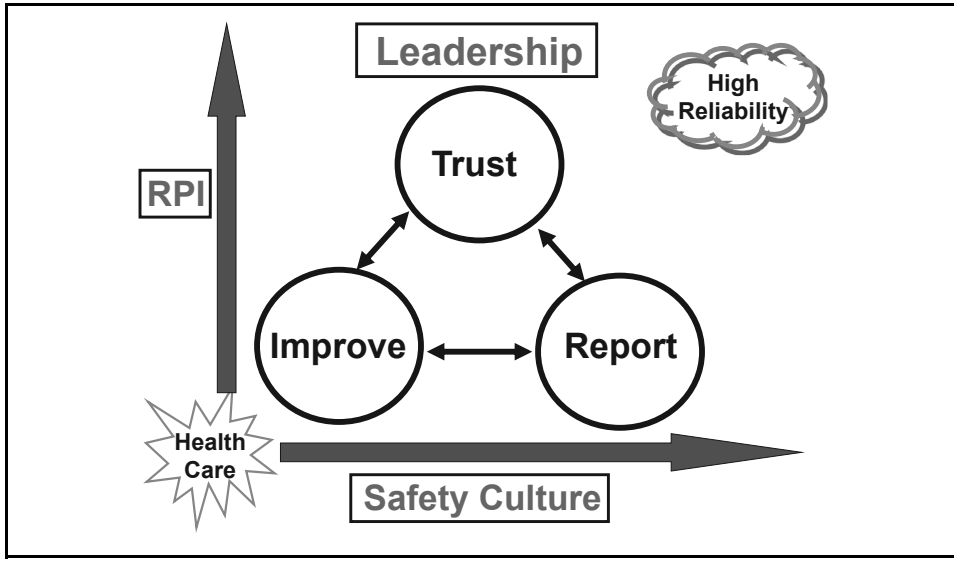

Figure 1. *The Trust-Report-Improve Cycle with Robust Process Improvement® (RPI®)*

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 organization are addressed, so as not to inhibit others from reporting safety concerns.[16] 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.[17] 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:[4,12,17]

- 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

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

These issues are still occurring in organizations nationwide. In a 2013 survey of hospitals by the Institute for Safe Medication Practices (ISMP), 73% of 4,884 respondents 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.[18] 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.[18] 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.[18] 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.[2,8] In order to accomplish this, organizations 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.[10,15] 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.[14,18,19] 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 organization 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.[1–10]

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.[5]

References

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Sidebar 2 *(continued)*

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/
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3. Marx D. How building a 'just culture' helps an organization learn from errors. *OR Manager*. 2003 May;19(5):1, 14–15, 20.
4. Reason J, Hobbs A. *Managing Maintenance Error.* Farnham, Surrey, United Kingdom: Ashgate Publishing, 2003.
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6. National Patient Safety Agency. Incident Decision Tree. Accessed Sep 7, 2013. http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900
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^2: Improving Root Cause Analyses and Actions to Prevent Harm. Jun 16, 2015. Accessed Jun 23, 2015. http://www.npsf.org/?page=RCA2
9. The Joint Commission. *Webinar Replay and Slides: Building Your Safety Culture: A Job for Leaders.* Chassin M. April 27, 2017. Accessed Jul 28, 2017. https://www.jointcommission.org/webinar_replay_slides_sea_issue_57_building_your_safety_culture_leaders/
10. The Joint Commission. *Take 5: Building a Strong Safety Culture - A Job For Leaders.* Benedicto A. May 10, 2017. Accessed Jul 28, 2017. https://www.jointcommission.org/podcast.aspx

Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When organizations adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the organization 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. Organizations 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 organization 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.[20–24]

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 organizations to collect data to monitor their performance, and Standard **LD.03.02.01**, which requires organizations to use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Organizations 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 organizations 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.[25] The effective use of data enables organizations to identify problems, prioritize issues, develop solutions, and track to determine success.[9] Objective data can be used to support decisions, influence people to change their behaviors, and to comply with evidence-based care guidelines.[9,26]

The Joint Commission and the Centers for Medicare & Medicaid Services (CMS) both require organizations 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 organizations to do the following:

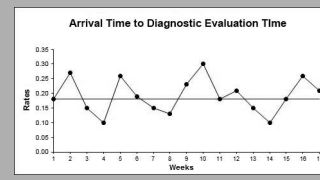
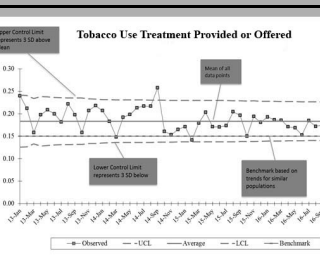
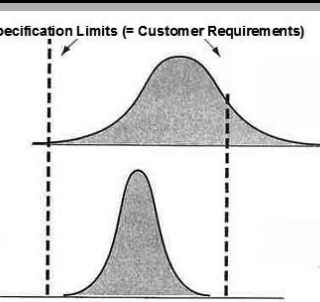
- Collect information to monitor conditions in the environment (Standard **EC.04.01.01**)
- Identify risks for acquiring and transmitting infections (Standard **IC.01.03.01**)
- Use data and information to guide decisions and to understand variation in the performance of processes supporting safety and 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**)
- 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 an organization 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 organization to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the organization not only understand the current performance of organization systems but also can help it predict its performance going forward.[23]

Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps an organization determine what has occurred in a system and provides clues as to why the system responded as it did.[23] 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[1]	■ When the organization needs to identify variation within a system ■ When the organization needs a simple and straightforward analysis of a system ■ As a precursor to an SPC chart	
Statistical Process Control Chart	■ When the organization needs to identify variation within a system and find indicators of why the variation occurred ■ When the organization needs a more detailed and in-depth analysis of a system	
Capability Chart[2]	■ When the organization needs to determine whether a process will function as expected, according to requirements or specifications	 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:

1. 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).
2. George ML, et al. *The Lean Six Sigma Pocket Toolbook: A Quick Reference Guide to Nearly 100 Tools for Improving Process Quality, Speed, and Complexity*. New York: McGraw-Hill, 2005. Used with permission.

Using Data to Drive Improvement

After data has been turned into information, leadership should ensure the following (per the requirements shown):[27–29]

- 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**)
- 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, an organization can correct process problems in order to reduce the likelihood of experiencing adverse events.

In a proactive risk assessment the organization 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-frequency 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 an organization to take a proactive approach to reduce harm. Organizations also benefit from identifying hazardous conditions while designing any new process that could impact patient safety. A 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.[‡] 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, "Strategies for an Effective Risk Assessment.")

A proactive approach to hazardous conditions should include an analysis of the related systems and processes, including the following aspects:[30]

- **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 11, which recommends using the results of proactive risk assessments to improve safety.

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

[‡]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.

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).
- 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.[31]

Organizations 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 https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-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 https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools 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 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 organization readmissions. Patients who are less activated suffer poorer health outcomes and are less likely to follow their provider's advice.[32,33]

A patient-centered approach to care can help organizations assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the organization. This includes adopting the following principles:[34]

- 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 organization 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.

Organizations 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.[34]

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

- 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 organizations 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 organizations 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 an organization's comprehensive systematic analysis as well as the action plan to help the organization 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 organizations transform into high reliability organizations. For specific quality and patient problems, the Center's Targeted Solutions Tool® (TST®) guides 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 accessing the Standards FAQs at 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 https://www.jointcommission.org/ahc_2016_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 Alerts*, go to http://www.jointcommission.org/sentinel_event.aspx.)
- *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
- *Joint Commission Resources*: A Joint Commission not-for-profit affiliate that produces books and periodicals, holds conferences, provides consulting services, and develops software products 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™ 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™*: 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 BoosterPak topics have included credentialing and privileging in nonhospital settings, waived testing, 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 organizations 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
  - Workplace violence prevention resources: https://www.jointcommission.org/workplace_violence.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 organization notifies the public it serves about how to contact its organization 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 organization's website.*

Elements of Performance for APR.09.01.01

1. The organization informs the public it serves about how to contact its management to report concerns about patient safety and quality of care.
2. The organization 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, or services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the organization.

Elements of Performance for APR.09.02.01

1. The organization educates its staff and other persons who provide care, treatment, or services that concerns about the safety or quality of care provided in the organization may be reported to The Joint Commission.
2. The organization informs its staff that it will take no disciplinary or punitive action because an employee or other individual who provides care, treatment, or services reports safety or quality-of-care concerns to The Joint Commission.
3. The organization takes no disciplinary or punitive action against employees or other individuals who provide care, treatment, or services when they report safety or quality-of-care concerns to The Joint Commission.

Environment of Care (EC)

Standard EC.04.01.01

The organization collects information to monitor conditions in the environment.

Elements of Performance for EC.04.01.01

1. The organization establishes a process(es) for continually monitoring, internally reporting, and investigating the following:
   - Problems and incidents related to risks addressed in the environment of care management plans
   - Injuries to patients or others within the organization's facilities
   - Occupational illnesses and staff injuries
   - Incidents of damage to its property or the property of others

   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 organization reports and investigates the following:

2. Problems and incidents related to each of the environment of care management plans.

3. Injuries to patients or others within the organization's facilities.
4. Occupational illnesses and staff injuries.
5. Incidents of damage to its property or the property of others.

15. Ⓓ Every 12 months, the organization evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness. R

Standard EC.04.01.03

The organization analyzes identified environment of care issues.

Element of Performance for EC.04.01.03

2. The organization uses the results of data analysis to identify opportunities to resolve environmental safety issues.

Standard EC.04.01.05

The organization improves its environment of care.

Element of Performance for EC.04.01.05

1. The organization takes action on the identified opportunities to resolve environmental safety issues.

Human Resources (HR)

Standard HR.01.05.03

Staff participate in ongoing education and training.

Elements of Performance for HR.01.05.03

1. Ⓓ Staff participate in ongoing education and training to maintain or increase their competency and, as needed, when staff responsibilities change. Staff participation is documented.
   For ambulatory surgical centers that elect to use The Joint Commission deemed status option: Staff participate in ongoing education and training with respect to their roles in the fire response plan. (For information on staff's roles in the fire response plan, *see* EC.02.03.01, EP 10.)

14. Ⓓ The organization verifies and documents that technologists who perform diagnostic computed tomography (CT) examinations participate in ongoing education that includes annual training on the following:
    - Radiation dose optimization techniques and tools for pediatric and adult patients addressed in the Image Gently® and Image Wisely® campaigns
    - Safe procedures for operation of the types of CT equipment they will use

    Note 1: *Information on the Image Gently and Image Wisely initiatives can be found online at http://www.imagegently.org and http://www.imagewisely.org, respectively.*

    Note 2: *This element of performance does not apply to CT systems used for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.*

    Note 3: *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.*

25. Ⓓ The organization verifies and documents that technologists who perform magnetic resonance imaging (MRI) examinations participate in ongoing education that includes annual training on safe MRI practices in the MRI environment, including the following:
    - Patient screening criteria that address ferromagnetic items, electrically conductive items, medical implants and devices, and risk for nephrogenic systemic fibrosis (NSF)
    - Proper patient and equipment positioning activities to avoid thermal injuries
    - Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional)[§]
    - MRI safety response procedures for patients who require urgent or emergent medical care
    - MRI system emergency shutdown procedures, such as MRI system quench and cryogen safety procedures
    - Patient hearing protection
    - Management of patients with claustrophobia, anxiety, or emotional distress

[§] Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (http://www.astm.org).

Standard HR.02.01.03

The organization grants initial, renewed, or revised clinical privileges to individuals who are permitted by law and the organization to practice independently.

Elements of Performance for HR.02.01.03

7. Before granting renewed or revised privileges to a licensed independent practitioner, the organization does following:
   - Reviews information from any of its performance improvement activities pertaining to professional performance, judgment, and clinical or technical skills.
   - Evaluates the results of any peer review of the individual's clinical performance.
   - Reviews any clinical performance in the organization that is outside acceptable standards.

Infection Prevention and Control (IC)

Standard IC.01.03.01

The organization identifies risks for acquiring and transmitting infections.

Elements of Performance for IC.01.03.01

1. The organization identifies infection risks based on the following:
   - Its geographic location, community, and population served
   - The care, treatment, or services it provides
   - The analysis of its infection surveillance and control data

3. Ⓓ The organization prioritizes the identified risks for acquiring and transmitting infections. These prioritized risks are documented.

Leadership (LD)

Standard LD.02.01.01

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

Elements of Performance for LD.02.01.01

1. Leaders work together to create the organization's mission, vision and goals.
2. The organization's mission, vision, and goals guide the actions of leaders.
3. Leaders communicate the mission, vision, and goals to staff and the population(s) the organization serves.

Standard LD.02.03.01

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

Elements of Performance for LD.02.03.01

1. Leaders discuss issues that affect the organization and the population(s) it serves, including the following:
   - Performance improvement activities
   - Reported safety and quality issues
   - Proposed solutions and their impact on the organization's resources
   - Reports on key quality measures and safety indicators
   - Safety and quality issues specific to the population served
   - Input from the population(s) served
2. The organization establishes time frames for the discussion of issues that affect the organization and the population(s) it serves.

Standard LD.03.01.01

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

Elements of Performance for LD.03.01.01

1. Leaders regularly evaluate the culture of safety and quality.
2. Leaders prioritize and implement changes identified by the evaluation.
4. Ⓓ Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
5. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

Standard LD.03.02.01

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

Elements of Performance for LD.03.02.01

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

Standard LD.03.03.01

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

Elements of Performance for LD.03.03.01

1. Planning activities focus on improving patient safety and health care quality.
2. Leaders can describe how planning supports a culture of safety and quality.
3. Planning is systematic, and it involves designated individuals and information sources.
4. Leaders provide the resources needed to support the safety and quality of care, treatment, or services.
5. Safety and quality planning is organizationwide.
6. Planning activities adapt to changes in the environment.
7. Leaders evaluate the effectiveness of planning activities.

Standard LD.03.04.01

The organization 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

1. Communication processes foster the safety of the patient and the quality of care.
2. Leaders are able to describe how communication supports a culture of safety and quality.
3. Communication is designed to meet the needs of internal and external users.
4. Leaders provide the resources required for communication, based on the needs of patients, staff, and management.
5. Communication supports safety and quality throughout the organization. (*See also* LD.04.04.05, EPs 6 and 12)
6. When changes in the environment occur, the organization communicates those changes effectively.
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 organization.

Elements of Performance for LD.03.05.01

1. Structures for managing change and performance improvements exist that foster the safety of the patient and the quality of care, treatment, or services.
2. Leaders are able to describe how the organization's approach to performance improvement and its capacity for change support a culture of safety and quality.
3. The organization has a systematic approach to change and performance improvement.
4. Leaders provide the resources required for performance improvement and change management, including sufficient staff, access to information, and training.
5. The management of change and performance improvement supports both safety and quality throughout the organization.
6. The organization's internal structures can adapt to changes in the environment.
7. Leaders evaluate the effectiveness of processes for the management of change and performance improvement.

Standard LD.03.06.01

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

Elements of Performance for LD.03.06.01

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

Standard LD.04.01.01

The organization complies with law and regulation.

Elements of Performance for LD.04.01.01

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

   Note: *Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate*[‖] *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)*

2. The organization provides care, treatment, or services in accordance with licensure requirements, laws, and rules and regulations.
3. Leaders act on or comply with reports or recommendations from external authorized agencies, such as accreditation, certification, or regulatory bodies.

[‖] 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.

15. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The organization complies with part 493 of the Code of Federal Regulations.

    Note: *Part 493 of the Code of Federal Regulations requires organizations who perform laboratory testing to maintain compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).*

19. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** Organizations that do not provide their own laboratory services have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of the Code of Federal Regulations. The referral laboratory is certified in the associated specialties and subspecialties needed to perform tests ordered.

Standard LD.04.01.05

The organization effectively manages its programs, services, or sites.

Elements of Performance for LD.04.01.05

2. Programs, services, or sites providing patient care are directed by one or more qualified professionals or by a qualified licensed independent practitioner with clinical privileges.

3. Ⓓ The organization defines, in writing, the responsibility of those with administrative and clinical direction of its programs, services, or sites.

4. Staff are held accountable for their responsibilities.

5. Leaders provide for the coordination of care, treatment, or services among the organization's different programs, services, or sites.

11. **For organizations that elect The Joint Commission Primary Care Medical Home option:** The organization evaluates how effectively the primary care clinician and the interdisciplinary team work in partnership with the patient to support the continuity of care and the provision of comprehensive and coordinated care, treatment, or services.

13. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** If radiologic services are provided by the ambulatory surgical center, the governing body must appoint an individual qualified in accordance with state law and organizational policies who is responsible for making certain that all radiologic services are provided in accordance with law and regulation.

    Note: *The Joint Commission elements of performance that relate to laws and regulations for radiologic services are outlined in the ambulatory surgical center crosswalk on E-dition.*

Standard LD.04.04.01

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

Elements of Performance for LD.04.04.01

1. Leaders set priorities for performance improvement activities and patient health outcomes. (*See also* PI.01.01.01, EPs 1 and 3)
2. Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (*See also* PI.01.01.01, EPs 4, 6–8, 14, and 15)
3. Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.
4. Performance improvement occurs organizationwide.
5. **For organizations that elect The Joint Commission Primary Care Medical Home option:** Ongoing performance improvement occurs organizationwide for the purpose of demonstrably improving the quality and safety of care, treatment, or services.
6. **For organizations that elect The Joint Commission Primary Care Medical Home option:** The interdisciplinary team actively participates in performance improvement activities.

16. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The infection control program is an integral part of the ambulatory surgical center's quality assessment and performance improvement program.

17. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The governing body makes certain that the quality assessment and performance improvement program is defined, implemented, and maintained.

18. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The governing body makes certain that adequate staff, time, information systems, and training are allocated to the quality assessment and performance improvement program.

19. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The governing body makes certain that the performance improvement data collection methods, frequency, and details are appropriate.

20. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center sets priorities for its performance improvement activities that affect health outcomes, patient safety, and quality of care.

21. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center develops an ongoing, data-driven quality assessment and performance improvement program.

22. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center implements its quality assessment and performance improvement program.

23. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center maintains its quality assessment and performance improvement program.

24. **For organizations 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.*

26. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** Leaders establish priorities that consider the incidence, prevalence, and severity of high-volume, high-risk, or problem-prone areas found in performance improvement activities.

Standard LD.04.04.05

The organization has an organizationwide, integrated patient safety program.

Elements of Performance for LD.04.04.05

1. The leaders implement an organizationwide patient safety program.
2. One or more qualified individuals manage the safety program.
3. The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as close calls ["near misses"] or good catches) to hazardous conditions and sentinel events.
4. All departments, programs, and services within the organization participate in the safety program.
5. As part of the safety program, the leaders create procedures for responding to system or process failures. (*See also* PI.03.01.01, EP 10)

   Note: *Responses might include continuing to provide care, treatment, or services to those affected, containing the risk, and preserving factual information for subsequent analysis.*
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.03.04.01, EP 5; LD.04.04.03, EP 3; PI.03.01.01, EP 10)

   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.*
7. The leaders define patient safety event and communicate this definition throughout the organization. (*See also* PI.03.01.01, EP 10)

   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.*

8. The organization 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.

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.*

11. To improve safety, the organization analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. (*See also* LD.04.04.03, EP 3)

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; PI.03.01.01, EP 10)

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

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

Elements of Performance for MM.07.01.03

1. Ⓓ The organization has a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

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

2. Ⓓ The organization has a written process addressing prescriber notification in the event of an adverse drug event, significant adverse drug reaction, or medication error.

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

3. The organization complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

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

4. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** All adverse drug events are reported to the physician (as defined in section 1861(r) of the Social Security Act) responsible for the patient and are documented in the clinical record.

5. The organization implements its process for responding to adverse drug events, significant adverse drug reactions, and medication errors.

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

Standard MM.08.01.01

The organization 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

1. The organization 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.*

2. The organization analyzes data on its medication management system.

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

3. The organization 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.*

5. Based on analysis of its data, as well as review of the literature for new technologies and best practices, the organization identifies opportunities for improvement in its medication management system.

6. The organization takes action on improvement opportunities identified as priorities for its medication management system. (*See also* PI.03.01.01, EP 2)

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

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

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

Performance Improvement (PI)

Standard PI.01.01.01

The organization collects data to monitor its performance.

Elements of Performance for PI.01.01.01

1. The leaders set priorities for data collection. (*See also* LD.04.04.01, EP 1)

2. The organization identifies the frequency for data collection.

The organization collects data on the following:

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

28. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The organization, with the participation of the medical staff, collects data on the medical necessity of procedures.

29. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The organization, with the participation of the medical staff, collects data on the appropriateness of care.

36. Ⓓ **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center documents the improvement projects it is conducting. The documentation includes, at a minimum, the reason(s) for implementing the project and a description of the project's results.

For organizations that elect The Joint Commission Primary Care Medical Home option: The organization collects data on the following:

40. Disease management outcomes.
41. Patient access to care within time frames established by the organization.

42. **For organizations that elect The Joint Commission Primary Care Medical Home option:** The organization collects data on 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

    (Refer to PI.01.01.01, EP 16)

46. The organization collects data on patient thermal injuries that occur during magnetic resonance imaging exams.

47. The organization 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 organization compiles and analyzes data.

Elements of Performance for PI.02.01.01

4. The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.

6. The organization reviews and analyzes incidents where the radiation dose index (computed tomography dose index [CTDIvol], 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 CTDIvol, 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.*

8. The organization uses the results of data analysis to identify improvement opportunities. (*See also* LD.03.02.01, EP 5)

11. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The number and scope of distinct improvement projects conducted annually reflects the scope and complexity of the ambulatory surgical center's services and operations.

Standard PI.03.01.01

The organization improves performance.

Elements of Performance for PI.03.01.01

2. The organization takes action on improvement priorities. (*See also* MM.08.01.01, EP 6)

4. The organization takes action when it does not achieve or sustain planned improvements.

11. **For organizations that elect The Joint Commission Primary Care Medical Home option:** The organization 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 organization respects patient rights.

Elements of Performance for RI.01.01.01

1. Ⓓ The organization has written policies on patient rights.

2. Information about patient rights is available to the patient. (*See also* RI.01.01.03, EPs 1–3)

4. The organization treats the patient in a dignified and respectful manner that supports his or her dignity.

5. The organization respects the patient's right to and need for effective communication. (*See also* RI.01.01.03, EP 1)

6. The organization respects the patient's cultural and personal values, beliefs, and preferences.

7. The organization respects the patient's right to privacy. (*See also* IM.02.01.01, EPs 1–4)

   Note: *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.*

8. The organization respects the patient's right to pain management. (*See also* HR.01.04.01, EP 4; HR.02.02.01, EP 4; PC.01.02.07, EP 1)

10. The organization 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.

13. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The organization respects the patient's right to receive care in a safe setting.

Standard RI.01.01.03

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

Elements of Performance for RI.01.01.03

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

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

Note: ***For organizations that elect The Joint Commission Primary Care Medical Home option:*** *Language interpreting options may include trained bilingual staff, contract interpreting services, or employed language interpreters. These options may be provided in person or via telephone or video. The documents translated, and the languages into which they are translated, are dependent on the organization's patient population.*

3. The organization communicates with the patient who has vision, speech, hearing, or cognitive impairments in a manner that meets the patient's needs. (*See also* RI.01.01.01, EP 2)

4. Ⓓ **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center provides the patient or his or her surrogate decision-maker with verbal and written notice of the patient's rights prior to the start of the surgical procedure in a language and manner that the patient or his or her surrogate decision-maker understands.

5. Ⓓ **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The ambulatory surgical center posts a copy of its notice of patient rights in a location where it is likely to be noticed by patients. The notice of rights includes contact information for reporting complaints to the state agency and the website for the Office of the Medicare Beneficiary Ombudsman.

Standard RI.01.02.01

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

Elements of Performance for RI.01.02.01

1. The organization involves the patient in making decisions about his or her care, treatment, or services.

2. When a patient is unable to make decisions about his or her care, treatment, or services, the organization involves a surrogate decision maker in making these decisions. (*See also* RI.01.03.01, EP 1)

4. The organization respects the patient's or surrogate decision maker's right to refuse care, treatment, or services, in accordance with law and regulation.

8. The organization involves the patient's family in care, treatment, or services decisions to the extent permitted by the patient or surrogate decision-maker, in accordance with law and regulation.

20. The organization provides the patient or surrogate decision-maker with the information about the following:
    - Outcomes of care, treatment, or services that the patient needs in order to participate in current and future health care decisions
    - Unanticipated outcomes of the patient's care, treatment, or services that are sentinel events as defined by The Joint Commission (Refer to the Glossary for a definition of sentinel event.)

31. **For organizations that elect The Joint Commission Primary Care Medical Home option:** The organization respects the patient's right to make decisions about the management of his or her care.

32. **For organizations that elect The Joint Commission Primary Care Medical Home option:** The organization 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.*

Standard RI.01.03.01

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

Elements of Performance for RI.01.03.01

1. Ⓓ The organization follows a written policy on informed consent that describes the following:
    - The specific care, treatment, or services that require informed consent
    - Circumstances that would allow for exceptions to obtaining informed consent
    - When a surrogate decision-maker may give informed consent (*See also* RI.01.02.01, EP 2)

2. The informed consent process includes a discussion about the following:
    - The patient's proposed care, treatment, or services.

- Potential benefits, risks, and side effects of the patient's proposed care, treatment, or services; the likelihood of the patient achieving his or her goals; and any potential problems that might occur during recuperation.
- Reasonable alternatives to the patient's proposed care, treatment, or services. The discussion encompasses risks, benefits, and side effects related to the alternatives and the risks related to not receiving the proposed care, treatment, or services.

15. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** Informed consent is obtained before a treatment or procedure is performed.

Standard RI.01.05.01

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

Elements of Performance for RI.01.05.01

1. Ⓓ The organization follows written policies on advance directives that specify whether the organization will honor advance directives. The organization communicates its policies on advance directives to patients upon request.

7. Ⓓ **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** Prior to the start of the surgical procedure the ambulatory surgical center provides the patient or his or her surrogate decision-maker with written information concerning its policies on advance directives, including a description of applicable state health and safety laws and, if requested, official state advance directive forms.

10. Upon request, the organization shares with the patient possible sources of help in formulating advance directives.

Standard RI.02.01.01

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

Element of Performance for RI.02.01.01

2. The organization informs the patient about his or her responsibilities.

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