

# Patient Safety Systems (PS)

## Introduction

The quality of care and the safety of patients and residents are core values of The Joint Commission accreditation process. This is a commitment The Joint Commission has made to patients, residents, 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- and resident-centered system that aims to improve quality of care and patient and resident 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 and residents. 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, residents, 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, patients, and residents by recommending methods that will improve quality and safety processes.
3. Encouraging and recommending proactive quality and patient/resident 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.

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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, ed. Washington, DC: The National Academies Press, 1990.

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

- Ensuring reliable processes
- Decreasing variation and defects (waste)
- Focusing on achieving positive measurable outcomes
- Using evidence to ensure that a service is satisfactory

Patient and resident 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, residents, families, staff, and the public expect from Joint Commission–accredited organizations. While patient or resident safety events may not be completely eliminated, harm to patients and residents 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 or resident harm. Joint Commission–accredited organizations should be continually focused on eliminating systems failures and human errors that may cause harm to patients, residents, families, and staff.<sup>1,2</sup>

The ultimate purpose of The Joint Commission’s accreditation process is to enhance quality of care and safety for patients and residents. 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. Nursing care centers should have an integrated approach to safety so that high levels of safe care can be provided for every patient or resident in every care setting and service.

Nursing care centers are complex environments that depend on strong leadership to support an integrated patient and resident 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 and resident 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 or resident safety events, including close calls and other system failures that have not yet led to patient or resident harm.

## What Does This Chapter Contain?

The “Patient Safety Systems” (PS) chapter is intended to help inform and educate nursing care centers about the importance and structure of an integrated patient and resident 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 the safety of patients and residents.

This chapter does the following:

- Describes an integrated patient and resident safety system
- Discusses how nursing care centers can develop into learning organizations
- Explains how nursing care centers can continually evaluate the status and progress of their patient and resident safety systems
- Describes how nursing care centers can work to prevent or respond to patient or resident safety events (Sidebar 1 defines key terminology)
- Serves as a framework to guide nursing care center leaders as they work to improve patient and resident safety in their facilities
- Contains a list of standards and requirements related to patient safety and resident 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.

### Sidebar 1. Key Terms to Understand

- *Patient [or resident] safety event:* An event, incident, or condition that could have resulted or did result in harm to a patient.
- *Adverse event:* A patient [or resident] safety event that resulted in harm to a patient or resident.

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## Sidebar 1. (continued)

- **Sentinel event:**<sup>†</sup> A subcategory of adverse events, a sentinel event is a patient [or resident] safety event (not primarily related to the natural course of the patient's or resident's illness or underlying condition) that reaches a patient or resident and results in any of the following:
  - Death
  - Permanent harm
  - Severe temporary harm
- **Close call or near miss, or good catch:** A patient [or resident] 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 or resident'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 and resident 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 or resident 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 or resident safety events. In order to become a learning organization, a nursing

<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.

care center 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 health care organization's leaders.

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

## The Role of Nursing Care Center Leaders in Patient and Resident Safety

Nursing care center leaders and staff provide the foundation for an effective patient and resident 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 or resident harm events are freely shared with staff
- Modeling professional behavior
- Addressing intimidating behavior that might undermine the safety culture
- 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 and resident safety system appear in the Joint Commission's Leadership (LD) standards, including Standard **LD.03.09.01** (which focuses on having an organizationwide, integrated patient and resident safety program).

Without the support of nursing care center leaders, organizationwide changes and improvement initiatives are difficult to achieve. Leadership engagement in patient and resident 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 organization.<sup>10</sup>

## **Safety Culture**

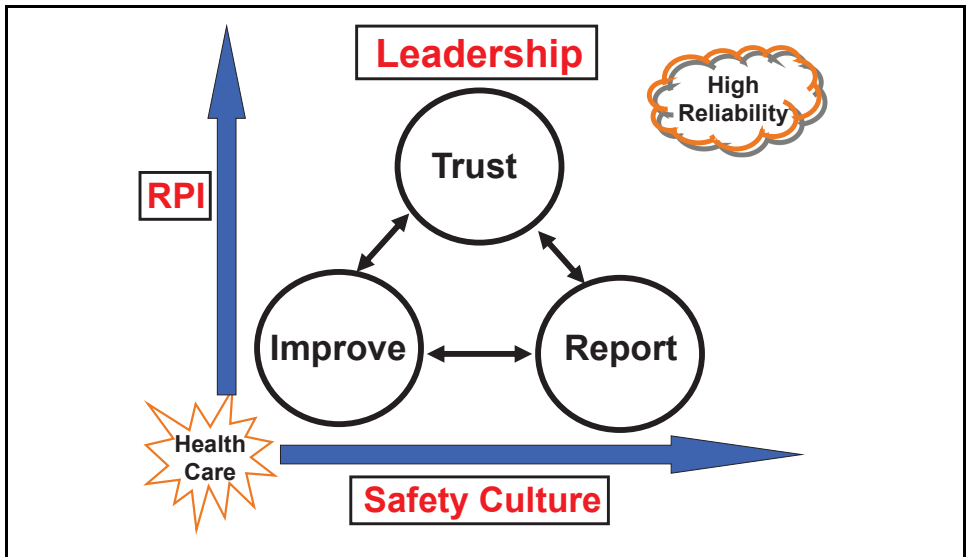
A strong safety culture is an essential component of a successful patient and resident safety system and is a crucial starting point for nursing care centers striving to become learning organizations. In a strong safety culture, the health care organization has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of nursing care center 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 a nursing care center is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to the quality and safety of its patients and residents.

Nursing care centers 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, residents, 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 or resident 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 or resident 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 or resident safety event.<sup>6,14</sup>
- By reporting and learning from patient or resident safety events, staff create a learning organization.

A safety culture operates effectively when the nursing care center fosters a cycle of trust, reporting, and improvement.<sup>10,15</sup> 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 or resident safety event.<sup>10</sup> When trust is established, staff are more likely to report patient or resident safety events, and nursing care centers 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.<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.)



**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 and staff need to ensure that intimidating or unprofessional behaviors within the nursing care center 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 and resident 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
- 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 health care organizations 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 the quality and safety of patients and residents.



## A Fair and Just Safety Culture

A fair and just safety culture is needed for staff to trust that they can report patient or resident safety events without being treated punitively.<sup>2,8</sup> In order to accomplish this, nursing care centers should provide and encourage the use of a standardized reporting process for staff to report patient or resident safety events. This is also built into the Joint Commission's standards at Standard **LD.03.09.01**, EP 3, 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 or residents are harmed, and *reactive risk reduction* attempts to prevent the recurrence of problems that have already caused patient or resident harm.<sup>10,15</sup>

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 for a discussion of tools that can help leaders determine a fair and just response to a patient or resident 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 nursing care center 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>1-10</sup>

There are a number of sources for information (some of which are listed in the “References” section) that provide rationales, tools, and techniques that will assist an organization in creating a formal decision process to determine what events should

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## Sidebar 2. (continued)

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 or resident 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 another formal decision process can help make determinations of culpability more transparent and fair.<sup>5</sup>

### References

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sentinel-event-alert-newsletters/sentinel-event-alert-57-the-essential-role-of-leadership-in-developing-a-safety-culture/webinar-replay-and-slides-building-your-safety-culture-a-job-for-leaders/

10. The Joint Commission. *Take 5: Building a Strong Safety Culture - A Job For Leaders*. Benedicto A. May 10, 2017. Accessed Jan 17, 2020. <https://www.jointcommission.org/resources/news-and-multimedia/podcasts/#q=Building%20a%20Strong%20Safety%20Culture>

## Data Use and Reporting Systems

An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When nursing care centers adopt a transparent, nonpunitive approach to reports of patient or resident 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 or resident safety events. Nursing care centers 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 nursing care center can analyze the patient or resident 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 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.

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

- Create a nonpunitive approach to patient or resident safety event reporting
- Educate staff on identifying patient or resident safety events that should be reported
- Provide timely feedback regarding actions taken on patient or resident safety events

## **Effective Use of Data**

### **Collecting Data**

When nursing care centers collect data or measure staff compliance with evidence-based care processes or patient and resident outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient and resident safety.<sup>25</sup> The effective use of data enables organizations 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 requires health care organizations to collect and use data related to certain outcomes regarding care and harm to patients and residents. 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 (Standard **LD.03.09.01**)
- 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 a nursing care center to “diagnose” problems within its system similar to the way one would diagnose a patient’s or resident’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 nursing care center not only understand the current performance of the organization’s 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 an organization determine what has occurred in a system and provides clues as to why the system responded as it did.<sup>23</sup> Table 1 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	<ul style="list-style-type: none"> <li>When the nursing care center needs to identify variation within a system</li> <li>When the nursing care center 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 nursing care center needs to identify variation within a system and find indicators of why the variation occurred</li> <li>When the nursing care center needs a more detailed and in-depth analysis of a system</li> </ul>	
Capability Chart	<ul style="list-style-type: none"> <li>When the nursing care center 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.

## Using Data to Drive Improvement

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

- Information is presented in a clear manner (Standard **LD.03.04.01**)
- Information is shared with the appropriate groups throughout the organization (from the front line to the board) (Standards **LD.03.04.01**, **LD.03.09.01**)
- Opportunities for improvement and actions to be taken are communicated (Standards **LD.03.05.01**, **LD.03.07.01**)
- Improvements are celebrated or recognized

## A Proactive Approach to Preventing Harm

Proactive risk reduction prevents harm before it reaches the patient or resident. By engaging in proactive risk reduction, a nursing care center 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, and 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 and resident 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 nursing care center to take a proactive approach to reduce harm. Nursing care centers also benefit from identifying hazardous conditions while designing any new process that could impact patient and resident safety. A hazardous condition is defined as any circumstance that increases the probability of a patient or resident 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.)

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) and inadequate staffing levels.
- **Supervisory influences.** Examples include inadequate supervision, planned inappropriate operations, failure to address a known problem, and authorization of activities that are known to be hazardous.
- **Organizational influences.** Examples include inadequate staffing, inadequate policies, and lack of strategic risk assessment.

The Joint Commission addresses proactive risk assessments at Standard **LD.03.09.01**, EP 7, which requires nursing care centers to select one high-risk process and conduct a proactive risk assessment at least every 18 months.

Nursing care centers 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.

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

There are several methods of conducting proactive risk assessments, including the following:

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<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.



### Sidebar 3. (continued)

- Promote a blame-free reporting culture and provide a reporting system to support it.
- 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 residents 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 and residents.
- 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>

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

## Encouraging Patient or Resident Activation

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

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

- Patient and resident safety guides all decision making.
- Patients, residents, and families are partners at every level of care.
- Patient-, resident- and family-centered care is verifiable, rewarded, and celebrated.
- The licensed independent practitioner responsible for the patient's or resident's care, or his or her designee, discloses to the patient, resident, and family any unanticipated outcomes of care, treatment, and services.
- Though Joint Commission standards do not require apology, evidence suggests that patients and residents benefit—and are less likely to pursue litigation—when care providers disclose harm, express sympathy, and apologize.
- Staffing levels are sufficient, and staff has the necessary tools and skills.
- The nursing care center has a focus on measurement, learning, and improvement.

- Staff and licensed independent practitioners must be fully engaged in patient-, resident-, and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Nursing care centers can adopt a number of strategies to support and improve patient or resident 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 and resident rights and provide an excellent starting point for nursing care centers seeking to improve patient or resident activation. These standards require that nursing care centers do the following:

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

To assist nursing care centers on their journey toward creating highly reliable patient or resident safety systems, The Joint Commission provides many resources, including the following:

- *Office of Quality and Patient Safety*: An internal Joint Commission department that offers nursing care centers guidance and support when they experience a sentinel event. The Office of Quality and Patient Safety assesses the thoroughness and credibility of a nursing care center'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 nursing care centers transform into high reliability organizations. For specific quality and patient or resident 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 areas of greatest interest to nursing care centers: hand hygiene, handoff communications, and preventing falls. 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 <https://www.jointcommission.org/standards/standard-faqs/>. 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 Alerts*, go to [http://www.jointcommission.org/sentinel\\_event.aspx](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. <https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/>
- *Joint Commission Resources*: A Joint Commission 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 safety topics.
- *Speak Up™ program:* The Joint Commission’s campaign to educate patients and residents 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>.)
- *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: <https://www.jointcommission.org/resources/patient-safety-topics/emergency-management/>
  - Workplace violence prevention resources: <https://www.jointcommission.org/resources/patient-safety-topics/workplace-violence-prevention/>

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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 or resident safety systems, including the following examples.

### 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

The organization internally reports and investigates the following:

3. Injuries to residents or others in the organization’s facilities. **R**
4. Occupational illnesses and staff injuries. **R**
5. Incidents of damage to its property or the property of others in locations it controls. **R**
6. Security incidents involving patients, residents, staff, or others in locations it controls. **R**
8. Hazardous materials and waste spills and exposures. **R**
9. Fire safety management problems, deficiencies, and failures. **R**
10. Medical equipment management problems, failures, and use errors. **R**
11. Utility systems management problems, failures, or use errors. **R**
12. The organization conducts environmental tours every six months in patient and resident care areas to evaluate the effectiveness of previously implemented activities intended to minimize or eliminate risks in the environment of care. **R**
13. The organization conducts annual environmental tours in nonresident care areas to evaluate the effectiveness of previously implemented activities intended to minimize or eliminate risks in the environment. **R**



**Standard EC.04.01.03** 

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The organization analyzes identified environment of care issues.

**Elements 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** 

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The organization improves its environment of care.

**Elements of Performance for EC.04.01.05**

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

**Infection Prevention and Control (IC)****Standard IC.01.03.01** 

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The organization identifies risks for acquiring and spreading infections.

**Elements of Performance for IC.01.03.01**

1. The organization identifies its risks for acquiring and spreading infections based on the care, treatment, and services it provides.  
(See also IC.02.05.01, EP 2) **R**

**Leadership (LD)****Standard LD.03.01.01** 

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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 using a valid and reliable tool.

**Note:** *An example of a valid and reliable tool is the Agency for Healthcare Research and Quality (AHRQ) Nursing Home Survey on Patient Safety Culture found at [www.ahrq.gov](http://www.ahrq.gov).*

2. Leaders prioritize and implement changes identified by the evaluation.
3. Leaders provide opportunities for all individuals who work in the organization to participate in safety and quality initiatives.
4. ② 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 for the following:
  - Improving the safety and quality of care, treatment, or services
  - Decision making that supports the safety and quality of care, treatment, and services
  - Identifying and responding to internal and external changes in the environment
2. Leaders evaluate how effectively data and information are used throughout the organization.

### **Standard LD.03.04.01**

The organization communicates information related to safety and quality to those who need it, including staff, patients, residents, families, and external interested parties.

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

1. Communication processes are effective in doing the following:
  - Meeting the needs of internal and external users
  - Supporting safety and quality throughout the organization
2. Leaders evaluate the effectiveness of communication methods.

## Standard LD.03.07.01

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

### Elements of Performance for LD.03.07.01

1. Performance improvement occurs organizationwide.
2. As part of performance improvement, leaders do the following:
  - Set priorities for performance improvement activities and patient health outcomes (*See also* PI.01.01.01, EPs 1 and 2)
  - Reprioritize performance improvement activities in response to changes in the internal or external environment

## Standard LD.03.09.01

The organization has an organizationwide, integrated patient and resident safety program.

### Elements of Performance for LD.03.09.01

1. The leaders implement an organizationwide patient safety program as follows:
  - One or more qualified individuals or an interdisciplinary group manage the safety program.
  - All departments, programs, and services within the organization participate in the safety program.
  - 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.
2. 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.*
3. 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.03.08.01, EP 1)

**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.*

4. 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 as described in the "Sentinel Events" (SE) chapter of this manual.*

5. 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.
6. 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.*

7. At least every 18 months, the organization selects one high-risk process and conducts a proactive risk assessment. (See also LD.03.08.01, EP 1)

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

8. To improve safety, the organization analyzes and uses information about system or process failures and the results of proactive risk assessments. (See also LD.03.08.01, EP 1)
9. 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.
10. © 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, residents, and families were informed of the event
  - All actions taken to improve safety, both proactively and in response to actual occurrences
  - All results of the analyses related to the adequacy of staffing (*See also* PI.02.01.01, EP 14)
11. 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.*

### Standard LD.04.01.05

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

#### Elements of Performance for LD.04.01.05

4. Staff are held accountable for their responsibilities.

## Medication Management (MM)

### 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. As part of its evaluation of the effectiveness of medication management, the organization does the following: **R**
- Collects data on the performance of its medication management system (*See also* PI.01.01.01, EPs 12 and 13)
  - Analyzes data on its medication management system
6. When opportunities are identified for improvement of the medication management system, the organization does the following: **R**
- Takes action on improvement opportunities identified as priorities for its medication management system (Refer to PI.03.01.01, EP 2)

- Evaluates its actions to confirm that they resulted in improvements

(See also MM.09.01.01, EP 8)

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

8. The organization takes action when planned improvements for its medication management processes are either not achieved or not sustained. **R**
16. **Ⓣ** When automatic dispensing cabinets (ADC) are used, the organization has a policy that describes the types of medication overrides that will be reviewed for appropriateness and the frequency of the reviews. A 100% review of overrides is not required.

### **Standard PI.01.01.01**

The organization collects data to monitor its performance.

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

The organization collects data on the following:

8. The use of restraints.
11. Quality control activities.  
**Note:** *Examples of topics for quality control activities include the delivery and content of food trays and laundry services.*
12. Significant medication errors. (See also MM.08.01.01, EP 1)
13. Significant adverse drug reactions. (See also MM.08.01.01, EP 1)
14. Patient and resident (and, as needed, the family) perception of the safety and quality of care, treatment, and services. (See also LD.03.01.02, EP 1)

30. **Ⓣ** **For organizations that elect The Joint Commission Post–Acute Care Certification option:** The organization collects data relevant to patient re-admissions from the organization to the hospital, emergency department, or other rehabilitation or advanced care setting.

**Note:** *This element of performance applies only for those patients receiving post-acute care under the optional certification.*

31. ② **For organizations that elect The Joint Commission Post–Acute Care Certification option:** The organization collects data on opportunities for improvement identified following the patient’s discharge. (*See also* PC.04.02.02, EP 1)
- Note:** *This element of performance applies only for those patients receiving post-acute care under the optional certification.*
32. The organization collects data on patient, resident (and, as appropriate, the family), and staff perceptions of the organization’s performance in regard to supporting patient and resident choices, preferences, and self-determination.
33. ② The organization collects data on psychotropic medication use, including the use of antipsychotics.

### 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; PI.02.01.01, EP 8)
4. The organization takes action when it does not achieve or sustain planned improvements.

## Rights and Responsibilities of the Individual (RI)

### Standard RI.01.01.01

The organization respects the patient’s or resident’s rights.

#### Elements of Performance for RI.01.01.01

4. The organization treats the patient or resident in a respectful manner that supports his or her dignity.
6. The organization respects the patient’s or resident’s cultural, psychosocial, personal, and spiritual values, beliefs, and preferences.

7. The organization respects the patient's or resident's right to privacy. (See also IM.02.01.01, EPs 3 and 4)

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

**Note 2:** *Respect for privacy can be demonstrated in various ways; for example, via policies and procedures, practices, or the design of the environment.*

9. The organization accommodates the patient's or resident's right to pastoral and other spiritual services.
18. Upon admission, patients and residents are informed about the organization's policies and procedures regarding the handling of life-threatening emergencies. (See also PC.02.01.09, EP 1; RI.01.02.01, EP 2)

**Note:** *Refer to standard PC.02.01.09 regarding policies and procedures for life-threatening emergencies.*

19. Upon admission or when a patient or resident is transferred or discharged, the organization informs the patient or resident of its policies and practices about transfers (including room-to-room transfers) and discharges, as well as its obligations to provide access to comparable care, treatment, and services to patients and residents regardless of the payer source. (See also PC.04.01.03, EPs 2–4; LD.04.03.07, EPs 1 and 6)
20. © The organization obtains from the patient or resident written acknowledgment that he or she received information on patient or resident rights and on changes to these rights.

### Standard RI.01.01.03

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

### Elements of Performance for RI.01.01.03

1. The organization provides written and verbal information in a manner tailored to the patient's or resident's language and ability to understand. (See also PC.04.01.05, EP 8)
2. The organization provides interpreting and translation services, as necessary.



3. The organization communicates with the patient or resident who has vision, speech, hearing, or cognitive impairments in a manner that meets the patient's or resident's needs.

### Standard RI.01.02.01

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

#### Elements of Performance for RI.01.02.01

1. The organization involves the patient or resident in making decisions about his or her care, treatment, and services.
2. When a patient or resident is unable to make decisions about his or her care, treatment, and services, or chooses to delegate decision making to another, the organization involves the surrogate decision-maker in making these decisions. (See also PC.01.02.07, EP 5; RI.01.01.01, EP 18; RI.01.06.13, EP 4)

**Note:** *A surrogate decision-maker is someone appointed to make decisions on behalf of the patient or resident. This individual may be a family member or may be someone unrelated to the patient or resident. A surrogate decision-maker makes decisions when the patient or resident is without decision making capacity, or when the patient or resident has given permission to the surrogate to make decisions. In exercising this responsibility on the patient's or resident's behalf, the surrogate decision-maker may need to receive information, provide information, or participate in processes such as informed consent, education, and complaint resolution. In situations in which the patient or resident has decision making capacity but has chosen to use a surrogate decision-maker, the patient or resident may reserve the right to involve the surrogate in some activities (such as coordinating information with the licensed independent practitioner) but not others (such as receiving education in self-care).*

3. © The organization provides the patient or resident or surrogate decision-maker with verbal and written information about the right to refuse care, treatment, and services. (See also PC.01.02.07, EP 5)
4. The organization respects the right of the patient, resident, or surrogate decision-maker to refuse care, treatment, and services, in accordance with current advance directive information and with law and regulation. (See also PC.01.02.07, EP 5)

20. The organization provides the patient or resident or surrogate decision-maker with the information about the following:
  - Outcomes of care, treatment, and services that the patient or resident needs in order to participate in current and future health care decisions
  - Unanticipated events related to the patient's or resident'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.)

### **Standard RI.01.03.01**

The organization honors the patient's or resident'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. (*See also* PC.01.02.07, EP 5)
2. The informed consent process includes a discussion about the following:
  - The patient's or resident's proposed care, treatment, and services.
  - Potential benefits, risks, and side effects of the patient's or resident's proposed care, treatment, and services; the likelihood of the patient or resident achieving his or her goals; and any potential problems that might occur during recuperation.
  - Reasonable alternatives to the patient's or resident'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.
3. Ⓣ The organization obtains and documents informed consent in advance when it makes and uses recordings, films, or other images of patients and residents for internal use other than the identification, diagnosis, or treatment of the patient or resident (for example, performance improvement and education).

**Note 1:** *The term "recordings, films, or other images" refers to photographic, video, digital, electronic, or audio media.*

**Note 2:** *This element of performance does not apply to the use of security cameras.*

**Standard RI.01.05.01**

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

**Elements of Performance for RI.01.05.01**

3. Ⓣ The organization does the following regarding advance directives, including “do not hospitalize” orders, “do not resuscitate” orders, and organ-donation request procedures:
  - Informs patients of relevant laws and regulations.
  - Provides patients and residents with written information about advance directives, forgoing or withdrawing life-sustaining treatment, and withholding resuscitative services.
  - Provides the patient or resident with information upon admission on the extent to which the organization is able, unable, or unwilling to honor advance directives.
  - Informs staff and licensed independent practitioners who are involved in the patient’s or resident’s care, treatment, and services of whether or not the patient or resident has an advance directive.
  - Honors the patient’s or resident’s right to review and revise his or her advance directives.
  - Honors advance directives, in accordance with law and regulation and the organization’s capabilities.
9. Ⓣ The organization documents whether or not the patient or resident has an advance directive.
10. Upon request, the organization refers the patient or resident to resources for assistance in formulating advance directives.
17. The existence or lack of an advance directive does not determine the patient’s or resident’s right to access care, treatment, and services.

## Standard RI.02.01.01

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

### Elements of Performance for RI.02.01.01

1. Ⓣ The organization has a written policy that defines patient or resident 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 residents and a safe environment for all individuals in the organization
  - Supporting mutual consideration and respect by maintaining civil language and conduct in interactions with all who work in the organization
  - Meeting financial commitments
2. The organization informs the patient or resident about his or her responsibilities in accordance with its policy.

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