Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction

Joint Commission Resources

Joint Commission International

Third Edition
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Are errors in care, treatment, and services still attributed to individual human failure? This question may assume that humans generally perform flawlessly; perfect performance is a reasonable expectation. Therefore, if health care professionals just pay attention and work hard, nothing will go wrong.

Education and training efforts, more extensive in health care than in most other fields, focus on teaching health care professionals to do “the right thing.” The assumption is that proper education and training will help health care professionals not make mistakes. Hence, processes in health care organizations have historically been designed based on the premise that nothing will go wrong. When things do go wrong, the individuals involved are retrained, punished, or sanctioned. This widely held view, however, is seriously flawed.

Improvement in performance, continuous process assessment, and a strong culture of safety are key to reduced errors in health care. Leaders have a direct responsibility; they are, in effect, responsible for the care, treatment, and services that the organization provides to its population. Leaders administer the operations of a health care organization and direct it on a day-to-day basis. They keep operations running efficiently so that the important work of the organization can continue. Therefore, undertaking a proactive risk assessment must be supported and led by leadership as defined in Joint Commission International’s “Quality Improvement and Patient Safety” chapter (see Sidebar A-1, pages 3–9) and The Joint Commission’s “Leadership” and “Improving Performance” chapters (see Table A-2, pages 10–18).

What Is Failure Mode and Effects Analysis?

Health care is an exceedingly complicated system where accidents, errors, close calls (also known as near misses), sentinel events, failures, and adverse events happen. In addition, health care processes exist throughout health care organizations that are increasingly interdependent and are often interlocked or tightly coupled. Inconsistency, variable input, tight time constraints, a hierarchical culture, and the dependence on human intervention increase the risk of failure in system processes throughout an organization.

Failure mode and effects analysis (FMEA) is one technique for systems improvement that can enhance safety. FMEA is a team-based, systematic, proactive, and reasoned-based technique that is used to prevent process and product problems before they occur. It provides a look not only at what problems could occur but also at how severe the effects of the problems could be. FMEA assumes that no matter how knowledgeable or careful people are, failures will occur in some situations and could even be likely to occur. The focus is on what could allow the failure to occur. Ideally, FMEA can be used to help prevent failures from occurring. However, if a particular failure cannot be prevented, FMEA then focuses on protections that can be put in place to prevent the failure from reaching the individual receiving care, treatment, or services, or, in the worst case, mitigate its effects if the failure can cause harm.

Those who are accustomed to an evidence-based approach to safety may view FMEA with some skepticism, more as a spec-
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ative method than a scientific one. Even incident reporting isn’t 100% scientific. FMEA is a ready-made prospective process that has a good track record and a number of benefits. It is proactive instead of retrospective. It addresses problems that people have actually seen happen or errors they have almost made before it reaches the person receiving care. It is excellent, then, for capturing incidents that can and do occur and that generally are not captured any other way. Also, the multidisciplinary process pulls several kinds of information together (root causes as well as potential effects) and allows staff to target responses in new ways.

FMEA can improve the safety for individuals receiving care by helping to identify failures and close calls and by protecting individuals from harm or mitigating harm when, despite an organization’s best efforts, failures do occur. It can narrow or eliminate gaps in quality and performance and yield improved outcomes. It is easy to learn and enhances organizationwide collaboration and understanding. In short, its use is good business practice. As with any other tool, the more you use FMEA, the more familiar and comfortable it becomes.

Purpose of This Book
Joint Commission International and The Joint Commission require accredited health care organizations to conduct proactive risk assessments. The purpose of this book is to provide health care leaders and staff from around the world with a step-by-step guide to conducting FMEA if it is chosen by your organization as its proactive risk assessment method. Each chapter addresses a different step of the FMEA process.

This book also offers case studies provided by several organizations that have conducted FMEA projects resulting in significant improvements. As you read through each step in the FMEA process, you will see how each of these organizations addressed each step.

Joint Commission International Standards
As the international arm of The Joint Commission, Joint Commission International has been working with health care organizations, ministries of health, and organizations in more than 80 countries since 1994. In September 2007, Joint Commission International received accreditation by the International Society for Quality in Health Care (ISQua). Accreditation by ISQua provides assurance that the standards, training, and processes used by Joint Commission International to survey the performance of health care organizations meet the highest international benchmarks for accreditation entities.
Much variation exists in how health care organizations have conducted FMEA to date and how they define the key steps and terms of a FMEA approach. Health care leaders and staff around the world can use this book to familiarize themselves with the concept of FMEA and then creatively design a proactive risk assessment and reduction process that is most likely to meet the organization-specific needs. More than a few hours or a couple of days are needed to learn to use and conduct a FMEA, although the process is not difficult. Advice from organizations that have conducted a FMEA can speed the process along. The tools and examples provided in this book can be easily adapted for use in a FMEA process.

In addition, “Tip” boxes are provided throughout the book that may be used as a quick point of reference when conducting a FMEA. Online Extras are also available on Joint Commission Resources’ Web site at http://www.jcrinc.com/FMEA10/extras. When this symbol is found with an example, the example can also be found on the Web site.

FMEA is a powerful tool—at this point, perhaps the most powerful tool in the arsenal of proactive failure prevention and mitigation weapons for most high-risk processes in health care. The benefits of FMEA in preventing sentinel events that cause harm to individuals far outweigh its costs.

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Table A-1. Joint Commission International Standards and Requirements

**Quality Improvement and Patient Safety Chapter Standards and Requirements**

**Standard QPS.1** Those responsible for governing and managing the organization participate in planning and measuring a quality improvement and patient safety program.

**Measurable Elements**

1. The organization's leadership participates in developing the plan for the quality improvement and patient safety program.
2. The organization's leadership participates in measuring the quality improvement and patient safety program.
3. The organization's leadership establishes the oversight process or mechanism for the organization's quality improvement and patient safety program.
4. The organization's leadership reports on the quality and patient safety program to governance.

**Standard QPS.1.1** The organization's leaders collaborate to carry out the quality improvement and patient safety program.

**Measurable Elements**

1. The organization's leaders collaborate to carry out the quality improvement and patient safety program.
2. The quality improvement and patient safety program is organizationwide.
3. The program addresses the systems of the organization and the role of system design and redesign in quality and safety improvement.
4. The program addresses coordination among all components of the organization's quality measurement and control activities.
5. The program employs a systematic approach to quality improvement and patient safety.

(continued)
Standard QPS.1.2 The leaders prioritize which processes should be measured and which improvement and patient safety activities should be carried out.

Measurable Elements
1. The leaders set priorities for measurement activities.
2. The leaders set priorities for improvement and patient safety activities.
3. The priorities include the implementation of the International Patient Safety Goals.

Standard QPS.1.3 The leaders provide technological and other support to the quality improvement and patient safety program.

Measurable Elements
1. The leaders understand the technology and other support requirements for tracking and comparing measurement results.
2. The leaders provide technology and support, consistent with the organization's resources, for tracking and comparing measurement results.

Standard QPS.1.4 Quality improvement and patient safety information is communicated to staff.

Measurable Elements
1. Information on the quality improvement and patient safety program is communicated to staff.
2. The communications are on a regular basis through effective channels.
3. The communications include progress on compliance with the International Patient Safety Goals.

Standard QPS.1.5 Staff are trained to participate in the program.

Measurable Elements
1. There is a training program for staff that is consistent with their role in the quality improvement and patient safety program.
2. A knowledgeable individual provides the training.
3. Staff members participate in the training as part of their regular work assignment.

Standard QPS.2 The organization designs new and modified systems and processes according to quality improvement principles.

Measurable Elements
1. Quality improvement principles and tools are applied to the design of new or modified processes.
2. The following design elements are considered when relevant to the process being designed or modified:
   a) Is consistent with the organization’s mission and plans
   b) Meets the needs of patients, families, staff, and others
   c) Uses current practice guidelines, clinical standards, scientific literature, and other relevant evidence-based information on clinical practice design
   d) Is consistent with sound business practices
Table A-1. continued
Joint Commission International Standards and Requirements

e) Considers relevant risk management information
f) Builds on available knowledge and skills in the organization
g) Builds on the best/better/good practices of other organizations
h) Uses information from related improvement activities
i) Integrates and connects processes and systems

3. Measures are selected to measure how well the newly designed or redesigned process operates.
4. Measurement data are used to evaluate the ongoing operation of the process.

Standard QPS.2.1 Clinical practice guidelines and clinical pathways are used to guide clinical care.
Measurable Elements
1. On an annual basis, clinical leaders determine those priority areas on which to focus the use of guidelines, clinical pathways, and/or clinical protocols.
2. The organization follows the following process in implementing clinical practice guidelines, clinical pathways, and/or clinical protocols:
   a) Select from among those applicable to the services and patients of the organization (mandatory national guidelines are included in this process, if present);
   b) Evaluate for their relevance to identified patient populations;
   c) Adapt when needed to the technology, drugs, and other resources of the organization or to accepted national professional norms;
   d) Assess for their scientific evidence;
   e) Formally approved or adopted by the organization;
   f) Implement and measure for consistent use and effectiveness;
   g) Supported by staff trained to apply the guidelines or pathways; and
   h) Periodically updated based on changes in the evidence and evaluation of processes and outcomes.
3. The organization implements at least two clinical guidelines, clinical pathways, or clinical protocols for each identified priority area per 12-month period.
4. Clinical leaders can demonstrate how the use of clinical practice guidelines, clinical pathways, and/or clinical protocols has reduced variation in processes and outcomes.

Standards QPS.3 through QPS.3.3 The organization’s leaders identify key measures in the organization’s structures, processes, and outcomes to be used in the organizationwide quality improvement and patient safety plan.
Measurable Elements
1. The organization’s leaders identify targeted areas for measurement and improvement.
2. The measurement is part of the quality improvement and patient safety program.
3. The results of measurement are communicated to the oversight mechanism and periodically to the organizational leaders and the governance structure of the organization.

Standard QPS.3.1 The organization’s leaders identify key measures for each of the organization’s clinical structures, processes, and outcomes.
Table A-1. continued
Joint Commission International Standards and Requirements

Measurable Elements
1. The clinical leaders identify key measures for each of the following clinical areas:
   1. Patient assessments
   2. Laboratory services
   3. Radiology and diagnostic imaging services
   4. Surgical procedures
   5. Antibiotic and other medication use
   6. Medication errors and near misses
   7. Anesthesia and sedation use
   8. Use of blood and blood products
   9. Availability, content, and use of patient records
   10. Infection prevention and control, surveillance, and reporting
   11. Clinical research
2. At least 5 of the 11 required clinical measures are selected from the Joint Commission International Library of Measures.
3. The leaders look at the “science” or “evidence” supporting each of the selected measures.
4. Measurement includes structure, processes, and outcomes.
5. The scope, method, and frequency are identified for each measure.
6. Clinical measurement data are used to evaluate the effectiveness of improvements.

Standard QPS.3.2 The organization's leaders identify key measures for each of the organization's managerial structures, processes, and outcomes.

Measurable Elements
1. The managerial leaders identify key measures for each of the following managerial areas:
   a) The procurement of routinely required supplies and medication essential to meet patient needs
   b) Reporting of activities as required by law and regulation
   c) Risk management
   d) Utilization management
   e) Patient and family expectations and satisfaction
   f) Staff expectations and satisfaction
   g) Patient demographics and clinical diagnoses
   h) Financial management
   i) Prevention and control of events that jeopardize the safety of patients, families, and staff
2. The leaders look at the “science” or “evidence” supporting each of the selected measures.
3. Measurement includes structure, processes, and outcomes.
4. The scope, method, and frequency are identified for each measure.
5. Managerial measurement data are used to evaluate the effectiveness of improvements.
Table A-1. continued
Joint Commission International Standards and Requirements

Standard QPS.3.3 The organization’s leaders identify key measures for each of the International Patient Safety Goals.

Measurable Elements
1. The clinical and managerial leaders identify key measures for each International Patient Safety Goal.
2. International Patient Safety Goal measurement includes the areas identified in IPSG.1 through IPSG.6.
3. Measurement data are used to evaluate the effectiveness of improvements.

Standard QPS.4 Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the organization.

Measurable Elements
1. Data are aggregated, analyzed, and transformed into useful information.
2. Individuals with appropriate clinical or managerial experience, knowledge, and skills participate in the process.
3. Statistical tools and techniques are used in the analysis process when suitable.
4. Results of analysis are reported to those accountable for taking action.

Standard QPS.4.1 The frequency of data analysis is appropriate to the process being studied and meets organization requirements.

Measurable Elements
1. The frequency of data analysis is appropriate to the process under study.
2. The frequency of data analysis meets organization requirements.

Standard QPS.4.2 The analysis process includes comparisons internally, with other organizations when available, and with scientific standards and desirable practices.

Measurable Elements
1. Comparisons are made over time within the organization.
2. Comparisons are made with similar organizations when possible.
3. Comparisons are made with standards when appropriate.
4. Comparisons are made with known desirable practices.

Standard QPS.5 The organization uses an internal process to validate data.

Measurable Elements
1. The organization integrates data validation into its quality management and improvement processes.
2. The organization has an internal data validation process that includes the following:
   a) Re-collecting the data by a second person not involved in the original data collection
   b) Using a statistically valid sample of records, cases, and other data. A 100% sample would only be needed when the number of records, cases, or other data is very small.
   c) Comparing the original data with the re-collected data
   d) Calculating the accuracy by dividing the number of data elements found to be the same by the total number of data elements and multiplying that total by 100. A 90% accuracy level is a good benchmark.
### Table A-1. continued
**Joint Commission International Standards and Requirements**

- e) When data elements are found not to be the same, noting the reasons (for example, unclear data definitions), and taking corrective actions.
- f) Collecting a new sample after all corrective actions have been implemented to ensure the actions resulted in the desired accuracy level

3. The data validation process includes at least the measures selected as required in QPS.3.1.

**Standard QPS.5.1** When the organization publishes data or posts data on a public Web site, the data are validated by an independent third party.

**Measurable Elements**
1. The organization has a process for obtaining independent third-party validation of its quality measures.
2. The independent third-party data validation process occurs for any performance measures posted publicly.

**Standard QPS.6** The organization uses a defined process for identifying and managing sentinel events.

**Measurable Elements**
1. The hospital leaders have established a definition of a sentinel event that at least includes the following:
   a) Unanticipated death unrelated to the natural course of the patient’s illness or underlying condition (for example, suicide)
   b) Major permanent loss of function unrelated to the patient’s natural course illness or underlying condition
   c) Wrong-site, wrong-procedure, wrong-patient surgery
2. The organization conducts a root cause analysis on all sentinel events in a time period specified by the hospital’s leaders.
3. Events are analyzed when they occur.
4. Hospital leaders take action on the results of the root cause analysis.

**Standard QPS.7** Data are analyzed when undesirable trends and variation are evident from the data.

**Measurable Elements**
1. Intense analysis of data takes place when adverse levels, patterns, or trends occur.
2. All confirmed transfusion reactions, if applicable to the organization, are analyzed.
3. All serious adverse drug events, if applicable and as defined by the organization, are analyzed.
4. All significant medication errors, if applicable and as defined by the organization, are analyzed.
5. All major discrepancies between preoperative and postoperative diagnoses are analyzed.
6. Adverse events or patterns of adverse events during moderate or deep sedation and anesthesia use are analyzed.
7. Other events defined by the organization are analyzed.

**Standard QPS.8** The organization uses a defined process for the identification and analysis of near-miss events.

**Measurable Elements**
1. The organization establishes a definition of a near miss.
2. The organization defines the type of events to be reported.

(continued)
Table A-1. continued
Joint Commission International Standards and Requirements

3. The organization establishes the process for the reporting of near misses.
4. The data are analyzed and actions taken to reduce near-miss events.

**Standard QPS.9** Improvement in quality and safety is achieved and sustained.

**Measurable Elements**
1. The organization plans and implements improvements in quality and safety.
2. The organization uses a consistent process for identifying priority improvements that are selected by the leaders.
3. The organization documents the improvements achieved and sustained.

**Standard QPS.10** Improvement and safety activities are undertaken for the priority areas identified by the organization's leaders.

**Measurable Elements**
1. The priority areas identified by the organization's leaders are included in improvement activities.
2. Human and other resources needed to carry out an improvement are assigned or allocated.
3. Changes are planned and tested.
4. Changes that resulted in improvements are implemented.
5. Data are available to demonstrate that improvements are effective and sustained.
6. Policy changes necessary to plan, carry out and sustain the improvement are made.
7. Successful improvements are documented.

**Standard QPS.11** An ongoing program of risk management is used to identify and reduce unanticipated adverse events and other safety risks to patients and staff.

**Measurable Elements**
1. The organization's leaders adopt a risk management framework to include the following:
   a) Risk identification
   b) Risk prioritization
   c) Risk reporting
   d) Risk management
   e) Investigation of adverse events
   f) Management of related claims
2. The organization conducts and documents use of a proactive risk-reduction tool at least annually on one of the priority risk processes.
3. The organization's leaders take action to redesign high-risk processes based on the analysis.

Table A-2. Joint Commission Standards and Requirements Related to Proactive Risk Assessment

**Leadership Chapter Standards and Requirements**

**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**

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.
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**

1. Planning activities focus on improving 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.
8. All individuals who work in the organization, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality.
9. Literature and advisories relevant to safety are available to all individuals who work in the organization.
10. Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the organization.

**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, residents, the individuals served, families, and external interested parties.

**Elements of Performance**

1. Communication processes foster the safety of the patient, resident, or individual served, and the quality of care.
2. Leaders are able to describe how communication supports a culture of safety and quality.
Table A-2. continued
Joint Commission Standards and Requirements Related to Proactive Risk Assessment

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, residents, individuals served, the community, physicians, staff, and management.
5. Communication supports safety and quality throughout the organization.
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**

1. Structures for managing change and performance improvements exist that foster the safety of the patient, resident, or individual served, and the quality of care, treatment, and 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**

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 hospital support a culture of safety and quality.
3. Leaders provide for a sufficient number and mix of individuals to support safe, quality care, treatment, and services.

**Applicable to the home care program:**

**Note:** For hospices providing inpatient care in their own facilities: Staffing for all services should reflect the volume of patients, patient acuity, and the intensity of services needed to achieve the outcomes described in patients’ plans of care and to avoid negative outcomes.

**Applicable to the hospital program:**

**Note:** The number and mix of individuals is appropriate to the scope and complexity of the services offered.

**Applicable to the laboratory program:**

**Note 1:** The following indicators demonstrate adequacy of technical and support staff to meet the service needs of the patients, including evenings, weekends, and holidays:

- Overtime is not significantly high.

(continued)
Table A-2. continued

Joint Commission Standards and Requirements Related to Proactive Risk Assessment

- There are no lapses in quality control and proficiency testing.
- Performance testing and documentation of equipment maintenance have no lapses.
- Turnaround time is not prolonged.
- The quality of specimens, cultures, differential testing methods, or results is not jeopardized.

**Note 2:** The following indicators demonstrate adequacy of supervisory staff to meet the service needs of the patients, including evenings, weekends, and holidays:

- The background and experience of supervisory staff are consistent with work assignments and responsibilities.
- Quality control, proficiency testing, and maintenance are well performed and evaluated.
- Policies and procedures are current and well executed.
- Turnaround time is satisfactory.
- Record systems are well organized and current.
- Quality improvement mechanisms are implemented.
- Test analyses and specimen examinations are monitored to ensure that acceptable levels of analytic performance are maintained.

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.04.04.01** The organization complies with law and regulation.

**Elements of Performance**

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.

**Applicable to the ambulatory care, critical access hospital, home care, hospital, laboratory, long term care, and office-based surgery programs:**

**Note:** Each service location that performs laboratory testing (waived or non-waived) 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 laws.

**Applicable to the home care, laboratory, and long term care program:**

**Note:** Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.

**Applicable to the home care program:**

**Note:** For home health agencies that elect to use The Joint Commission deemed status option: If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.

2. The organization provides care, treatment, and 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.
Table A-2. continued
Joint Commission Standards and Requirements Related to Proactive Risk Assessment

Applicable to the ambulatory care program:
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 Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88).

Applicable to the critical access hospital program:
5. The critical access hospital has an agreement with respect to credentialing and quality assurance with at least the following:
   • One hospital that is a member of the network
   • One quality improvement organization (QIO) or equivalent entity
   • One other appropriate and qualified entity in the state rural health care plan

6. Except as permitted for critical access hospitals having distinct part units under 42 CFR 485.647, as of January 1, 2004, the critical access hospital maintains no more than 25 inpatient beds that can be used for either inpatient or swing bed services.

7. The critical access hospital provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

8. The critical access hospital carries out or arranges for, at a minimum, an annual evaluation of its total program which includes a review of the utilization of its services, a representative sample of active and closed records, and health care policies.

9. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital has utilization review standards appropriate to rehabilitation or psychiatric services, or verification that the quality improvement organization (QIO) is conducting review activities.

11. For rehabilitation and psychiatric distinct part units in critical access hospitals: The rehabilitation or psychiatric distinct part unit(s) beds are physically separate from the critical access hospital’s other beds.

12. For rehabilitation and psychiatric distinct part units in critical access hospitals: The critical access hospital provides no more than 10 beds in a distinct part unit.

Note: Beds in the rehabilitation and psychiatric distinct part units are excluded from the 25 inpatient bed-count limits specified in the CoP from 42 CFR 485.620(a).

Note: The average annual 96-hour length-of-stay requirement specified under the CoP from 42 CFR 485.620(b) does not apply to the 10 beds in the distinct part units specified in 42 CFR 485.647(b)(1). Admissions and days of inpatient care in the distinct part units are not taken into account in determining the critical access hospital’s compliance with the limits on the number of beds and length of stay in the CoP from 42 CFR 485.620.

Performance Improvement Chapter Standards and Requirements
Standard PI.01.01.01 The organization collects data to monitor its performance.

Elements of Performance
1. The leaders set priorities for data collection.
2. The leaders identify the frequency for data collection.
The organization collects data on the following:
3. Performance improvement priorities identified by leaders.

(continued)
### Table A-2. continued
Joint Commission Standards and Requirements Related to Proactive Risk Assessment

Applicable to the ambulatory care, critical access hospital, hospital, and office-based surgery programs:

4. Operative or other procedures that place patients at risk of disability or death.

5. All significant discrepancies between preoperative and postoperative diagnoses, including pathologic diagnoses.

6. Adverse events related to using moderate or deep sedation or anesthesia.

Applicable to the ambulatory care, critical access hospital, hospital, laboratory, and office-based surgery programs:

7. The use of blood and blood components.

Applicable to the ambulatory care, critical access hospital, hospital, and laboratory programs:

8. All reported and confirmed transfusion reactions.

Applicable to the critical access hospital and long term care programs:


Applicable to the critical access hospital program:

10. The use of seclusion.

Applicable to the critical access hospital and hospital programs:

11. The results of resuscitation.

Applicable to the hospital and long term care programs:


Applicable to the long term care program:

13. Quality control activities.

**Note:** Examples of topics for quality control activities include the delivery and content of food trays and laundry services.

Applicable to the ambulatory care, behavioral health care, critical access hospital, home care, hospital, long term care, and office-based surgery programs:


15. Significant adverse drug reactions.

Applicable to the ambulatory care, critical access hospital, home care, hospital, laboratory, long term care, and office-based surgery programs:

16. Patient, resident (and as needed, the family), or individual served perception of the safety and quality of care, treatment, and services.

**Laboratory only: Note:** The laboratory can use the hospital’s patient satisfaction survey as long as it addresses laboratory services.

Applicable to the behavioral health care program:

16. The organization collects data on the following:
   - Whether the individual served was asked about treatment goals and needs
   - Whether the individual served was asked if his or her treatment goals and needs were met
   - The view of the individual served regarding how the organization can improve the safety of the care, treatment, or services provided

Applicable to the home care program:

17. Patient satisfaction with and complaints about products and services.

18. The timeliness of response to patient questions, problems, and concerns.
### Table A-2. continued
**Joint Commission Standards and Requirements Related to Proactive Risk Assessment**

19. The impact of the organization’s business practices on the adequacy of patient access to equipment, items, services, and information.

20. For DMEPOS suppliers serving Medicare beneficiaries: The frequency of billing and coding errors.

21. Adverse events involving patients due to inadequate or malfunctioning equipment, supplies, or services (for example, injuries, accidents, signs and symptoms of infections, and hospitalizations).

**Applicable to the laboratory program:**

22. Processes or outcomes related to patient preparation, including the provision of patient instructions and preparatory steps for the procedures.

23. Processes or outcomes related to handling specimens, including specimen collection, labeling, preservation, transportation, and rejection.

24. Processes or outcomes related to communication processes, including efficient transfer of information, completeness of test requisition, timeliness of reporting results, and accuracy of reports.

25. The laboratory collects data to determine whether tests it offers meet the needs of the clinical staff and the population served.

**Note:** *Data needed to support the review process may include age, disability groups, diagnoses, problems, levels of care, and treatment.*

26. To support the review of clinician practices, the laboratory collects data on test utilization.

**Applicable to the behavioral health care program:**

27. The organization collects data to measure the performance of high-risk, high-volume, problem-prone processes provided to high-risk or vulnerable populations, as defined by the organization.

**Note:** *Examples of such processes include the use of restraints, seclusion, suicide watch, and behavior management and treatment.*

**Applicable to the ambulatory care program:**

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.

**Applicable to the ambulatory care, behavioral health care, critical access hospital, home care, hospital, laboratory, and long term care programs:**

30. The hospital considers collecting data on the following:
   - Staff opinions and needs
   - Staff perceptions of risk to individuals
   - Staff suggestions for improving patient safety
   - Staff willingness to report adverse events

**Applicable to the behavioral health care program:**

31. For foster care: The agency collects data on its performance, including the safety of the placement and the maintenance or improvement of the individual’s level of functioning.

32. For foster care: The agency collects data on the permanency of the placement and the permanency of outcome when they are within the organization’s scope of services.

*(continued)*
Applicable to the home care program:
33. For hospices that elect to use The Joint Commission deemed status option: The governing body approves the frequency and detail of the data collection.
34. For hospices that elect to use The Joint Commission deemed status option: The hospice collects data on adverse patient events.
35. For DMEPOS suppliers serving Medicare beneficiaries: The organization seeks input from employees, beneficiaries, and referral sources when assessing the quality of its operations and services.

Applicable to the ambulatory care program:
36. For ambulatory surgery 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.

Applicable to the behavioral health care program:
37. For opioid treatment programs: The program collects data about treatment outcomes and processes.

Note: Examples of data collected include the following:
- Use of illicit opioids, illegal drugs, and the problematic use of alcohol and prescription medications
- Criminal activities and entry into the criminal justice system
- Behaviors contributing to the spread of infectious diseases
- Restoration of physical and mental health and functional status
- Retention in treatment
- Number of patients who are employed
- Abstinence from drugs or abuse

Applicable to the critical access hospital and hospital programs:
38. The hospital evaluates the effectiveness of all fall reduction activities including assessment, interventions, and education. Note: Examples of outcome indicators to use in the evaluation include number of falls and number and severity of fall-related injuries.
39. The hospital collects data on the effectiveness of its response to change or deterioration in a patient’s condition. Note: Measures may include length of stay, response time for responding to changes in vital signs, cardiopulmonary arrest, respiratory arrest, and mortality rates before and after implementation of an early intervention plan.

Standard PI.02.01.01 The organization compiles and analyzes data.

Elements of Performance
1. The hospital compiles data in usable formats.
2. The hospital identifies the frequency for data analysis.

Applicable to the critical access hospital, hospital, laboratory, and long term care programs:
3. The hospital uses statistical tools and techniques to analyze and display data.

Applicable to all programs:
4. The hospital analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.
Table A-2. continued
Joint Commission Standards and Requirements Related to Proactive Risk Assessment

Applicable to the behavioral health care and laboratory program: Note: Examples of external sources of information include the following:
- Recent scientific, clinical, and management literature, including Sentinel Event Alerts
- Practice guidelines or parameters
- Performance measures
- Reference databases
- Other organizations with similar processes (Laboratory program: and standards that are periodically reviewed and revised)

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

Applicable to the hospital program:

6. The hospital analyzes data from ORYX core measures that, over three or more consecutive quarters for the same measure, identify the hospital as a negative outlier.

Applicable to the critical access hospital and hospital program:

7. The hospital analyzes its organ procurement conversion rate data as provided by the organ procurement organization (OPO). Note: Conversion rate is defined as the number of actual organ donors over the number of eligible donors defined by the OPO, expressed as a percentage.

8. The hospital uses the results of data analysis to identify improvement opportunities.

Applicable to the home care program:

10. For hospices that elect to use The Joint Commission deemed status option:
The hospice uses the data collected to monitor the effectiveness and safety of services and the quality of care.

Applicable to the ambulatory care program:

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 PL.03.01.01 The organization improves performance on an ongoing basis.

Elements of Performance
1. Leaders prioritize the identified improvement opportunities.
2. The organization takes action on improvement priorities.
3. The organization evaluates actions to confirm that they resulted in improvements.
4. The organization takes action when it does not achieve or sustain planned improvements.

Applicable to the home care program:

8. For hospices that elect to use The Joint Commission deemed status option: The number and scope of annual performance improvement projects is based on the patients’ needs and internal organization needs. The projects reflect the scope, complexity, and past performance of the hospice’s services.

9. For hospices that elect to use The Joint Commission deemed status option: The hospice documents what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on them.
Table A-2. continued
Joint Commission Standards and Requirements Related to Proactive Risk Assessment

Applicable to the ambulatory care program:
10. For ambulatory surgical centers that elect to use The Joint Commission deemed status option: The ambulatory surgical center implements preventive strategies throughout the facility targeting adverse patient events and makes certain that all staff are familiar with these strategies.