



# Clinical Care Program Certification

4<sup>th</sup> Edition

Proposed Standards & Requirements  
for  
Field Review

Effective 1 January 2024

English

## Please Note

The JCI Clinical Care Program Certification Standards, 4<sup>th</sup> Edition has been revised and reorganized to align with the applicable requirements found in the JCI Accreditation Standards for Hospitals, 7<sup>th</sup> Edition, the Joint Commission Disease-Specific Care Certification Core Manual, January 2022 Edition, current evidence-based practices, clinical practice guidelines, and for the purpose of clarifying requirements and expectations. This document does not include the International Patient Safety Goals (IPSG) chapter since changes to that chapter are not scheduled for the time leading up to the publication of this manual. The intents for the standards are “in progress,” and are planned for completion in time to align with the standards when approved for publication for the 4<sup>th</sup> Edition.

**RED font vs. BLACK font:** standards, measurable elements, and intents that are new or existing and have undergone significant changes that have impacted the intent of the requirement are in **RED** font. Requirements in **BLACK** font may have undergone significant language/grammatical changes as well, but the intents were not impacted by the changes.

**“P” symbol vs. “required documentation” in the requirements:** Standards and measurable elements that require a written policy or procedure for a specific process, are followed by a “P” icon. Additionally, some program standards and measurable elements also require a written documentation of compliance, and those requirements are explicit in the ME text. This is a new change in practice.

The manual has undergone a multitude of changes. On a high-level, the changes are categorized as the following:

- New standards and measurable elements added to the manual
- Previously existing standards and measurable elements removed from the manual
- Existing standards and measurable elements: necessitated significant changes that modified the intent of the standard or requirement
- Existing standards and measurable elements necessitated grammatical changes in the interest of clarity
- Existing standards and measurable elements moved to various locations within a standard or chapter
- Existing standards and measurable elements moved to various locations, not in the same standard or chapter as previously located.

**Field Review Questionnaire:** The Field Review Questionnaire can be accessed again after you submit it. The purpose of this is to allow you the option of completing this in more than one visit. Please note, that you will have to click your way through the entire questionnaire in order to save your response, and then reopen the survey to continue until completed. It is recommended that you complete the survey in no more than two visits.

To participate in the field review, please complete the following survey below:

**Field Review Survey Link:** <https://www.surveymonkey.com/r/FJWLTHP>

**Field Review Period:** (December 7 – 29, 2022)

# Program Leadership and Management (PLM)

## Standard PLM.1

The program defines the roles and responsibilities of its program leaders. P

### Intent of PLM.1

Those identified as program leaders require education and experience, both in providing care for this patient population and in leadership roles, to develop and oversee a clinical care program. All program leaders are involved in designing the program and have sufficient authority to allow for effective advocacy of resources associated with the care of the patients. The clinical care, interdisciplinary team structure, patient outcomes, and overall management of a clinical care program requires clear leadership from qualified individuals to ensure that care is provided in a uniform manner and is consistent with the program's mission, vision, and objectives. Leaders are also responsible for helping to recruit and retain qualified staff and defining the structure of the interdisciplinary team. The structure of the interdisciplinary team can be generally defined as a team of healthcare professionals comprised of various disciplines, both clinical and non-clinical, who work collaboratively to address the physical, psychological, and spiritual needs of the patient. Whenever possible, the patient and the patient's family should be a part of the interdisciplinary team. The team structure must complement the program's mission, vision, and objectives. Leadership commitment to the program aligns with the organizational leadership commitment to provide safe care to patients and maintain a culture of safety.

### Measurable Elements of PLM.1

1. The program leader(s) identify members of the program's interdisciplinary team, including those with leadership roles.
2. Program leadership is collectively responsible for designing the program in collaboration with the interdisciplinary team.
3. The program leaders involved in program development and oversight have the educational background, experience, training, and/or certification consistent with the program's mission, vision, and objectives.
4. The program leader(s) makes certain that practitioners practice within the scope of their licensure, certification, training, and current competency.
5. The program leader(s) identifies, in writing, the composition of the interdisciplinary team. P

## Standard PLM.2

The program is collaboratively designed, implemented, and evaluated.

### Intent of PLM.2

Patient care services provided in the clinical care program are planned and designed to respond to the needs of the population identified to improve quality and patient safety. Previous practices of interdisciplinary

collaboration “in name only” have led to adverse events and jeopardized the safety culture of an organization, which is why it is critical that interdisciplinary collaboration is structured, and the responsibility of the program leader is to design, implement, oversee, and evaluate. Leaders of the program identify the various clinical departments and services that are essential to implementation of the program. As the program scope and objectives are defined, all disciplines represented in the program must work together to coordinate and integrate all the program’s clinical services and activities. Interdisciplinary program collaboration throughout the organization exemplifies the commitment to the program and acts as a testimony that the program has the structure, resources, and support it needs to be successful. Interdisciplinary team member collaboration is evident in various elements of the program such as program design, evaluation, and revision. Participation at program committee meetings is monitored, and a minimum quorum for decision-making is established and reflected in the program plan or charter as well as meeting minutes. The leaders set expectations in the program plan or charter to improve quality and patient safety, and the interdisciplinary team participates in evaluating the program, including the processes and outcomes set by the program leaders. Continuous evaluation of the program by the interdisciplinary team and program leaders can ensure that all patients receive the same high-quality care, treatment, and services reflective of the program’s scope of services and mission.

## Measurable Elements of PLM.2

1. The interdisciplinary team designs the program.
2. The interdisciplinary team implements the program.
3. The program leader(s) assures the uniform performance of care, treatment, and services.
4. The leaders establish and implement processes to improve quality and patient safety.
- 5 The interdisciplinary team evaluates the program at intervals specified in the program plan or charter.
6. Program leaders take action to address and resolve opportunities identified through the evaluation process.

## Standard PLM.3

The program meets the needs of the target population.

### Intent of PLM.3

The total population is representative of a group of people that share at least one attribute of interest. **For example**, all stroke patients evaluated in the organization would be considered the total population of stroke patients for the organization. The target population is derived from the total population and is comprised of a defined group of people that share more specific clinical and demographic attributes representative of the program’s scope. The care, treatment, and services provided by the certification program is designed to respond to the needs of the population to be served, also known as the program’s “target population.” The program ensures that the care, treatment, and services available are relevant to its targeted population and excludes populations that do not meet the specific attributes (selection criteria) that represent the program’s scope of services.

**For example,** if the program is primary stroke with a population specific to the care of ischemic stroke without endovascular treatment, the target population may not include large vessel occlusions in need of endovascular treatment or the people with hemorrhagic stroke. Although the program may have excluded this population from its scope of services, this population is representative of the total population for stroke. Therefore, the program will have to include a process to address the hemorrhagic stroke patient population that presents to the organization, such as the development of a transfer protocol to a designated hospital that provides care to that patient population.

### **Measurable Elements of PLM.3**

1. The program identifies its target population.
2. The program ensures that the care, treatment, and services available are relevant to its targeted population.
3. The target population is representative of the total population as defined by program.

### **Standard PLM.4**

The program determines the care, treatment, and services it provides.

#### **Intent of PLM.4**

The program requires a written plan or charter that defines the program's purpose and includes elements that describe the program such as the mission, vision, objectives, scope of service, and the target population and which must be provided in accordance with applicable laws and regulations. Additionally, the roles and responsibilities of the program leader(s) and the interdisciplinary team members must be clearly defined in the charter.

Patients and their families receive sufficient information to make knowledgeable decisions. Information is provided about the proposed care, the expected outcomes, and any expected cost to the patient or family. During participation in the program, patients may require services from other departments, such as laboratory or radiology services. The patient's needs are matched with the appropriate resources. The program provides services designed to respond to the needs of the target population, including access to emergent/urgent and after-hours care. Additionally, all contracted services are evaluated to ensure that the level of care and/or services are consistently provided in a safe, quality manner and align with the program's scope. The evaluations are performed and documented according to the requirements of the program and/or an organizational policy or procedure for contracted services.

### **Measurable Elements of PLM.4**

1. The program has a written plan or charter. P
2. The program leader(s) defines in the plan or charter the program's mission and scope of service. P
3. The program provides care, treatment, and services to patients in a planned and timely manner.
4. The program informs patients about how to access care, treatment, and services, including after hours or in an emergency.
5. The program complies with applicable laws and regulations.

6. The program has a process to provide emergent/urgent care, including after-hours.
7. The program evaluates services provided through contractual arrangement to ensure that the scope and level of care and/or services are consistently provided in a safe, quality manner. This evaluation is documented. P

## Standard PLM.5

The scope and level of care and/or services provided are uniform and comparable for patients with the same acuity and type of disease or condition being managed, regardless of their ability to pay or the source of payment.

### Intent of PLM.5

A current evidence-based level of care is provided to patients within the clinical care program. The scope and level of care and/or services provided are uniform and comparable for patients with the same acuity and type of disease or condition being managed, regardless of their ability to pay or the source of payment, **staffing resources, or care setting. Appropriate identification of patients within the targeted population is accomplished through appropriate assessment, diagnoses, and anticipated treatments related to disease-specific management.** The program leaders plan and coordinate patient care. In particular, services provided to targeted patient populations are **supported by clinical practice guidelines and current evidence-based practices and** guided by policies and procedures that result in their uniform delivery. A uniform level of patient care results in the efficient use of resources and permits the evaluation of outcomes of similar care throughout the program. **Specifically, the acuity of a patient's condition, as determined by appropriate assessments, diagnoses, and anticipated treatments related to disease-specific management, determines the resources allocated to meet the patient's identified needs. In situations where the organization faces region or country-specific challenges to providing care that align with best practices, the organization demonstrates a credible effort to reconcile and resolve any issues with access to care. A credible effort is characterized as special funding sources, petitions to the Ministry of Health (MOH), or legislative actions taken.**

A current evidence-based level of patient care is reflected in the following:

- a) **Clinical care aligns with best practices**
- b) Access to and appropriateness of care and treatment do not depend on the patient's ability to pay or the source of payment.
- c) Acuity of the patient's condition determines the resources allocated to meet the patient's needs.
- d) The level of care provided to patients is the same throughout the program.

### Measurable Elements of PLM.5

1. The program provides the number and types of resources needed to deliver or facilitate the delivery of care, treatment, and services.
2. **Variables such as staffing, setting, or payment source do not affect outcomes of care, treatment, and services.**
3. **The scope and level of care, treatment, and services provided are comparable for individuals with the same acuity and type of disease being managed.**

## Standard PLM.6

The targeted population has access to the care, treatment, and services provided by the program.

### Intent of PLM.6

The targeted population has access to the care, treatment, and services provided by the program. The program has a process for informing patients of the clinical care program, and patients are given multiple opportunities to participate in the program. Opportunities provided to patients to participate in the program such as via discussions, pamphlets, education, etc. are documented in the patient's health record. This can include communications, attempts to communicate, and as well as the information and education provided.

The program care, treatment, and services are in alignment with current, and best available evidence-based practices and clinical practice guidelines. Best available evidence is typically known as the trustworthy evidence clinicians can use to support the clinical decisions made for the population served. There are topics that have a multitude of supporting scientific evidence, and then there are topics where scientific evidence is very scarce. For this reason, best available evidence can come in varying sources such as hundreds of medical centers participating in a study utilizing Six Sigma, the professional experience of a colleague, case studies of just a few hospitals, a decision based on the professional experience of a colleague with no scientific evidence available, and even a hospital pilot-testing different approaches to determine the best approach to take. Evidence is generally deemed best available and trustworthy to a program after all available evidence that is relevant has been researched and reviewed, the limitations have been identified, the program has deemed the evidence as trustworthy, and in alignment with the current and best available evidence-based practices and clinical practice guidelines for the target population, if available.

### Measurable Elements of PLM.6

1. The process for informing patients of the clinical care program is identified.
2. Care, treatment and services are relevant to the targeted population, and in alignment with the clinical practice guidelines and current evidence-based practice.
3. Patients are given multiple opportunities to participate in the program. The opportunities are documented.

## Standard PLM.7

The program follows a code of ethics.

### Intent of PLM.7

The leaders of the program have an ethical and legal responsibility to their patients, patients' families, health care providers, and the community. The program leader(s)'s actions and the program's guidelines for ethical behavior must be congruent with the program's mission, vision, scope, national and international norms to human rights and professional code of ethics, staff policies, and other documents that support the program. A code of ethics is a set of principals based on morals (values, beliefs) set by an organization to determine what is right or wrong. Program leaders are required to define a code of ethics for the program. Often, the



program will follow the organization's code of ethics, in part or in whole, depending on whether modifications are required to correspond with the needs of the program.

A code of conduct is a set of rules and regulations that explain appropriate behavior in specific situations. Program leaders develop and implement a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety. Compliance with the code of conduct is monitored.

The leaders understand the responsibilities as they apply to the clinical activities as well as the business activities. Patients and families participate in the care process by making decisions about care, asking questions about care, and having the prerogative to refuse certain aspects of care. Patients and families are provided with information on the program, which includes information on patient participation and the utilization of patient data related to their care. At a minimum, verbal agreement of patient participation and the program's use of patient data related to their care is obtained and documented in the patient's health record. The program supports the patient's and family's rights to decline to participate in the program or request discharge from the program. This declination is documented in the patient's health record along with supporting information such communications with the patient and family. Specifically, the reason for declining to participate or requesting discharge from the program, concerns or challenges voiced, and support and guidance provided.

Patients have a right to voice complaints about their care and to have those complaints reviewed and, when possible, resolved. Decisions regarding care sometimes present questions, conflicts, or other dilemmas affecting decision makers. In addition, health care providers may be confronted by interprofessional disagreements regarding health care decisions. The program has an established process for seeking resolution of patient complaints and ethical dilemmas that do not pose a conflict with the health care providers' ability to make clinical care decisions, thus protecting the integrity of the clinical decision-making process.

Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the organization. Program leaders set expectations for behaviors that promote accountability and teamwork and support a culture of safety.

## Measurable Elements of PLM.7

1. Program leaders define a code of ethics.
2. Program leaders develop and implement a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
3. The program protects the integrity of clinical decision making.
4. The program respects the patient's right to decline participation in the program. This is documented.
5. The program has a process for receiving and resolving complaints and grievances in a defined manner and timeframe.
6. The program monitors compliance with the code of conduct.

## Standard PLM.8

The program uses current scientific information, reference materials, and resource materials to support patient care, health professional education, and clinical research.



## Intent of PLM.8

Practitioners seek to develop clinical care processes and make decisions based on the best available and most current scientific evidence for the clinical care program. Evidence-based practice generally comes in four forms: 1) scientific literature, preferably current, such as research findings from empirical studies published in academic journals, 2) evidence from an organization such as data (turnover rates, patient satisfaction scores, financial data, perceptions of the organization's culture, medication errors, etc. 3) evidence from practitioners such as professional knowledge and expertise, and 4) evidence from stakeholders, such as their values and concerns via feedback. Evidence-based practice is commonly derived from clinical practice guidelines (CPGs), which are developed through a systematic process of integrating carefully selected published literature, primarily current scientific literature, into a collection of best practices and clinical recommendations to be used in a healthcare setting. If selected accurately, the approach for developing guidelines represents the quality of the evidence and the strength of the recommendation. The goal for CPGs is to guide clinicians in providing the most up-to-date, evidence-based, and highest quality care for their patients. To do this, clinical practice guidelines must be trustworthy, understandable, adoptable, and effectively implemented. Additionally, the program ensures that financial compensation or risk for leaders, managers, and clinical staff is not considered when clinical decisions are made.

The program will have selected current resource and reference materials that support the program's scope and reflect current evidence-based practices. Program reference and resource materials are readily accessible to support health professional education and clinical research.

## Measurable Elements of PLM.8

1. Clinical care processes and clinical decisions are based on current scientific evidence.
2. Scientific information, references, and resources support program-level clinical education and research.
3. The program has reference materials (hard copy or electronic) that are readily accessible to clinical staff, including current scientific evidence such as clinical practice guidelines.

## Standard PLM.9

The program's facilities are safe, secure, and accessible.

## Intent of PLM.9

Risk prevention is essential to creating a safe and supportive patient care facility. To plan effectively, those responsible for the program must be aware of all the risks present in the facility. The goal is to prevent accidents and injuries; to maintain safe and secure conditions for patients, families, staff, and visitors; and to reduce and control hazards and risks such as those related to fire and medical equipment. Any deficiencies identified are immediately corrected. When corrections cannot be immediately carried out, interim measures are implemented to reduce risk and ensure safety of patients, staff, and visitors until deficiencies can be fully corrected. The results of all inspections, testing, and maintenance are documented, including corrections and interim measures that are implemented. Program leadership participates in developing a proactive plan to reduce the risks for patients, families, staff, and visitors. Training and education, as applicable to the staff member's role and responsibilities, on identifying and responding to fire risks and risks associated with medical equipment should be included in the proactive plan and can be executed during staff member onboarding, and annual and ongoing training and education.

## Measurable Elements of PLM.9

1. The program identifies and evaluates potential risks in the facility in which the program operates.
2. The program implements strategies to minimize safety and security risks.
3. When risks are identified, the program takes actions to reduce those risks.
4. The program implements strategies to minimize the risk of fire and address fire safety–related issues.
5. The program identifies activities to minimize risks associated with medical equipment used in the program.  
P
6. The program implements activities to minimize risks associated with medical equipment used in the program.

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# Delivering or Facilitating Clinical Care (DFC)

## Standard DFC.1

All clinical staff are qualified, competent, and appropriately trained.

### Intent of DFC.1

The clinical care program hires an appropriate variety of skilled and qualified staff members to provide safe and effective care and treatment to patients in the program's patient population. Education, experience, training, and/or certification must be consistent with the program's scope of services, and objectives, the care provided, and in accordance with applicable laws and regulations. Primary source verification is required, and every effort needs to be made to verify essential information through primary source verification. **Primary source verification, every effort made to acquire verification, and associated supporting documentation must be documented in each staff member's personnel file.**

Program leaders are also responsible for the recruitment and retention of qualified staff who meet the needs of the program's patient population and scope of service. In doing so, leaders must consider the services provided and the education, skills, knowledge, and experience needed by the program's staff to provide those services. Qualified staff members are hired through a process that matches the requirements of the job description. **Maintaining qualified, competent, and appropriately trained staff is an evolutionary process. In addition to qualifications at time of hire, to meet the expectation that all clinical staff must have education, experience, training, and/or certification, consistent with the program's scope of services, and objectives, and the care provided, the program must also offer ongoing education and assess the competency of the program's staff on a regular basis. The qualifications that define the roles and responsibilities of each job description for the clinical staff of the program reflect the core criteria used to evaluate the clinical staff. This recruitment and retention process ensures that the staff member's skills are initially and over time consistent with the needs of the patients the program serves. Education, training, licensures, certifications, at hire, annually and ongoing, together with supporting documentation are documented in each staff member's personnel file.**

### Measurable Elements of DFC.1

1. All clinical staff have education, experience, training, and/or certification, consistent with the program's scope of services, and objectives, and the care provided. P
2. **The program assesses clinical staff competency at time of hire, including experience, professional education, and advanced training as applicable to the role. The assessment is documented. P**
3. Core criteria for evaluating clinical staff in the program include, at a minimum, current licensure, and current competence. P
4. Professional education, advanced training, and experience are verified from primary sources upon hire. P
5. **The program verifies licensure and certifications using a primary source verification process upon hire and at expiration. P**
6. The program leaders are accountable for recruitment and retention of qualified staff.

## Standard DFC.2

All clinical and nonclinical staff are oriented to the program and to their specific job responsibilities.

## Intent of DFC.2

To perform well, all staff, regardless of their roles, must understand the program and the organization in which the program operates. This is accomplished through orientation to the clinical care program and to the organization in which it operates. Orientation, training, and education to the organization and to the program is provided on different levels, as a continuum, depending on the staff member's role and responsibilities in the program. **For example**, a general orientation may be provided to staff members who are not directly involved in the program, while a more comprehensive orientation through training and education is provided to the clinical care team members (including policies and procedures, guidelines, and any other necessary information). The program defines the content of the orientation and educational material for all staff, according to staff roles and responsibilities. The goal for completing orientation and training is for the program staff to understand their responsibilities and can safely care for and meet the needs of the program's patient population.

Ongoing educational needs are identified from monitoring data, when new technology or skills are introduced to the program, when updating and revising clinical practice guidelines, or through review of job performance. Additionally, ongoing in-service and other education and training activities address identified educational needs, relevant to the program's scope of services and staff roles and responsibilities.

## Measurable Elements of DFC.2

1. Orientation provides information and necessary training pertinent to program responsibilities. Completion of the orientation is documented. P
2. The program identifies and responds to each clinical staff's program-specific learning needs. P
3. Ongoing in-service and other education and training activities are relevant to the clinical care program's scope of services and the ongoing education plan is included in the program's plan or charter. P

## Standard DFC.3

The program uses a standardized professional practice evaluation process(es) to evaluate the quality and safety of the clinical care provided by each staff member. P

## Intent of DFC.3

An initial evaluation ensures that a staff member can assume the responsibilities in the job description. This evaluation is carried out before or at the time of starting to perform work responsibilities. The program may have a "probationary" or other period during which the clinical staff member is closely supervised and evaluated, or the process may be less formal. Whatever the process, the hospital ensures that staff providing high-risk services or providing care to high-risk patients are evaluated at the time they begin providing care, before the probationary or orientation period is completed. This evaluation of necessary skills, knowledge, and desired work behaviors is carried out by the department or service to which the staff member is assigned. An ongoing evaluation ensures that training occurs when needed and that the staff member can assume new or changed responsibilities. Although such an evaluation is best carried out in an ongoing manner, there is at least one documented evaluation of each clinical staff member working under a job description each year.

There is a standardized process to, at least annually, gather relevant performance data on each staff member for evaluation by appropriate leaders within defined time frames. Such a performance evaluation allows for identification of practice trends, negative or positive, that impact the quality of care and patient safety.

Including measures related to individual staff member performance in the program in staff evaluations provide opportunities to identify performance deficiencies. When deficiencies or substandard performance are identified, corrective actions are implemented. Documentation of corrective actions taken, and the outcome produced is necessary when evaluating the performance of the staff.

### Measurable Elements of DFC.3

1. The program has a standardized process for evaluation of staff members. P
2. The program assesses clinical staff competence on an ongoing basis. This assessment is documented.
3. The performance of individual staff members is reviewed when indicated by variances noted on trend or as negative deviations to clinical practices.
4. The ongoing professional practice evaluation of each staff member is documented in the staff member's file and at a minimum, includes an annual evaluation.
5. Staff member evaluations include individual measures related to the performance in the clinical care program.
6. Corrective action is taken when deficiencies or substandard performance are identified. Corrective action is documented.

### Standard DFC.4

The program uses a standardized process originating in clinical practice guidelines or evidence-based practice to deliver or facilitate the delivery of clinical care.

### Intent of DFC.4

Clinical practice guidelines promote quality of care and help reduce variation with care and processes. Clinical practice is continuously changing and evolving to adapt to new evidence and published guidelines. The clinical care program is defined by the title conferred with the certification and associated clinical practice guidelines used to design the program. The organization defines their inclusion and exclusion criteria to encompass all individuals in the targeted population who are included in the adopted guidelines from professional organizations or societies with expertise in clinical care and/or disease management. Individuals are included in the program for a length of time that is pertinent to demonstrate the recommended best practice outcome measures in the reference clinical practice guidelines.

The objectives of a clinical care program include

- standardizing clinical care processes based on current evidence;
- reducing variations within care processes; and
- providing clinical care in a timely, effective manner using available resources efficiently.

A variety of tools may be used to reach these objectives. The program seeks to use the best available and current scientific evidence in developing the clinical care process. Clinical practice guidelines are useful tools in applying the best science to a particular disease, condition, or service. Clinical practice guidelines are

relevant to the program and the population being served, and are

- evidence-based guidelines sponsored and supported by the auspices of medical specialty associations, relevant professional societies, public or private organizations, or government agencies at the international, national or regional level;
- adapted when needed based on the patient's presenting clinical symptoms and diagnostic decisions made in support of clinical integrity;
- formally approved or adopted by program leaders and clinical staff in the program; and
- annually reviewed and updated when needed.

The clinical practice guidelines are monitored for consistent use and effectiveness and modified as determined by analysis of outcomes.

### Measurable Elements of DFC.4

1. The selected clinical practice guidelines used in the clinical care program are based on the target population served and in alignment with evidence-based practice.
2. The selected clinical practice guidelines used in the clinical care program are evaluated for their relevance to the target population.
3. Adapted or adopted clinical practice guidelines used in the clinical care program are reviewed annually to ensure that they are appropriate for the targeted population and relevant to current practice.
5. When current evidence-based practice advances, and adoption of new clinical practice is indicated, the program leaders will define in writing the changes to targeted population's current clinical care.
5. The program provides evidence that it is following the clinical practice guidelines when providing care, treatment, and services.
6. The program leader(s) reviews and approves updates to clinical care based on scientific evidence prior to implementation. This could include, but is not limited to clinical practice guidelines, newly published research, scientific statements, technology updates, etc. P

### Standard DFC.5

All clinical staff are knowledgeable about the adapted or adopted clinical practice guidelines and implement care, treatment and services that are consistent with the clinical practice guidelines.

### Intent of DFC.5

Clinical practice guidelines must be implemented and monitored for consistent use and effectiveness. Clinical staff in the program must support the use of the guidelines, be actively involved in the adoption or adaptation of guidelines and processes and receive appropriate training in applying the guidelines to ensure effective integration and coordination of care, treatment, and services, including assessing and reassessing the needs of the patient, and identified risks. The integration and coordination of care, treatment, and services consistent with current clinical practice guidelines continues through the continuum of care post-discharge. Clinical practice guidelines are developed using the best and most current scientific evidence available. Evidence-based practice also considers patient preferences and physician practices and expertise, leading to deviations from the published guidelines when considering an individualized plan of care that meets the patient's goals



and preferences.

### Measurable Elements of DFC.5

1. Clinical staff are educated about current scientific evidence based on the targeted population, these include clinical practice guidelines and scientific statements.
2. The assessment(s) and reassessment(s) are completed according to the patient's needs, identified risks, and clinical practice guidelines.
3. The program implements care, treatment, and services based on the patient's assessed needs, identified risks, and clinical practice guidelines.

### Standard DFC.6

The program tailors the plan of care to meet the patient's needs.

### Intent of DFC.6

The assessment process for building an individualized plan of care starts at triage and continues through discharge. It is developed during assessment, diagnoses, treatment, and evaluation of the patient's response to the plan of care. It is interdisciplinary, with family and patient as key team members. The plan of care must be consistent and predictable, include the patient and family risks, and result in a complete and timely plan to deliver the needed care. The program uses specified methods for prioritizing the needs of patients and identifying patient risks that are tailored to the targeted population's age and developmental needs. These methods include criteria that are used to prioritize patient needs and identify patients who may need immediate assistance. Information gathered through triage, visual evaluation, physical examination, or previous history is used to match patient needs and conditions with the mission and resources of the program, including coordination of care with other programs as determined by the patient's health history and comorbidities. **For example**, the plan of care for a patient with a history of smoking must include a smoking cessation goal, at least one identified risk factor, a documented referral or intervention, and subsequent documentation of an updated risk factor status-post intervention. The program evaluates and revises the plan of care, and then implements those revisions to meet the patient's ongoing needs.

Furthermore, the program explains the plan of care to the patient in a manner they understand and informs the patient of their responsibilities to provide information, to facilitate treatment, and cooperate with practitioners and of all potential consequences of not complying with care, treatment, and services.

### Measurable Elements of DFC.6

1. The plan of care is developed using an interdisciplinary approach and patient participation.
2. The program individualizes and documents the plan of care for each patient.
3. The individualized plan of care is based on the patient's assessed needs, goals, and the time frames to meet those goals.
4. The individualized plan of care reflects coordination of care with other programs, as determined by patient

comorbidities.

5. The program explains the plan of care to the patient in a manner they understand.
6. The program informs the patient of all potential consequences of not complying with care, treatment, and services.
7. The program informs the patients of their responsibilities to provide information, to facilitate treatment, and cooperate with practitioners.
8. The program continually evaluates, revises, and implements revisions to the plan of care to meet the patient's ongoing needs.
9. The program uses specified methods for prioritizing the needs of patients and identifying patient risks that are tailored to the targeted population's age and developmental needs.

## Standard DFC.7

The program develops a process for patient assessment for the target population.

### Intent of DFC.7

The goal of assessment is to determine the care, treatment, and services that will meet the initial and continuing needs of the target population. An effective patient-assessment process results in decisions about the target population's treatment needs for emergency, elective, or planned care, even when conditions change. Patient assessment is an ongoing, dynamic process, and may include additional assessments by other health care practitioners. These assessments must be integrated, and the most urgent care needs for the target population are identified. The program must define the patient assessment process including the family risks. The process includes the plans for assessments, reassessments, ongoing assessments, interventions to identified risks, diagnosis, and plan of care. Additionally, the program determines the timeframes for all assessments and reassessments. Patient needs must be reassessed throughout the course of care, treatment, and services. Reassessment is key to understanding the patient's response to the care, treatment, and services provided and is essential in identifying whether care decisions are appropriate and effective.

### Measurable Elements of DFC.7

1. The program defines the patient assessment process, including family risks.
2. The organization implements a process for the initial and ongoing assessment, reassessment, and intervention of patients according to identified risk(s), diagnosis, the patient's assessed needs, and the plan of care.
3. An assessment is completed for all patients within the time frame determined by the program.

## Standard DFC.8

The program has a process to provide continuity of patient care services and coordination among health care practitioners across the continuum of care.

## **Intent of DFC.8**

Organizations must consider the care provided as part of an integrated provider system of care, health care practitioners, and levels of care, which make up a continuum of care. The goal is to correctly match the patient's health care needs with the services available, to coordinate timely and high-quality services provided to the patient in the organization, and then to plan for discharge, transfer, and follow-up. This requires a high degree of collaboration and communication among health care practitioners, but the result is improved patient care outcomes and more efficient use of available resources.

Health care providers need to gather information from multiple sources to evaluate each patient's medical, surgical, and psychosocial history. If care has been provided in another setting, information about that care must be included in the health record and integrated into the plan for care. To develop and implement an appropriate plan of care, information comes from a variety of sources and settings. The program develops a process for gathering and disseminating information across the continuum of care. This includes but is not limited to:

- patient health status;
- a summary of the care provided; and
- the patient's response to care.

## **Measurable Elements of DFC.8**

1. The program gathers information directly from the patient and, if appropriate, the family.
2. The program gathers information from all relevant clinical staff or health care organizations and integrates the information into the plan of care. Information is documented in the health record.
3. The program shares information directly with the patient and/or family, if appropriate.
4. The program shares information with other relevant clinical staff or health care organizations to facilitate continuity of patient care as needed.
5. The program includes a process for patient referrals and/or patient discharge based on the patient's identified ongoing needs.

## **Standard DFC.9**

The program manages comorbidities and concurrently occurring conditions and/or communicates the necessary information to manage these conditions to the appropriate clinical staff.

## **Intent of DFC.9**

The patient care process is dynamic and may involve more than one care provider; more than one clinical care program; or multiple care settings. The integration and coordination of patient care activities are necessary for efficient care processes and the likelihood of better patient outcomes. The program uses tools and techniques to better integrate, coordinate, and communicate to appropriate clinical staff the care to be provided for their patients. When the program does not have the clinical capability to provide the needed services, the patient is assisted in identifying sources of services to meet his or her needs.

The health care services, and patient needs may change as the result of new information or may be evident from a sudden change in the patient's condition. The care provided involves identifying and prioritizing the treatments, procedures, and other care to meet those needs.

## Measurable Elements of DFC.9

1. The program coordinates care for patients with multiple health needs. The individualized plan of care reflects coordination of care with other programs, as determined by patient comorbidities.
2. The program's clinical staff communicate to other staff important information regarding co-occurring conditions and comorbidities needed to manage the patient's conditions.
3. Patients with comorbidities and co-occurring conditions needing clinical and/or psychosocial care, treatment, and services are managed by the program's clinical staff or referred to others for care.

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# Supporting Self-Management (SSM)

## Standard SSM.1

The program involves the patient and, when appropriate, the family in making decisions about managing their diseases or conditions.

### Intent of SSM.1

Patients and, when appropriate, families participate in the care process by making decisions about care, asking questions about care, and having the prerogative to refuse diagnostic procedures and treatment. The program supports and promotes patient and family involvement in all aspects of care by clearly explaining any proposed treatments or procedures to the patient and, when appropriate, the family so that they can make decisions about care. The information provided should include proposed treatments, potential risks, benefits and alternatives, and possible outcomes of nontreatment. **Shared decision-making provides opportunities for patient preferences for treatment and outcomes to be discussed and considered.** Additionally, the patient and, when appropriate, the family, have a responsibility to provide information to clinical staff that may impact treatment. **With shared decision-making and transparency of information, a balanced plan of care can be developed. The program informs the patient of their responsibilities to provide information, and of all potential consequences of not complying with a recommended treatment. Furthermore, the program provides the information in a manner that the patients and, when appropriate, families understand.**

### Measurable Elements of SSM.1

1. The program involves patients and, when appropriate, the family in decisions about their clinical care, treatment, and services.
2. The program informs the patients and, when appropriate, the family of their responsibilities to provide information that may impact treatment and to cooperate with the health care team.
3. The program informs the patients and, when appropriate, the family about potential consequences of not complying with a recommended treatment.

## Standard SSM.2

The program addresses the patient's and, when appropriate, the family's educational and self-management needs.

### Intent of SSM.2

**Patient and family education is regarded as** specific knowledge and skills the patient and family will need to make care decisions, to participate in their care, and to continue care at home. **There are many patient and family variables that determine if the patient and family are willing to learn and capable of learning. For the education to be planned well and to be effective, the patient and, when appropriate, the family must be assessed for**

- beliefs and values;
- literacy, level of education, and language;
- emotional barriers and motivations;
- physical and cognitive limitations; and
- willingness to receive information.

Education provided supports a variety of learning methods such as printed, audio and/or video based upon the patient's and/or family member's learning needs, and in the language the patient and/or family understand. Additionally, education supports healing and, when possible, a return to previous function. Moreover, to sustain optimal health, education also supports changes to the previous lifestyle. The patient and, when appropriate and culturally acceptable, the family are assessed for health history, lifestyle, and physiologic data that may put them at increased risk. Barriers to making the necessary lifestyle changes and the patient's response to recommended changes are also assessed. Community resources that support health promotion and disease prevention are identified, and an ongoing relationship is established.

There is an assessment process that identifies educational needs related to lifestyle changes, health promotion, and disease management. In addition, patient and family education addresses information needs related to the patient's illness(es) and treatment(s).

## **Measurable Elements of SSM.2**

1. The program assesses the patient's and/or family member's readiness, willingness, and ability to engage in disease-specific education and self-management activities. P
2. Based on the assessment, the program addresses individual educational needs related to lifestyle changes that support self-management regimens.
3. Based on the assessment, the program addresses individual educational needs related to health promotion.
4. Based in the assessment, the program addresses educational needs related to disease progression and self-management activities.
5. The program makes initial and ongoing assessments of the patient's comprehension of program-specific information. P
6. Each patient's educational needs and ability and willingness to learn are assessed and recorded in his or her health record.
7. Lifestyle changes are documented in the health record.
8. The program evaluates barriers to lifestyle changes.
9. The program assesses and documents the patient's response to recommended lifestyle changes.

## **Standard SSM.3**

The program educational materials are consistent with the clinical practice guidelines and relevant to the target population served.

### **Intent of SSM.3**

The program uses standardized materials consistent with the clinical practice guidelines and scientific



evidence relevant to the program including lifestyle changes, health promotion, disease management, and self-management. The program will have selected current educational materials that support the program's scope and reflect current evidence-based practices. The program's educational materials consider beliefs and values, literacy, level of education, and language, emotional barriers and motivations, physical and cognitive limitations, and the patient and family's willingness to receive information. Program educational materials provided are available to support a variety of learning methods such as printed, audio and/or video based upon the patient's and/or family member's learning needs, and in the language the patient and/or family understand.

### Measurable Elements of SSM.3

1. The program's educational materials comply with recommended elements of intervention in the literature or promoted through the current clinical practice guidelines. P
2. The program presents content in a manner that is culturally sensitive.
3. The program presents content in an understandable manner according to the patient's level of literacy.
4. Program educational materials provided are available to support a variety of learning methods such as printed, audio and/or video based upon the patient's and/or family member's learning needs.

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# Clinical Information Management (CIM)

## Standard CIM.1

Patient information is confidential and secure.

### Intent of CIM.1

The program maintains the privacy and confidentiality of data and information. There is a balance between data sharing and data confidentiality. The program determines and communicates to the patient and, when appropriate, the family what information and data will be used by the program. There is a process that indicates if patients have access to their health information and how to gain access when permitted. In addition, there is a process for retaining patient health records and other data and information in accordance with applicable laws and regulations. Patient information and health records are protected against loss, destruction, tampering, and unauthorized access or use.

### Measurable Elements of CIM.1

1. The program maintains the confidentiality, security, privacy, and integrity of data and information through processes to manage and control access.
2. The program safeguards health records and information against loss, theft, destruction, tampering, and unauthorized access or use.
3. The program has determined how long health-records and other data and information are retained, in accordance with applicable laws and regulations and patient need.
4. Patients are made aware of how data and information related to them will be used by the program, and, if so, how the data and information will be used.

## Standard CIM.2

The program identifies those authorized to have access to and/or to make entries in the patient health record.

### Intent of CIM.2

The program assures that entries into the health record are completed by authorized practitioners and staff members. Access to information contained in the patient health record is based on need and defined by job title and function. An effective process defines

- who has access to information;
- the information to which an individual has access;
- the user's obligation to keep information confidential; and
- the process followed when confidentiality and security are violated.

The program identifies the content and format for entries in patient health records. There is a process to ensure that only authorized individuals make entries in patient health records and that each entry identifies

the author of the entry and the date and the time the entry was made. The time of the entry is also noted for items such as timed treatments or medication orders.

### Measurable Elements of CIM.2

1. The program complies with processes for authorized users of health records as identified by the organization. P
2. The program measures compliance with health record access limitations.
3. The program assures compliance with the organization's process for responding to a violation of confidentiality or security. P
4. The program supports the organization's process for addressing a violation of confidentiality or security.
5. The author, date, and time of each entry in the patient's health record can be identified.

### Standard CIM.3

The program uses standardized diagnosis codes, procedure codes, symbols, abbreviations, definitions, and methods for adding comments/addenda.

### Intent of CIM.3

Standardization of codes, terminology, definitions, vocabulary, and nomenclature, and the uniform use of symbols and abbreviations prevents miscommunication and potential errors in patient care. In addition, the uniform use of standardized diagnosis and procedure codes supports data aggregation and analysis and information between and among health care providers. Abbreviations and symbols also include a "do not use" list. Such standardization is consistent with recognized local and national standards.

When a program uses abbreviations, the program develops and/or adopts a do-not-use list of abbreviations and symbols. **For example**, the Institute for Safe Medication Practices (ISMP) maintains a list of abbreviations, symbols, and dose designations that "should never be used when communicating medical information." The items in the list were reported to ISMP as being frequently misinterpreted and involved in harmful medication errors.

The program's use of standardized codes and uniform use of approved symbols and abbreviations is consistent with standards of professional practice and complies with local laws and regulations as applicable. Staff are educated and trained on the principles of the standardization and uniform use of the hospital's codes, symbols, and abbreviations. The principles of the standardized use of codes and uniform use of approved symbols and abbreviations apply to electronic medical record systems and electronic communications, such as e-mail and texting, that are used for communicating about patient care.

### Measurable Elements of CIM.3

1. The program implements the use of standardized diagnosis codes in a consistent manner. Compliance is monitored.
2. The program implements the use of standardized procedure codes in a consistent manner. Compliance is monitored.

3. The program implements the use of standardized data, definitions, measure specifications, and methods for adding comments/addenda in a consistent manner. Compliance is monitored.
4. The program implements the standardized use approved symbols in a consistent manner and identifies those not to be used. Compliance is monitored.
5. The program implements the standardized use of approved abbreviations in a consistent manner and identifies those not to be used. Compliance is monitored.

## Standard CIM.4

The program initiates, maintains, and makes accessible a health record for every patient.

### Intent of CIM.4

Every patient assessed or treated in the program has a health record. The record is assigned an identifier, in addition to the patient's name, that is unique to the patient to link the patient with his or her health record. The health record contains sufficient information to support any diagnosis, to justify the treatment, and to document the course and results of treatment. Thus, the record contains at least

- documentation of the care provided;
- orders for diagnostic and treatment services to be performed from within or outside the organization;
- medications prescribed or dispensed within or outside the organization; and
- procedures performed and the results.

The integrity of the patient health record is critical to the quality and safety of patient care and continuity of care, as it is the principal tool for communication between health care practitioners. The health record facilitates medical decision making, clinical follow-up, transitions of care, and medication ordering and dosing. As part of its monitoring and performance improvement activities, the program regularly assesses patient health record content and the completeness of patient health records. A standardized format and content of a patient's health record helps promote complete and accurate records and helps ensure the flow of information to all those who care for the patient or make entries into the record. The program patients' health-record review is based on a sample representing inpatients and outpatients (if applicable). The review is conducted by each relevant discipline who is authorized to make entries in the patient record. Patient health record review is based on a sample representing the practitioners involved in providing care and is conducted by each relevant clinical professional who is authorized to make entries in the patient record.

### Measurable Elements of CIM.4

1. The health record is assigned an identifier, in addition to the patient's name, that is unique to the patient to link the patient with his or her record.
2. All relevant practitioners have access to patient information as needed.
3. The health record contains sufficient information to support the diagnosis and promote continuity of care.
4. The health record contains sufficient information to justify care, treatment, and services provided.
5. The health record contains sufficient information to document the course and results of care, treatment, and services.

6. The program reviews its health records for completeness and accuracy.
7. The medical record contains sufficient information to track the patient's movement and facilitate continuity of care both within and outside the program.
8. The program defines methods for adding comments, in the form of statements or addenda into the formal records.
9. Health records are periodically reviewed by all relevant disciplines, for complete, accurate, and timely maintenance.

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# Performance Measurement and Improvement (PMI)

## Standard PMI.1

The program has an organized, comprehensive approach to performance improvement.

### Intent of PMI.1

For the program to initiate and to maintain improvement and to reduce risks to patients, planning is essential. Because quality improvement, defined as “the approach to the continuous study and improvement of the processes of providing health care services to meet the needs of patients and others,” and patient safety are data driven, the program needs to identify which performance measures are most important to monitor based on the program’s mission and the services provided, as well as the patient’s needs.

Performance improvement is defined as “the systematic process of detecting and analyzing performance problems, designing and developing interventions to address the problems, implementing the interventions, evaluating the results, and sustaining improvement.” The program uses information obtained from analysis of data to identify potential improvements or to reduce adverse events. Routine monitoring of data contributes to understanding where improvements should be planned and what priority should be given to the improvement. To ensure that the improvement is sustained, measurement data are then collected for ongoing analysis. Effective changes are incorporated into standard operating procedure, and any necessary staff education is carried out. program documents those improvements achieved and sustained as part of its quality management and improvement program. All relevant disciplines are involved in development and implementation of the performance improvement plan. A qualified individual(s) guides the implementation of the organization’s program for quality improvement and patient safety and manages the activities needed to carry out an effective program of continuous quality improvement and patient safety within the hospital.

The process of performance improvement includes the following:

- Planning for performance improvement
- Monitoring of processes through performance measure data collection
- Data analysis
- Issue identification
- Identification of improvement goals
- Identification of action steps to achieve improvement goals
- Implementation of action steps that result in and sustain improvement

Performance improvement is contingent on reliable measurement and assessment to understand current performance and to target areas for improvement. In addition, systematic improvement methods are required to guide measurement, assessment, and improvement. A *standard* is a statement that defines performance expectations, structures, or processes that must be substantially in place to enhance quality of care. A *performance measure* provides an indication of a program’s performance in relation to a specified process or outcome. Standards and performance measures are complementary in that complex interrelationships exist among any given standard and an array of relevant performance measures.

Performance measurement in health care is an indication of what is done and how well it is done. A performance measure is a quantitative tool that is calculated from a group of data elements. The following criteria demonstrate the characteristics of a good measure:

- Based on evidence
- Description of rationale and intent
- Defined data elements and allowable values
- Within provider control
- Useful to the clinical care program and the organization

## **Measurable Elements of PMI.1**

1. The program has a written performance improvement plan. P
2. The program leader(s) identifies goals and sets priorities for improvement in a performance improvement plan. P
3. The program collects data related to its target population to identify opportunities for performance improvement.
4. The program analyzes its performance measurement data to identify opportunities for performance improvement.
5. The program documents actions taken to achieve improvement and determines if improvements have been achieved and are being sustained. P
6. The program leader(s) involves the interdisciplinary team and other practitioners across disciplines and/or settings in performance improvement planning and activities.
7. A qualified individual(s) guides the implementation of the hospital's program for quality improvement and patient safety and manages the activities needed to carry out an effective program of continuous quality improvement and patient safety within the hospital. P

## **Standard PMI.2**

The program maintains data quality and integrity.

### **Intent of PMI.2**

Quality improvement and patient safety are data driven. Understanding how well the organization is doing depends on the analysis of data and reporting of the results. The aggregation and analysis of data and information and planning of subsequent improvements require the use of data that are

- relevant to the program;
- timely, accurate, and complete;
- reliable and valid;
- free of bias; and
- based on sound measurement principles.

Variables that impact program outcomes are identified and included in the analysis of data.

Maintaining data integrity is an important aspect of information management. The information contained in a database must be accurate to ensure the reliable interpretation of results from data analysis.

## Measurable Elements of PMI.2

1. The program uses standardized data, definitions, codes, measurement classifications, and terminology throughout the organization.
2. Data collection is timely, accurate, complete, and relevant to the program.
3. The program monitors and maintains data accuracy, integrity, reliability, and validity.
4. The program uses sampling methodology based on measurement principles.
5. The program uses data analysis tools.

## Standard PMI.3

The program identifies performance measures to improve processes and outcomes.

### Intent of PMI.3

The program collects and analyzes aggregate data to support patient care and program management. Aggregate data provides a profile of the program over time and allows the comparison of the program's performance with other similar programs. Thus, aggregate data are important to the performance improvement activities of the program. Aggregate data can help the program understand its current performance and identify opportunities for improvement. The format and methods of disseminating data and information are tailored to meet the user's expectations. Identifying the process, procedure, or outcome to be measured is an important step in quality improvement and patient safety initiatives. Valid, reliable performance measures should be based on clinical practice guidelines and other evidence relevant to the management of the disease or condition. To monitor processes, the program needs to determine how to organize monitoring activities, how often to collect data, and how to incorporate data collection into the daily work process. When selecting the measures, the program includes the following criteria:

- The process, procedure, or outcome to be measured
- The availability of science or evidence supporting the measure
- How measurement will be accomplished
- The frequency of measurement

The analysis of the data being monitored may result in strategies for improvement in the area being monitored. The program reports aggregated data to Joint Commission International at defined intervals.

## Measurable Elements of PMI.3

1. The program selects valid, reliable performance measures that are relevant to the target population and based on clinical practice guidelines or other evidence-based practice.
2. The program collects and analyzes data to identify opportunities for improvement both on an individual patient level as well as a program level.
3. The program selects at least one interdisciplinary performance measure based on data analysis.
4. The program collects data on all program performance measures.
5. The program aggregates and analyzes data, using quality improvement tools.

6. The program reports data aggregated at the program level to Joint Commission International at defined intervals.

## **Standard PMI.4**

The program has a performance improvement action plan based on processes and outcomes.

### **Intent of PMI.4**

A performance improvement action plan identifies the strategies that the program intends to implement to reduce the risk of similar events occurring in the future. When formulating a performance improvement action plan, the measurement data is used to develop a plan based on processes and outcomes. The action plan is implemented, and the interdisciplinary team should then analyze the strength of its proposed solutions. An evidence-based tool can help the program identify strong actions that provide effective and sustained improvement. The performance improvement action plan addresses the following:

- Identifying corrective actions to eliminate or reduce hazards or vulnerabilities directly related to causal and contributory factors
- Implements the performance improvement action plan
- Developing strategies to evaluate the effectiveness of the performance improvement actions at defined intervals
- Communicating to staff and organizational leaders the identified improvement opportunities and outcomes.
- Demonstrating improvement in processes and patient outcomes
- Developing strategies to sustain the improvement

### **Measurable Elements of PMI.4**

1. The program collects and uses measurement data to develop a performance improvement action plan based on processes and outcomes.
2. The program implements the performance improvement action plan.
3. The program evaluates the outcomes of the performance improvement action plan at defined intervals.
4. The program communicates to staff and organizational leaders the identified improvement opportunities and outcomes.
5. The program demonstrates improvement in processes and patient outcomes.

## **Standard PMI.5**

The program has a sentinel event process that includes identifying, reporting, managing, and tracking sentinel events.

## Intent of PMI.5

Sentinel events are a subcategory of adverse events. A *sentinel* event is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm). Serious physical injury specifically includes loss of limb or function. Such events are called *sentinel* because they signal the need for immediate investigation and response. *Severe temporary harm* is defined as critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

Sentinel events are not only events that occur during the care and treatment of individuals. Physical and verbal violence, abductions, and power failures are all potential sentinel events that can affect the health care organization and its patients. JCI considers the following list of events, though not comprehensive, to be sentinel events if they occur under any JCI-accredited or -certified health care organization, although some of these events are unlikely to occur in certain health care settings. The program establishes an operational definition of a sentinel event that includes at least the following events:

- a) Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)
- b) Unanticipated death of a full-term infant
- c) Discharge of an infant to the wrong family
- d) Abduction of any patient receiving care, treatment, and services
- e) Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
- f) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- g) Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital
- h) Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
- i) Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
- j) Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- k) Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)
- l) Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or > 25% above the planned radiotherapy dose
- m) Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
- n) Any intrapartum (related to the birth process) maternal death
- o) Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm

The program's definition of a sentinel event includes a) through o) above and may include other events as required by laws or regulations or viewed by the program as appropriate to add to its list of sentinel events.

All events that meet the definition of a sentinel event must be assessed by performing a credible root cause analysis. Accurate details of the event are essential to a credible root cause analysis; thus, the root cause analysis needs to be performed as soon after the event as possible. The analysis and action plan are completed within 45 days.

The program leader(s) implements changes based on its analysis of sentinel events systemwide of the event or becoming aware of the event. The goal of performing a root cause analysis is for the program to better understand the origins of the event. When the root cause analysis reveals that systems improvements or other actions can prevent or reduce the risk of such sentinel events recurring, the program redesigns the processes and takes whatever other actions are appropriate.

It is important to note that the terms *sentinel event* and *medical error* are not synonymous. Not all errors result in a sentinel event, nor does a sentinel event occur only as a result of an error. Identifying an incident as a sentinel event is not an indicator of legal liability.

## Measurable Elements of PMI.5

1. A process exists for identifying sentinel events, based on an operational definition that includes at least a) through o) in the intent.
2. A root cause analysis of all sentinel events identifies all system and process origins and is performed in a specified time period that does not exceed 45 days from the date of the event or when made aware of the event.
3. The program leader(s) implements changes based on its analysis of sentinel events related to the program.

## Standard PMI.6

The process for identifying, reporting, managing, and tracking all program-specific errors and adverse events is defined, analyzed, and implemented by the program leader(s).

### Intent of PMI.6

When the program detects or suspects undesirable change, it initiates analysis to determine where best to focus improvement. In particular, analysis is initiated when levels, patterns, or trends vary significantly and undesirably from

- what was expected;
- that of other similar programs; or
- recognized standards.

An analysis includes

- all confirmed transfusion reactions, if applicable to the program;
- all serious adverse drug events, as defined by the program;
- all significant medication errors, as defined by the program; and
- other events related to the health and safety of patients.

The information from data analysis is used to identify potential improvements or to reduce (or prevent) adverse events. Routine measurement data, as well as data from intensive assessments, contribute to this understanding of where improvement should be planned and what priority should be given to the

improvement. The program leaders are responsible to plan and implement changes for improvement based on the analysis of errors or adverse events related to the program.

### **Measurable Elements of PMI.6**

1. The program attempts to prevent errors or adverse events that result in undesirable changes from what was expected.
2. A process exists for identifying errors or sentinel events related to the program, if and when they occur.
3. A process exists for tracking errors or adverse events if and when they occur.
4. A process exists for analyzing errors or adverse events if and when they occur.
5. The program leader(s) implements changes based on the analysis of errors or adverse events related to the program.

### **Standard PMI.7**

The process for identifying, reporting, managing, and tracking all program-specific “near-miss” events and complication is defined, analyzed, and implemented by the program leader(s).

### **Intent of PMI.7**

To proactively learn where systems may be vulnerable to adverse events, the program collects data and information on “near-miss” events and complications—a process variation that did not affect the outcome—and evaluates them in an effort to prevent the actual occurrence of adverse events. The program establishes a definition of a near miss and what types of events are to be reported, as well as potential complications related to the target population and the care, treatment and services provided. There is a process for reporting, aggregating, and analyzing the data to learn where proactive process changes can reduce or eliminate the related events, near misses, and complications.

### **Measurable Elements of PMI.7**

1. The program attempts to prevent unanticipated events or errors that could have resulted in death or serious physical or psychological injury.
2. A process exists for identifying near-miss events and complications related to the program if and when they occur.
3. A process exists for tracking near-miss events and complications related to the program if and when they occur.
4. A process exists for analyzing near-miss events and complications related to the program if and when they occur.
5. The program leader(s) implements changes based on the analysis of near-miss events and complications related to the program.



## Standard PMI.8

The program evaluates patient and family satisfaction with the quality of care at the program level.

### Intent of PMI.8

Patient and family satisfaction is fundamental to quality care. **There is value in having a standardized process to collect, measure, and evaluate patient and family satisfaction. Seeking and obtaining feedback on patient satisfaction provides opportunities for all stakeholders to express concerns and provide recommendations.** Measuring satisfaction and the perception of the quality of care will provide valuable insight when making improvements to the program.

### Measurable Elements of PMI.8

1. **The program has a process in place for collecting patient and family satisfaction with perception of the quality of care at the program level.**
2. When culturally appropriate, the program evaluates patient and family satisfaction with perception of the quality of care at the program level.
3. The program uses patient and family satisfaction data to analyze the program-specific quality of care and to make improvements to the program. P

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