

Attestation Guide for the Patient Safety Structural Measure in CMS Quality Reporting

I. Preface

The purpose of the Patient Safety Structural Measure is to drive action and improvement in patient safety across key domains. The development of the measure is anchored in best practices and evidence for improving patient safety and reducing harm using a total systems framework that views patient safety events as a result of system failure rather than individual error.^{1,2,3}

The Patient Safety Structural Measure consists of five domains, each with statements to which the hospital must respond. Affirmative attestation to all statements within a domain will be required for the hospital to receive a point for that domain; partial credit will not be awarded. At one point per domain, hospitals affirmatively attesting to all statements will receive the maximum five points. Hospitals participating in the Hospital Inpatient Quality Reporting (IQR) Program and the Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program would complete attestation during the CMS-specified time period. Hospitals will submit data to the National Healthcare Safety Network at the Organization Identification Number (OrgID) level, however the data will be reported and used at the CMS Certification Number (CCN) level. If multiple OrgIDs under a shared CCN report different score values for the Patient Safety Structural measure, CMS will apply the lowest facility score of the OrgIDs to the CCN.

This Attestation Guide for the Patient Safety Structural Measure provides information and examples for illustrative purposes to support hospital response to the statements included in the measure. Guidance is provided on select measure domains and statements, as needed; a glossary of key terms and concepts is also provided. For each “Statement-specific guidance” provided below within each domain, the statement is identified as it appears in the Patient Safety Structural Measure specifications, identified by the domain number and statement letter as it appears in the measure specifications; the guidance for that statement immediately follows. [As guidance is provided for select, but not all, measure statements, the statements identified in this guide will not appear sequentially (e.g., Statement A, then Statement B, then Statement C, etc.). Statements for which guidance was not deemed necessary have not been included.]

II. Domain-Specific Guidance

Domain 1: Leadership Commitment to Eliminating Preventable Harm

Overarching guidance:

- There are varying governance structures at hospitals. For this measure:
 - Hospital leadership is identified as the “senior governing board” and C-suite “leaders” or “executives.” Hospital leadership works directly with, and may include, medical staff responsible for quality delivery of care within the hospital.

- Senior governing board is intended to be the body with fiduciary responsibility for the hospital, in charge of resource management, with ultimate authority. The senior governing board may or may not oversee other, subordinate hospital boards and committees. While hospital quality and/or safety committees and subcommittees have an important role in improving patient safety, for this measure it is the senior governing board with fiduciary responsibility and resource management ownership who is deemed ultimately responsible.
- For hospitals that are part of larger health systems, it is the most senior *hospital-level board* that is responsible for overseeing patient safety activities and performance for that individual hospital. *Health system boards* are encouraged to oversee the quality of their system, but hospital-level boards are ultimately accountable.
- In cases where there is not a hospital-level board, the governing body that is responsible for the individual hospital is responsible for overseeing these activities at the hospital level (versus reviewing information for the entire health system).

Statement-specific guidance:

- **Domain 1, Statement B:** *Our hospital leaders, including C-suite executives, place patient safety as a core institutional value. One or more C-suite leaders oversee a system-wide assessment on safety (examples provided in the Attestation Guide), and the execution of patient safety initiatives and operations, with specific improvement plans and metrics. These plans and metrics are widely shared across the hospital and governing board.*

“System-wide assessment on safety” refers to a hospital self-assessment of safety practices and capacity, such as the Institute for Healthcare Improvement’s (IHI) Self-Assessment Tool that accompanies the National Action Plan to Advance Patient Safety.⁴ This type of assessment is designed to be implemented by hospital leaders to evaluate organizational practices and capacity, which is different than a safety culture survey or assessment that targets frontline hospital staff (as noted in Domain 3, Statement A).

- **Domain 1, Statement D:** *Reporting on patient and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event cause analysis, infection outbreak, culture of safety, or other patient safety topics) accounts for at least 20% of the regular board agenda and discussion time for senior governing board meetings.*

For this measure attestation statement, “regular board agenda” of the senior governing board is intended to be the meeting agenda set for the board’s routinely scheduled meetings (versus “ad hoc” or “special” meetings). The frequency of routinely scheduled meetings of the senior governing board may vary among hospitals.

Standing agenda items focused on patient safety may include review of key performance indicators such as hospital acquired infections, adverse events, mortality rates, readmission rates, medication errors, suicide risk reduction, incidence of workplace

violence, and other items based on the hospital's priorities. Culture of safety results and issues identified in safety huddles should also be reviewed. Updates from quality and safety programs such as Infection Prevention and Quality Assessment Performance Improvement (QAPI) should be provided at these meetings.

Patient safety discussions and considerations that are integrated into other board agenda items are encouraged and considered counted towards the 20% threshold.

- **Domain 1, Statement E:** *C-suite executives and individuals on the governing board are notified within 3 business days of any confirmed serious safety events resulting in significant morbidity, mortality, or other harm.*

“Serious safety events resulting in significant morbidity, mortality, or other harm” refers to an event judged by the clinical team OR the patient to be temporary major (e.g., burns, surgical materials left in patient, drug side effect, recovery delayed) or greater, including:

- Permanent minor (e.g., loss of fingers, loss or damage to organs, includes non-disabling injuries)
- Permanent significant (e.g., deafness, loss of limb, loss of eye, loss of one kidney or lung)
- Permanent major (e.g., paraplegia, blindness, loss of two limbs, brain damage), permanent grave (e.g., quadriplegia, severe brain damage, lifelong care, or fatal prognosis), and death.⁵

With regards to reporting time frame, some incidents may require more immediate reporting per state and local laws.

For the purposes of this measure, “confirmed” serious safety events for notification to the governing board are those for which a safety event, as defined immediately above, has been verified by the patient’s clinical team or a monitoring or other entity within the hospital authorized to report or investigate safety events. It is anticipated and understood that notification within three business days of a confirmed serious safety event may not be accompanied by a full reporting of the root causes of the event nor meaningful corrective actions beyond immediate mitigation, when applicable. A thorough review of root causes and corrective actions informed by this review may take more than three days.

Domain 2: Strategic Planning & Organizational Policy

Statement-specific guidance:

- **Domain 2, Statement A:** *Our hospital has a strategic plan that publicly shares its commitment to patient safety as a core value and outlines specific safety goals and associated metrics, including the goal of “zero preventable harm.”*

“A strategic plan that publicly shares its commitment to patient safety” refers to public declaration – both within the hospital and to public audiences, including patients and the broader community – via hospital policy (for hospital audiences), website, hospital

bulletins and storyboards, patient resources, marketing materials and/or other communication channels.

Hospitals should acknowledge the ultimate goal of zero preventable harm, even while recognizing that this goal may be longer-term. Setting an aim to eliminate preventable harm is necessary for establishing a culture that prioritizes safety and fostering a mindset that preventable harm to patients is unjustifiable.

- **Domain 2, Statement B:** *Our hospital safety goals include the use of metrics to identify and address gaps in safety outcomes based on the patient characteristics determined by the hospital to be most important to health care outcomes for the specific populations served.*

Currently, there is not a set of standardized outcome and process measures to monitor patient safety. To evaluate and track safety performance, hospitals should use harm indicators such as the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators⁶, Leapfrog Safety Measures⁷, National Database of Nursing Quality Indicators safety measures,⁸ Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) measures,⁹ and measures reported in Centers for Medicare & Medicaid Services (CMS) quality programs. Differences in these metrics based on patient characteristics deemed by your hospital to be associated with health outcomes can illuminate gaps in healthcare outcomes and inform improvement activities. CMS encourages hospitals to use stratification as an optimal approach for identifying potential gaps in patient safety metrics; a wide range of patient characteristics important to health outcomes may be considered.

- **Domain 2, Statement D:** *Our hospital requires implementation of a patient safety curriculum and competencies for all clinical and non-clinical hospital staff, including C-suite executives and individuals on the governing board, regular assessments of these competencies for all roles, and action plans for advancing safety skills and behaviors.*

Patient safety curriculum and competencies (i.e., skills and behaviors) for clinical and non-clinical staff will vary based on role. Training should be based on validated, industry-standard competencies. Examples of trainings and competencies include: National Association for Healthcare Quality's (NAHQ) Healthcare Quality Competency Framework^{TM10}; Comprehensive-Unit-based Safety Program (CUSP)¹¹; AHRQ's Communication and Optimal Resolution (CANDOR) toolkit¹²; the Centers for Disease Control and Prevention's (CDC) Infection Control Assessment and Response program and tool¹³; TeamSTEPPS communication framework¹⁴; Institute for Healthcare Improvement's Root Cause Analyses and Action (RCA²) resources¹⁵; shared decision making¹⁶; tools to reduce central line infections¹⁷; utilization of data analytics; performance improvement methodologies such as Plan-Do-Study-Act¹⁸; and ethical standards.

Domain 3: Culture of Safety & Learning Health System

Statement-specific guidance:

- **Domain 3, Statement A:** *Our hospital conducts a hospital-wide culture of safety survey using a validated instrument annually, or every two years with pulse surveys on target units during non-survey years. Results are shared with the governing board and hospital staff and used to inform unit-based interventions to reduce harm.*

A hospital-wide culture of safety survey refers to validated instruments designed for hospital staff and providers, such as the AHRQ Surveys on Patient Safety Culture (SOPS) Hospital Survey and the Safety Attitudes Questionnaire.^{19,20}

A pulse survey refers to a short set of questions, typically 5 to 15, sent to employees on a more frequent basis than an annual survey that can provide continuous feedback from staff and measure staff sentiment within an organization. They are particularly useful in helping to maintain an early warning system for safety issues and measuring the effectiveness of action plans and initiatives. The frequency with which pulse surveys are administered can vary; most organizations conduct them quarterly or monthly. For hospitals that conduct a hospital-wide culture of safety survey with a validated survey instrument every two years, rather than annually, pulse surveys should be administered on target units during non-hospital wide survey years to meet this attestation statement. Pulse survey questions should reflect organizational priorities and may be department or unit specific.²¹

- **Domain 3, Statement C:** *Our hospital has a patient safety metrics dashboard and uses external benchmarks (such as CMS Star Ratings or other national databases) to monitor performance and inform improvement activities on safety events (such as: medication errors, surgical/procedural harm, falls, pressure injuries, diagnostic errors, and healthcare-associated infections).*

Currently, there is not a set of standardized outcome and process measures to monitor patient safety. To evaluate and track safety performance, metrics could include harm indicators such as AHRQ Patient Safety Indicators⁶, Leapfrog Safety Measures⁷, measures reported in Centers for Medicare & Medicaid Services (CMS) quality programs, data from the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network²² and the National Database of Nursing Quality Indicators⁹, as well as survey data from Consumer Assessment of Healthcare Providers & Systems (CAHPS) Surveys²³, and AHRQ Surveys on Patient Safety Culture (part of SOPS Database Benchmarking Reports¹⁹).

Hospitals should leverage data from electronic health records (EHRs) whenever possible to track adverse events and unintended outcomes in real time. This information can be used to inform safety huddles and develop electronic trigger tools. Real time data from EHRs can be used to identify trends and pinpoint problem areas.

- **Domain 3, Statement D:** *Our hospital implements a minimum of 4 of the following high reliability practices:*

- *Tiered and escalating (for example, unit, department, facility, system) safety huddles at least 5 days a week, with 1 day being a weekend, that include key clinical and non-clinical (for example, lab, housekeeping, security) units and leaders, with a method in place for follow-up on issues identified.*
- *Hospital leaders participate in monthly rounding for safety on all units, with C-suite executives rounding at least quarterly, with a method in place for follow-up on issues identified.*
- *A data infrastructure to measure safety, based on patient safety evidence (for example, systematic reviews, national guidelines) and data from the electronic medical record that enables identification and tracking of serious safety events and precursor events. These data are shared with C-suite executives at least monthly, and the governing board at every regularly scheduled meeting.*
- *Technologies, including a computerized physician order entry system and a barcode medication administration system, that promote safety and standardization of care using evidence-based practices.*
- *The use of a defined improvement method (or hybrid of proven methods), such as Lean, Six Sigma, Plan-Do-Study-Act, and/or high reliability frameworks.*
- *Team communication and collaboration training of all staff.*
- *The use of human factors engineering principles in selection and design of devices, equipment and processes.²⁴*

“High reliability practices” refer to activities that apply principles of high reliability organizations (HROs). HROs are organizations that achieve safety, quality, and efficiency goals by applying 5 key principles: 1) sensitivity to operations (i.e., heightened awareness of the state of relevant systems and processes); 2) reluctance to simplify (i.e., acceptance that work is complex, with the potential to fail in new and unexpected ways); 3) preoccupation with failure (i.e., to view near misses as opportunities to improve, rather than proof of success; 4) deference to expertise (i.e., to value insights from staff with the most pertinent safety knowledge over those with greater seniority); and 5) practicing resilience (i.e., to prioritize emergency training for many unlikely, but possible, system failures).²⁵

A “tiered and escalating huddle” system involves a series of brief focused conversations, typically daily, that rapidly identify and escalate safety, quality, and operational issues from a broad array of frontline staff to a focused group of senior leaders. The outcomes associated with tiered huddles align with organizational goals of patient safety and high reliability and include rapid identification and resolution of safety issues and optimal employee engagement at all levels.²⁶

“Team communication and collaboration training” should include evidence-based curricula such as AHRQ’s TeamSTEPPS, which focuses on improving communication and teamwork among providers.¹⁴

- ***Domain 3, Statement E:*** *Our hospital participates in large-scale learning network(s) for patient safety improvement (such as national or state safety improvement collaboratives),*

shares data on safety events and outcomes with these network(s) and has implemented at least one best practice from the network or collaborative.

“Large-scale learning network(s)” refers to a collaborative of hospitals that share data and practices for research and improvement. Examples of learning networks focused on patient safety include Children’s Hospitals’ Solutions for Patient Safety²⁷ and the Partnership for Patients.²⁸

Domain 4: Accountability & Transparency

Statement-specific guidance:

- **Domain 4, Statement B:** *Our hospital voluntarily works with a Patient Safety Organization listed by the Agency for Healthcare Research and Quality (AHRQ) to carry out patient safety activities as described in 42 CFR 3.20, such as, but not limited to, the collection and analysis of patient safety work product, dissemination of information such as best practices, encouraging a culture of safety, or activities related to the operation of a patient safety evaluation system.*

Patient Safety Organizations (PSOs) authorized by the Patient Safety and Quality Improvement Act of 2005 (PSQIA) have been created to drive improvements in patient safety. Hospitals positively attesting to this statement are those working with an AHRQ-listed Patient Safety Organization;²⁹ these PSOs have been approved by AHRQ and provide the confidentiality and privilege protections of the PSQIA.

- **Domain 4, Statement C:** *Patient safety metrics are tracked and reported to all clinical and non-clinical staff and made public in hospital units (for example, displayed on units so that staff, patients, families, and visitors can see).*

See guidance on patient safety metrics under Domain 3, Statement C, above. There are several recommended approaches to reporting and presenting safety data, such as summary statistics, graphs, and tables. Visual methods such as run charts, control charts³⁰ and histograms can provide hospital staff with data that are easily understood, communicating variation and changes in safety metrics over time. Storyboards can be used to provide simple and concise summaries of current improvement projects.³¹ Data displays should be positioned in high traffic areas for maximum exposure and included in relevant websites.

- **Domain 4, Statement D:** *Our hospital has a defined, evidence-based communication and resolution program reliably implemented after harm events, such as AHRQ’s Communication and Optimal Resolution (CANDOR) toolkit, that contains the following elements:*
 - *Harm event identification*
 - *Open and ongoing communication with patients and families about the harm event*
 - *Event investigation, prevention, and learning*

- *Care-for-the-caregiver*
- *Financial and non-financial reconciliation*
- *Patient-family engagement and on-going support*

Communication and Optimal Resolution (CANDOR) is a patient-centered process that hospitals can use to respond in a timely, thorough, and just way to unexpected events causing patient harm. CANDOR emphasizes early disclosure of adverse events and a proactive method to achieving an amicable and fair resolution for patients, their families, and involved health care providers. AHRQ provides a CANDOR toolkit to assist hospitals in implementing communication and optimal resolution programs.³²

- ***Domain 4, Statement E:*** *Our hospital uses standard measures to track the performance of our communication and resolution program and reports these measures to the governing board at least quarterly.*

“Standard measures” may include number of resolutions achieved, amount of time for resolution to occur, and total compensation paid to patients when inappropriate medical care causes harm.

Domain 5: Patient & Family Engagement

Statement-specific guidance:

- ***Domain 5, Statement B:*** *Our hospital’s Patient and Family Advisory Council includes patients and caregivers of patients who are representative of the patient population.*

The Patient and Family Advisory Council should adequately represent the population of your specific hospital, in terms of patient characteristics deemed important to health outcomes for your patient population.

- ***Domain 5, Statement C:*** *Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via patient portals and other options, and the hospital provides support to help patients interpret information that is culturally and linguistically appropriate as well as submit comments for potential correction to their record.*

Examples of patient portals and other tools to optimize patient access to medical records include resources from OpenNotes³³ and personal health records (e.g., Epic’s MyChart). These tools should be available to non-English speakers based on the patient population served. Numerous translation services are currently available to healthcare providers. The U.S. Department of Health and Human Resources provides guidance on choosing translation services in the “Toolkit Guidelines for Culturally Appropriate Translation”.³⁴

Hospitals positively attesting to this statement are those that ensure patients not only have access to their medical records but also have an opportunity to provide potential corrections.

- **Domain 5, Statement E:** *Our hospital supports the presence of family and other designated persons (as defined by the patient) as essential members of a safe care team and encourages engagement in activities such as bedside rounding and shift reporting, discharge planning, and visitation 24 hours a day, as feasible.*
 - “Safe care team” refers to the group of individuals involved in a patient’s care and includes clinicians as well as family members and other care partners (as designated by the patient).
 - “Bedside rounding and shift reporting” refers to conducting check-ins and status reports at the end of shifts at the patient’s bedside.
 - Visits from family and other designated individuals (as defined by the patient) should be allowed 24 hours a day, as feasible, which may vary based on infection control protocols, hospital security, individual patient needs and patient preference.

III. Key Terms and Concepts

Patient safety event – any event that jeopardizes the safety of the patient, and is inclusive of near misses, precursor events, errors, and adverse events (*see definitions below*).

Serious safety event – a safety event judged by the clinical team or patient to be temporary major (e.g., burns, surgical materials left in patient, drug side effect, recovery delayed) or greater, including: permanent minor (e.g., loss of fingers, loss or damage to organs, includes non-disabling injuries); permanent significant (e.g., deafness, loss of limb, loss of eye, loss of one kidney or lung); or permanent major (e.g., paraplegia, blindness, loss of two limbs, brain damage), permanent grave (e.g., quadriplegia, severe brain damage, lifelong care, or fatal prognosis), and death.⁵

Near miss – An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect robustness of the patient (e.g., a patient with penicillin allergy receives penicillin, but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart). This definition is identical to that for close call.³⁵

Precursor event – safety event resulting in minimal harm, no detectable harm, or no harm.³⁶

Error – an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome.³⁷

Adverse event – unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death.³⁸ Main types of adverse events include adverse drug events, surgical or procedural events, healthcare-associated infections, and patient-care events (i.e., events associated with nursing care such as falls and pressure ulcers).³⁹

Unsafe conditions – circumstances that increase the probability of a patient safety event occurring.⁴⁰

Systems approach – Medicine has traditionally treated quality problems and errors as failings on the part of individual providers, perhaps reflecting inadequate knowledge or skill levels. The *systems approach*, by contrast, takes the view that most errors reflect predictable human failings in the context of poorly designed systems (e.g., expected lapses in human vigilance in the face of long work hours or predictable mistakes on the part of relatively inexperienced personnel faced with cognitively complex situations). Rather than focusing corrective efforts on reprimanding individuals or pursuing remedial education, the systems approach seeks to identify situations or factors likely to give rise to human error and implement systems changes that will reduce their occurrence or minimize their impact on patients. This view holds that efforts to catch human errors before they occur or block them from causing harm will ultimately be more fruitful than ones that seek to somehow create flawless providers.⁴¹

Just culture – Traditionally, health care's culture has held individuals accountable for all errors or mishaps that befall patients under their care. By contrast, a just culture recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes many individual or "active" errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts "no blame" as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).⁴²

High reliability organizations – High reliability organizations refer to organizations or systems that operate in hazardous conditions but have fewer than their fair share of adverse events.⁴³

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