2024 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2024-027	Patient Safety Structural Measure
Measure Steward & Developer	**Proposed CMS Programs**
Centers for Medicare & Medicaid Services (CMS)	Hospital Inpatient Quality Reporting Program; Hospital Value-Based Purchasing Program; Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

Measure Overview
Developer-provided rationale: Patient safety has been identified as a major priority by CMS. An attestation measure focused on patient safety activities aims to help hospitals better understand priorities for improving safety and serve as a prompt for action to reduce preventable harm to patients. When measure results are made public, patients and families will be able to make informed decisions on what facilities are best for them.
CMS-provided program rationale: The CMS National Quality Strategy is a person-centered approach to improving quality, and patient safety is a majority priority for CMS. This measure is aligned with the goals to promote safety and foster engagement among providers, individuals, and their families to promote informed and collaborative decision-making. As an attestation measure, it prompts hospitals to prioritize safety and preventable harm reduction for patients. With measure results, an informed public, patients, and families are then able to make informed decisions when choosing the facilities for their care.
Description: The Patient Safety Structural Measure is an attestation-based measure that assesses whether hospitals demonstrate having a structure and culture that prioritizes patient safety. The Patient Safety Structural Measure comprises five domains, each containing multiple statements that aim to capture the most salient structural and cultural elements of patient safety. This measure is designed to identify hospitals that practice a systems-based approach to safety, as demonstrated by: leaders who prioritize and champion safety; a diverse group of patients and families meaningfully engaged as partners in safety; and practices indicating a culture of safety and continuous learning and improvement.
Measure background: Measure currently used in a Medicare program, but the measure is undergoing substantive change

The analyses upon which this publication is based were performed under Contract Number 75FCMC23C0010, entitled, “National Consensus Development and Strategic Planning for Health Care Quality Measurement,” sponsored by the Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Measure Overview	
Numerator: The hospital outcome is defined by the five patient safety domains, each containing multiple statements. A hospital must positively attest to all statements within a domain to receive one point for that domain (for a total of 0 – 5 points for the outcome). The five domains defining the numerator are: Domain 1: Leadership Commitment to Eliminating Preventable Harm; Domain 2: Strategic Planning & Organizational Policy; Domain 3: Culture of Safety & Learning Health System; Domain 4: Accountability & Transparency; and Domain 5: Patient & Family Engagement. **Exclusions:** None	
Denominator: The denominator for each facility is five domains. **Exclusions:** None **Exceptions:** None	
Measure type: Structure	**Measure is a composite:** No **Measure is digital and/or an eCQM:** No **Measure is a paired or group measure:** No
Level of analysis: Facility	**Data source(s):** Digital-Other, Provider (facility) data entry (attestation-based measure)
Care setting(s): Hospital, Hospital Acute Care Facility	**Risk adjustment or stratification:** No
CBE endorsement status: Never submitted	**CBE endorsement history:** Never submitted
Is measure currently used in CMS programs? Yes, as per the Fiscal Year (FY) 25 Inpatient Prospective Payment System (IPPS) Final Rule, Hospital IQR will adopt the measure beginning with Calendar Year (CY) 2025 reporting period, and PCHQR will adopt the measure beginning with the FY 2027 program year.	**Measure addresses statutorily required area?** No

Meaningfulness

Importance	
Type of evidence:	Peer-Reviewed Systematic Review, Grey Literature [Source: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) Submission Form]

Importance: This measure is an attestation-based measure that assesses whether hospitals demonstrate having a structure and culture that prioritizes patient safety. The brief literature review provided in the submission materials supports the theoretical framework for this measure: that errors and accidents in medical care are generally not due to an individual's mistake but rather a reflection of system-level failures. This measure is aligned with the evidence on the benefit of a holistic, proactive, systems-based approach to patient safety. As patient safety is a key priority area and high concern from both a CMS and patient perspective, this measure has high importance for use in CMS programs.

As this measure is currently in use within CMS programs and proposed for further use, inclusion on the MUC List is a result of the substantive changes that are proposed. Proposed changes include the addition of two attestation statements to "Domain 2: Strategic Planning & Organizational Policy" to address drug shortages, an urgent patient safety issue. The additional statements are 2-F: "Our hospital purchases medications by utilizing contracting provisions that promote supply chain resiliency, including multi-year contracts with volume guarantees and stringent "failure to supply" clauses, either directly with vendors or indirectly through wholesalers or Group Purchasing Organizations." and 2-G: "Our hospital has policies and procedures to respond to medication shortages and outages, including ensuring continuity of pharmaceutical services to meet patient needs during emergencies for a minimum of 7 days."

The developer did not submit performance data for this structure measure.

Rating: Met

Conformance

Measure alignment with conceptual intent: As outlined in the Measure Information Form (MIF) and MERIT submission form, this measure's specification is appropriate and aligned with the measure target (attestation of structure and culture that prioritizes patient safety across five domains) within hospitals and acute care hospital facilities.

Rating: Met

Feasibility	
eCQM Feasibility testing conducted:	N/A, not an eCQM [Source: MERIT Submission Form]
Feasibility: The developer notes in the submission materials that attestation data are submitted to CMS provider digital data entry to a web interface. The structural measure data are hospital-level data not routinely collected in the electronic health record (EHR); a workflow analysis for collection of data was not determined and may potentially require changes to clinical workflows to capture. Overall, this measure has the potential for feasibility challenges, including added steps in clinician workflows and direct data entry for data collection. While these may increase likelihood of barriers or burden associated with implementation, they are addressable with implementation guides or best practice recommendations based on current use in programs.	
Rating: Met	

Validity	
Validity testing:	Face Validity [source(s): MERIT Submission Form, MIF]
Testing level(s):	Facility
Validity: Face validity of the measure was assessed through asking expert and patient/caregiver members of the technical expert panel (TEP) if the "Patient Safety Structural Measure will be useful in differentiating between hospitals that are highly committed to patient safety from those that are less so." Of the 18 TEP members asked, 15 reported in the affirmative, indicating that 83% of TEP expert, patient, and caregivers support the face validity of this measure. In general, data element validity testing is not required of structural measures.	
Threats to validity: This measure is not risk adjusted (risk adjustment is not common with structural measures) or recommended for stratification. The measure submission did not discuss potential for threats to measure validity from external confounders such as community- or facility-level challenges to the patient safety structural domains. These threats should be considered in the future through a logic model or other means.	
Rating: Met	

Reliability	
Reliability testing method(s):	None
Testing level:	None
Reliability discussion: No measure score-level reliability testing was conducted but the submission materials indicate a plan for testing with national data in the future. Data element-level reliability testing is not expected of structural measures.	
Additional reliability analyses: N/A	
Rating: Exempt	

Usability	
Usability considered in application:	None
Usability discussion: Based on materials submitted, there is an opportunity for improvement on this measure target in the clinical settings indicated, but more information on workflow changes and manual data collection or abstraction required for measure implementation would be helpful for further consideration of usability. In communication with the developer, additional context was provided for usability of this measure. Hospitals may attest the Patient Safety Structural Measure to CMS using existing electronic data submission portals with minimal administrative burden or workflow changes. Effort for collection of hospital data for attestation may vary among hospitals, dependent on factors including but not limited to the extent of hospital adherence to patient safety best practices and established documentation of these practices; facilities may have to do some workflow changes to support documentation for attestation. No unintended consequences are anticipated as a result of this measure, but hospitals that do not meet the required competencies in the five domains of this measure may choose to address the measurement area and move resources from other areas of focus.	
Rating: Met	

External Validity	
Was this measure tested in the same target population as the CMS program?	No
External validity discussion: Information provided by the developer indicates that the members of the technical expert panel spanned a broad range of expertise in patient safety, including: providers from hospitals and health care systems across the country, many in patient safety leadership positions; measure development experts in patient safety; and patients, caregivers, and patient advocates. The committee should consider if the TEP recommendation provides sufficient alignment between measure target population and proposed CMS program populations to support external validity.	
Rating: Met	

Appropriateness of Scale

Similar or related measures in program(s):	None
Measure appropriateness, equity, and value across target populations/measured entities: No similar or related measures were identified, suggesting that this measure would fill a gap within the current program measure sets. Regarding equity of this measure's performance and benefit across populations, the developer's literature review and analysis do not provide sufficient information to assess the potential for differential benefit or harm to specific subgroups of participating hospitals or their patient populations. The committee should consider if, based on their professional and patient experience, there is a chance for variation on distribution of benefit or burden across provider and patient populations.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	None
Measure implementation impacts over time: There is a need for further examination of near- and long-term impacts of this measure after implementation across provider and patient populations. Questions to consider: • What are the potential near- and long-term impacts of this measure on measured entities, the proposed programs, and patient populations? • Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame? • How will this measure mature through revisions in the future if added to program measure sets?	