

WHAT THE CMS PATIENT SAFETY STRUCTURAL MEASURES MEAN FOR PROVIDERS PARTICIPATING WITH PSOS IN 2025

December 20, 2024

In 2024, CMS unveiled a new quality measure to assess how well hospitals have executed strategies for systems-based improvement for patient safety and quality of care. These patient safety structural measures impact hospitals or other providers participating with Patient Safety Organizations (PSOs) and are set to take effect in 2025. This advisory summarizes the state of the proposals as of December 2024 and impacts for providers.

NEW ATTESTATION-BASED PATIENT SAFETY STRUCTURAL MEASURES

Earlier this year, CMS contracted with Yale New Haven Health Sciences Corporation – Center for Outcomes Research and Evaluation (CORE) to develop a hospital-based structural measure focused on patient safety. The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 4. This is an attestation-based measure that is aimed to assess whether hospitals have a structure and culture that prioritizes patient safety.

Five domains are included in the patient safety structural measure, each of which contains multiple statements that aim to capture a hospital's priority and systems-based approach to patient safety. Each domain is worth 1 point, for a potential total of 5 points if a hospital can attest "yes" to all five domains. Affirmative attestation to all statements within a domain will be required for the hospital to receive a point for the domain. The five domains include:

- 1. Leadership Commitment to Eliminating Preventable Harm
- 2. Strategic Planning & Organizational Policy
- 3. Culture of Safety & Learning Health System
- 4. Accountability & Transparency and
- 5. Patient & Family Engagement.

PROPOSED MEASURE: ACCOUNTABILITY AND TRANSPARENCY

Relevant for PSOs (and providers participating with PSOs), under Domain 4: Accountability and Transparency, the proposed measure would have required a hospital to attest that it reported serious safety events, near misses, and precursor events to a PSO listed by the Agency for Healthcare Research and Quality (AHRQ) that participated in voluntary reporting to AHRQ's Network of Patient Safety Databases (NPSD).

The challenge for many participants was twofold. First, it *required* reporting of serious safety events, near misses, and precursor events to a PSO. Secondly, it required participating with a PSO that reports to AHRQ Network of Patient Safety Databases, which most PSOs currently do not do. It would have been very difficult for many hospitals to attest "yes" to domain 4. CMS accepted comments from many stakeholders, which included those submitted by our team through industry partners.

FINAL RULE: ACCOUNTABILITY AND TRANSPARENCY

The Final Rule included revisions to proposed Domain 4 based on the feedback. The domain attestation was modified to require that a hospital:

Voluntarily participates with a PSO listed by [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.

The change demonstrates a focus on the beneficial activities through engagement with a PSO, without limiting the PSO requirement to those that report events and/or participate with a PSO that reports to the NPSD. The final rule offers much more flexibility, allowing providers that carry out "patient safety activities" to attest "yes" without a strict reporting requirement. Further, it allows providers more choice when choosing a PSO, not limiting options to those PSOs who report to the NPSD.

COMPARISON TO THE MEDICARE COP AND OTHER IMPACTS

This attestation is distinct from the Medicare Condition of Participation 24 CFR 482.21 that allows some flexibility for providers, permitting both PSO participation and other evidence-based measures for patient safety improvement. CMS has explained that Domain 4 Statement B is intended to encourage hospitals to work with a PSO, reasoning that most hospitals working with PSOs say this work has helped them better understand the causes of patient safety events and therefore prevent their recurrence. The attestation only requires a hospital to attest "yes" or "no." While the lack of PSO participation would be a point deduction for this domain, there is no financial penalty. The attestation also has no impact on Medicare reimbursement. Hospitals' scores on the Patient Safety Structural measures will be publicly available, as well as the average national and applicable state scores, anticipated to be available in 2026.

The attestation measure is set to take effect in 2025. Both the proposed and final versions of the Patient Safety Structural Measures are available online (MUC2024-027), with the comments available in the Federal Register (starting page 1319). If you have any questions about the impact for PSOs, providers participating with PSOs, or other compliance issues, please contact a member of our Patient Safety and PSOs or Compliance teams.

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