

Submitted via Electronic Submission

RE: Patient Safety Structural Measure – Number MUC 2023-188

The Alliance for Quality Improvement and Patient Safety (AQIPS) appreciates the opportunity to submit comments on a specific requirement under consideration under the proposed pre-rulemaking Patient Safety Structural Measure (Number MUC 2023-188). AQIPS is the professional association for Federally Listed Patient Safety Organizations (PSOs) and their healthcare provider members to foster healthcare providers ability to improve patient safety and the quality of patient care delivery using the processes and protections of the Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. 299b-21 et seq.; “The Patient Safety Act”). The Patient Safety Act made possible privileged and confidential collaborative efforts to improve patient safety and the quality of the delivery of patient care across the continuum of healthcare for the benefit of patients. The Patient Safety Act is a disclosure statute allowing healthcare providers to develop and share innovative safety strategies to improve the quality of patient care delivery. The Patient Safety Act incentivizes safety, quality and performance improvement as a shared responsibility among all healthcare providers throughout the healthcare continuum. As organizations that are committed to fostering safety culture, systems improvement, and high reliability in healthcare, AQIPS member PSOs and our hospital members have a significant interest in this proposed MUC.

AQIPS urges CMS to withdraw the Accountability and Transparency Domain subparagraph 2 that requires for a hospital to gain a point for this domain a hospital must attest, among other things, that:

Our hospital reports serious safety events, near misses and precursor events to a Patient Safety Organization (PSO) listed by the Agency for Healthcare Research and Quality (AHRQ) that participates in voluntary reporting to AHRQ’s Network of Patient Safety Databases.

This provision is inconsistent with the Patient Safety Act and CMS lacks legal authority to regulate PSOs. A plain reading of this proposed provision requires PSOs to report to the AHRQ Network of Patient Safety Databases (hereinafter “The National Patient Safety Database.) for hospitals to meet this measure. This proposed provision also requires hospitals to report to the NPSD, although indirectly. Such reporting under this measure is not “voluntary” by hospitals or PSOs and, therefore, is inconsistent with the Patient Safety Act. Recognizing that PSOs would be collecting a large amount of rich quality data that CMS, AHRQ, plaintiff lawyers and other entities would want to commandeer, Congress provided that PSOs cannot be compelled to disclose PSWP. 42 USC 299b-22(d)(4). This prohibition includes being indirectly compelled through a measure in a rulemaking.

As you know, PSOs are private, market-based programs accelerating patient safety to ensure the welfare of patients. The PSO program is a self-regulatory program to allow quality improvement beyond regulatory requirements. PSOs are not federally funded, are not subject to CMS jurisdiction and, as provided by the Patient Safety Act, cannot be directed by government agencies. Hospitals choose a PSO to work with based on the PSOs programs and performance in providing value to the hospital. (See Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70747 (Nov. 21, 2008)). Therefore, CMS cannot indirectly compel PSOs to “voluntarily” report to the NPSD.

The Patient Safety Structural Measure is an attestation-based measure that assesses whether hospitals demonstrate having a structure and culture that prioritizes patient safety. However, this proposal goes well beyond hospitals structure and culture and extends to compelling valuable data from private sector entities. AQIPS member PSOs gain rights to use of deidentified PSWP from their providers for patient safety activities, in the same manner as ‘23 and Me” gains rights to share genetic data with healthcare researchers, AI companies healthcare data and other private sector data collection companies. Like claims data and genetic data, PSOs can monetize patient safety and quality event data (that does not contain PHI) which is used for research through the research disclosure permission or for patient safety activities.

According to Agency for Healthcare Research and Quality, the work of federally listed PSOs and healthcare providers to reduce medical errors and increase patient safety in various clinical settings and specialties is highly valued, successful, and thriving. “Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety Act of 2005,” AHRQ, December 2021. The healthcare and PSO community have developed programs, including National Safe-Tables, to revolutionize patient safety practice and to connect the healthcare system.

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 pre-regulation proposed measure goes well beyond hospitals to improperly mandate requirements that impact private sector entities and should be withdrawn. Should you have any questions or require additional information, please contact me at Pbinzer@allianceforqualityimprovement.org.

Sincerely yours,

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