AQIPS ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY

Patient Safety Organizations and Healthcare Providers Advancing Patient Safety

MUC2024-027 – Patient Safety Structural Measure

To the Partnership for Quality Measurement's Pre-Rulemaking Review Committee and the Centers for Medicare & Medicaid Services:

The Alliance for Quality Improvement and Patient Safety (AQIPS) appreciates the opportunity to submit comments concerning the 2024 Patient Safety Structural Measure (MUC2024-027; MUC2023-188) during this pre-rulemaking measure review (PRMR) Measures Under Consideration (MUC) (See Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes, CMS-1808-P, RIN 0938-AV34.) AQIPS is the professional nonprofit association for over sixty (60) Federally Listed Patient Safety Organizations (PSOs) created pursuant to the Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. 299b-21 et. seq. or the Patient Safety Act) and their healthcare provider members. AQIPS' mission is to foster healthcare providers' ability to implement a culture of safety and high reliability to improve patient safety and the quality of patient care delivery using the privilege and confidentiality protections of the Patient Safety Act. The Patient Safety Act made possible privileged and confidential collaborative efforts among healthcare providers to improve patient safety and the quality of the delivery of patient care across the continuum of healthcare for the benefit of patients. As organizations that are committed to fostering safety culture, systems improvement and high reliability in healthcare, AQIPS member PSOs and our health system and hospital members have a significant interest in this PSSM.

AQIPS comments primarily focus on legal issues preventing many hospitals in many states from implementing some of the CMS Patient Safety Structural Measures (PSSM) that are incentivized by federal funding and measure scores. Because the measures cannot be implemented by all hospitals across the country without the risk of substantial liability in many states, the measures will result in a disparate impact for hospitals, healthcare providers and patients. In addition, the measures are not attainable by all hospitals and are not meaningful in improving patient safety or in informing patients about the quality of care of hospitals. Most of these legal issues were discovered after the final IPPS rule comment period closed on June 10, 2024, due to state case law issued after the comment period or evaluation of state and Federal law and case law upon implementation. Additionally, we expect that significant legal issues will materialize as legal challenges are brought under State and Federal law in states where the state and Federal privileges are uncertain. The extent that individual measures present substantial liability will unfold as the measures are implemented by hospitals, further measures are added and metrics within the measures are further defined by CMS and legal challenges are brought under state law and Federal law. Therefore, the full extent of the potential

liability surrounding the PSSM are unknown. For these reasons, the PSSM raises substantial legal and constitutional issues.

AQIPS proposes that the solution is for CMS to affirmatively and publicly support the Patient Safety Act protections, including withdrawing the HHS/CMS guidance that is inconsistent with the Federal Patient Safety Act. If the Federal Government is going to incentivize patient safety activities through federal funding and rating measures on Hospital Compare, the Federal government must actively and publicly support the Federal protections of the Federal Patient Safety Act that allow the hospitals in all 50 states, the District of Columbia and U.S. territories to implement those patient safety practices without facing substantial liability.

The Patient Safety Structural Measure is an attestation-based measure that is intended to assess whether hospitals have a structure and culture that prioritizes patient safety. AQIPS supports activities that incentivize health systems and hospitals to improve the quality of healthcare delivery, safety culture and high reliability. Importantly, many of AQIPS members have implemented many of the patient safety practices listed in the PSSM as well as other innovative quality improvement programs in states that honor the Federal Patient Safety Act protections. However, the measures must be feasible and attainable by all hospitals otherwise the measures do not provide meaningful information to consumers on hospital compare and raise legal concerns under the Affordable Care Act and the U.S. Constitution. For example, measures that are not attainable and meaningful because of state law are Domain 1(d) and (e). Domain 1 is the Leadership Commitment to Eliminating Preventable Harm domain. Subparagraph (d) is an affirmative attestation on reporting on patient and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event causal 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. Subsection (e) is an affirmative attestation that C-suite executive 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. 89 Fed. Reg. 36289 (May 2, 2024). Under recent case law, the NJ Supreme Court found that protected self-critical analysis of patient safety events can only occur in the Patient Safety Committee and not in committees with other purposes. The court opined that Patient Safety Committees cannot serve a dual purpose (e.g., patient safety and quality improvement committee or patient safety committee and government board) (See *Keyworth v. Care One,* No. A-17-23 (N.J. Aug. 5, 2024). *See also* N.J.S.A. 26:2H-12.25(h) ("[I]f obtained from any source or context other than those specified in [the state Patient Safety Act]," the law preserves the discoverability of material that "may have been considered in the process of self-critical analysis.") Therefore, hospital boards in New Jersey cannot review adverse events, safety data dashboards or conduct other self-critical analysis during their discussions of events under the PSSM Domain 1, sections (D) and (E) without the potential of the protected information and discussion being discoverable, board members deposed in lawsuits, or hospitals engaging in expensive lawsuits that they would not be subject to if they did not participate in the PSSM. Moreover, by affirmatively attesting that the measure is met the plaintiff's bar in New Jersey are alerted that the Hospital's Board members can be subject to deposition and other discovery for

information that is otherwise protected under state law and is not subject to discovery. This information can be used as evidence against the hospital and healthcare providers in any civil action. This means New Jersey hospitals are limited by state law from meeting CMS's Federal policy goal of board members analyzing patient safety events and collecting government funding and measure scores on hospital compare for that conduct. Apparently, the NJ legislature does not agree that hospital Boards should engage in self-critical analysis of patient harms and other patient safety activities and did not provide protections for these activities. New Jersey is not the only state that presents challenges to hospitals implementing the CMS PSSM. Many states have committee restrictions similar to New Jersey for peer review/QI protections where protections only apply in a peer or quality committee. This is compounded by the fact that defense attorneys in many states, including New Jersey, New York, and Ohio, do not believe that courts in their state will uphold the Federal Patient Safety Act protections and thus, there is a paucity of case law under the federal Patient Safety Act. Due to the lack of protections in these states, it is unlikely that senior governing boards will be able to discuss events and event investigation and causal analysis and other patient safety topics. Therefore, the measures are not feasible or attainable in these states.

The extent that individual measures present substantial liability will unfold as the measures are implemented by hospitals and legal challenges are brought under state law. For example, in a recent case in Tennessee (Castillo v. Rex, Tenn. October 2023), the court found that state peer protections did not protect the disclosure of Root Cause Analysis (self-critical analysis) information to patients because the Hospital shared particulars of the case that had been generated during a Quality Improvement Committee (QIC) meeting and the QIC information was shared with the family in a non-QIC context, which is outside the scope of the QIC privilege protection under Tennessee state law. This case raises the concern that in Tennessee as well as other states, including Massachusetts and Texas, hospitals may no longer enjoy strong protections for disclosing causation information to patients under state law. Further, there is a patchwork of state patient disclosure laws across the United States, some protect apology but none protect causation information. Many states have no protections for disclosure to patients concerning harm which may impact implementation of Domain 4(D), the patient disclosure and resolution measure because of the potential for liability.

PSSM activities that may also cause disparate impacts to hospital, providers and patients in states with weak patient safety state laws, such activities include, "escalation huddles", dashboards, and other patient safety activities regarding transparency contained in the PSSM. Therefore, as a practical matter, hospitals in states with weak patient safety protection laws may not be able to bear the risk to implement many of the practices that CMS has found to be valuable for patient safety.[1] Again, the extent of the risk of the information used against a hospital will be exposed as the measures are implemented by hospitals and challenged in subsequent discovery cases. On the other hand, hospitals in states with strong state patient safety protection and states that uphold

[1] AQIPS notes that there is a paucity of data on the value of many of the measures on providing a greater quality of patient care in hospitals. Other activities performed in hospitals may provide the same or equal benefit.

the Federal Patient Safety Act protections are in a safer legal environment to implement the CMS PSSM. Therefore, as a practical matter, the PSSM are not attainable, feasible, or meaningful in many states across the nation and therefore raise legal and constitutional issues.

As you know, the Federal Patient Safety Act was intended to provide national minimum peer protections across all 50 states so that high quality and reliability activities could occur in all healthcare facilities by all providers across all 50 states and territories for the benefit of patients nationwide. See Patient Safety Act Proposed Rule, 73 Fed. Reg. at 8113. This is consistent with the intention of the CMS PSSM to incentivize certain patient safety practices nationwide. Additionally, the Federal Patient Safety Act and rule are intended to enable health care providers to protect their internal deliberations and analysis of patient safety information because this type of information is patient safety work product. *Id*. Therefore, the Federal Patient Safety Act can be used to protect Board discussions of care quality and patient safety and other PSSM patient safety activities in the states that do not otherwise permit these activities. However, adoption of the CMS PSSM in states with weak patient safety protection laws can only occur if HHS and CMS affirmatively and publicly support the Federal Patient Safety Act protections, particularly for CMS PSSM activities. **It makes sense that if CMS is going to incentivize patient safety activities through federal funding and rating measures, the Federal government must support the Federal protections of the Federal Patient Safety Act to allow hospitals in all 50 states, the District of Columbia and U.S. territories to implement those patient safety practices without facing substantial liability.** If HHS does not embrace the Patient Safety Act protections for the PSSM, the PSSM must be withdrawn.

Compounding these concerns is the HHS 2016 Guidance and CMS sub-regulatory guidance that contain provisions that undermine the Federal Patient Safety Act protections for patient safety information contrary to the Federal Patient Safety Act. In 2016, HHS issued guidance on external obligations (HHS 2016 guidance) that contains several provisions that courts and the U.S. Department of Justice (U.S. DOJ) have found to be inconsistent with the Patient Safety Act and the AHRQ implementing regulations. (See HHS Guidance Regarding Patient Safety Work Product and Provider's External Obligations, 61 FR 32655 (May 4, 2016)). The HHS 2016 guidance states that information "could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO" (*Id*. at 32657). This guidance attempts to limit the type of information that can be protected under the Patient Safety Act. The DOJ, while representing HHS in a Patient Safety Act Declaratory Judgment Action, stated in its statement of interest of the United States that the 2016 Guidance is inconsistent with the Patient Safety Act and its implementing regulations.[2] DOJ reaffirmed that the PSQIA regulations expressly permit providers to maintain privileged patient safety work product within a Patient Safety Evaluation System for more than just reporting to a PSO. Moreover, stated in a statement of interest concerning the HHS 2016 guidance, …. "If the "exists separately" exception is read to cover information that "exists" in any part because of a state law requirement, it would defeat Congress's intent to preempt all state law

[2] A statement of interest states to the court the position of the U.S. Government.

requiring the production of documents that meet the definition of PSWP. The defeat of federal preemption would, in turn, defeat the main purpose of the Federal Act by gutting the incentive for health care providers to voluntarily report PSWP to PSOs and remediate preventable systemic medical errors." See Statement of Interest of the United States, at 11 *Lawrence Brawley v. Donald A. Smith, M.D., et.al., Case No. 17-CA-000119 (Fla. 13th Cir. Ct.)* (citing 73 Fed. Reg. at 70742) (Addendum "C"). See Statement of Interest of the United States, at 11 *Lawrence Brawley v. Donald A. Smith, M.D., et.al., Case No. 17-CA-000119 (Fla. 13th Cir. Ct.)* (citing 73 Fed. Reg. at 70742) (Addendum "C"). Moreover, in a recent 11th Circuit Court case, the court, citing *Kisor v. Wilkie*, 139 S. Ct 2400, 2411 (2019), opined that the HHS 2016 guidance is inconsistent with the Patient Safety Act. The court stated that "the only basis for the "sole purpose test" is a brief reference in the 2016 supplemental guidance, which by definition isn't law, and which moreover contradicts HHS's final rule that does have legal effect. The court found that under the plain text of the statute, it does not matter whether [the hospital] created, used, or maintained the disputed documents for multiple purposes. Contrary to the district court's order, nowhere does the statute require that privileged information be "kept solely for provision to a PSO." Even though these HHS/CMS guidance documents are not binding on PSOs or hospitals and are not enforced by CMS or HHS, plaintiffs' lawyers regularly cite to the HHS 2016 guidance document in challenges against hospitals, and several courts have given them deference. The guidance also attempts to limit the type of information that can be collected by a PSO, including analysis – such as root cause analysis - that is also used within a hospital. Importantly, AHRQ has relied upon the 2016 HHS guidance provisions that are inconsistent with the law in denying hospital PSO listing applications. (See Letter to Charles J. Chulack, Esquire, Re: Your December 16 Correspondence, from Andrea Timachenka, Esq. December 20, 2016, "[i]f peer review information is created for any other purpose other than, or in addition to, reporting to a PSO, that information would not meet the definition of PSWP"). It is inappropriate for HHS to interpret the protections in a manner that eradicates the Patient Safety Act privilege and confidentiality protections granted to Patient Safety Work Product by Congress under 42 U.S.C. 299b-21(7)(A)(ii).

Further, in a March 2023 CMS subregulatory guidance on the Patient Safety Act, CMS counsels that PSOs be limited to collecting information that is collected and developed by a provider for reporting to a PSO. Directors, Quality, Safety & Oversight Group (QSOG) and Survey Operations, "Patient Safety Work Products (PSWP), Survey Process, and Quality Assessment and Performance Improvement (QAPI) Survey Documents, September 29, 2023, at 2. This position, which is inconsistent with the Patient Safety Act, the implementing regulation and previous HHS guidance, would have stripped PSOs of the Patient Safety Act protections for its analysis and deliberations that are not reported to a provider. However, in Patient Safety Act litigation following the release of the CMS guidance, where the issue was squarely before the court, a Federal Court of Appeals found that the Patient Safety Act is not limited to the reporting pathway. *In re BayCare Medical Group* (11th Cir, 2024 WL. 2150114). "Nowhere does the statute require that privileged information be 'kept solely for provision to a Patient Safety Organization'. Instead, the Act privileges work product so long as it 'identif[ies] or constitutes[s] the deliberations or analysis of, or identif[ies] or constitute[s] the deliberations or analysis of, or identif[ies] the fact of reporting pursuant to 'a patient

safety evaluation system' …, regardless of whether it was reported to a Patient Safety Organization." *Id.* Additionally, the CMS subregulatory guidance states that "information that is used outside of the Patient Safety Evaluation System (PSES), for other purposes within the hospital, would not be considered PSWPs as they are used for other purposes and disclosed to other parties." CMS took this position even though the Patient Safety Act, the Patient Safety Act implementing regulations and Federal case law are clear and unambiguous that the PSQIA privilege and confidentiality protections cannot be waived upon disclosure by a PSO or hospital. 42 U.S.C. 299b-22(d); 42 C.F.R. 3.208(a); *Taylor v. Hy-Vee*, 2016 U.S. Dist. LEXIS 177764 (D. Kan., 12/22/16) (Once information is PSWP, what a provider ultimately does with data collected and reported to a PSO is not relevant. Such data is designated as PSWP by 42 U.S.C. 299b-21(7)(A), and there is nothing in the Patient Safety Act to suggest that data can lose that designation.); *Wantou v. Walmart Stores, Inc., No. 5:17CV18-RWS-CMS (*Under the Patient Safety Act, anyone to whom PSWP is disclosed, permissibly or impermissibly, becomes a "responsible person" required to keep PSWP confidential). The statute and regulations are not ambiguous on this point – the privilege and confidentiality protections of PSWP cannot be waived upon disclosure by a provider or PSO. In a recent state case, the Nevada Supreme Court ruled that the Patient Safety Act privilege is absolute. The court held that PSWP is privileged from discovery, and that the Patient Safety Act privilege cannot be waived even if the PSWP is impermissibly or permissibly disclosed unless a statutory exception from the privilege is applied (voluntary disclosure of nonidentifiable information or in a criminal proceeding). *Sunrise Hospital v. Grace, No. 85844, 140 Nev, Advance Opinion 12 (NV Sup. Ct. 3/7/2024).* Further, the AHRQ regulations permit the disclosure and use of identifiable PSWP among affiliated providers within hospital or health system. 42 C.F.R. § 3.20; affiliated providers.

Interpreting the Patient Safety Act to permit PSWP to lose its Patient Safety Act protections upon disclosure or use within the hospital is inconsistent with the Patient Safety Act and contravenes the purpose of the Patient Safety Act, that is, for providers to confidentiality share information to improve the quality of patient care. Clearly, HHS guidance documents have caused confusion in the courts and PSO community by being inconsistent among themselves and, as documented by several courts and the U.S. DOJ, contrary to the Patient Safety Act and Patient Safety Act case law. Given that the HHS guidance documents are inconsistent with the Patient Safety Act, the guidance documents should be withdrawn.

Importantly, hospitals share information with CMS surveyors to demonstrate they are in compliance with the CMS QAPI regulations. CMS surveyors have not had a problem with hospitals failing to share information, including protected Patient Safety Work Product, that demonstrates compliance with QAPI regulations. Hospitals make permitted disclosures to share PSWP with CMS surveyors, as appropriate. HHS has the authority to create a disclosure permission for CMS Surveyors through notice and comment rulemaking but has failed to do so (see 42 U.S.C. 299b-22(F)).

Without the Federal protections hospitals that implement the measures may face substantial liability or continued uncertainty under the current state and Federal peer review laws. This will prevent many hospitals in many states from implementing some of the CMS PSSM that are incentivized by federal funding and measure scores. In a 2019,

OIG study on the value of PSOs, OIG reported that 99.7 percent of the hospitals found that the privilege and confidentiality protections of the Patient Safety Act are important (99.7 percent cited this as important and 83 percent cited this as very important). Patient Safety Organizations: Hospital Participation, Value and Challenges – OEI-01-17-00420 at 21.) Importantly, even the over 50% of hospitals that found the privilege and confidentiality confusing found the protections to be important. (*Id*. at 25). This demonstrates that a nationally uniform privilege is essential to allow providers to participate in the PSSM.

Predictably, the HHS 2016 guidance has spurred a patchwork of state court opinions that has led to a breakdown of the use of the Patient Safety Act protections in several states. Without the broad privilege and confidentiality protections of the Patient Safety Act, many of the PSSMs will not be implemented due to the fear of discoverability in legal actions in states where the Federal Patient Safety Act privilege has been undermined. Because the measures cannot be implemented by all hospitals across the country without the risk of substantial liability in many states, the measures will result in a disparate impact for hospitals, healthcare providers and patients. In addition, the measures are not attainable by all hospitals and are not meaningful in improving patient safety or in informing patients about the quality of care of hospitals under the ACA. Unless HHS embraces the Federal Patient Safety Act protections the PSSM must be withdrawn.

Should you have any questions or require additional information, please contact me at pbinzer@allianceforqualityimprovement.org.

Sincerely yours,

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