DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-24-Hospital

DATE: September 29, 2023

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey Operations Group (SOG)

SUBJECT: Patient Safety Work Products (PSWP), Survey Process, and Quality Assessment and Performance Improvement (QAPI) Survey Documents

Memorandum Summary

- **Survey activities to assess for compliance with the regulations for QAPI programs require surveyors to review the facility's documentation to demonstrate the ongoing and sustainable actions taken to provide for patient safety and prevent adverse events.**
- **PSWP do not include the information to be disclosed to comply with CMS' Condition of Participation (CoP) or Condition for Coverage (CfC) requirements.**
- **Facilities may choose to identify certain documents as PSWP that cannot be disclosed and used in the assessment of compliance but are still required to provide alternate documentation to demonstrate compliance with the CoPs.**

Background:

On January 24, 2003, the Centers for Medicare and Medicaid Services (CMS) implemented the QAPI Program Condition of Participation requirements at 42 CFR 482.21. The regulations require hospitals to:

- Employ a systematic, hospital-wide approach to monitoring the quality and safety of all hospital programs and services;
- Identify, analyze, and prioritize opportunities for improvement;
- Identify and analyze medical errors, including both near misses and adverse events that have occurred;
- Develop and implement actions (both distinct time-limited projects as well as a variety of ongoing activities) designed to improve health outcomes and prevent and reduce medical errors; and
- Repeat the improvement cycle with respect to the actions that have been implemented.

In addition, under review of other CMS Conditions of Participation, CMS, and States that conduct work on CMS' behalf, must at times evaluate responses to adverse events to identify the extent to which a provider or supplier is meeting the expected health and safety standards to participate in Medicare and Medicaid. The evaluation of QAPI and the activities of surveyors in assessing compliance with the minimum standards may create additional questions about how a provider/supplier can meet the minimum ***mandated*** disclosure of information pursuant to the Medicare and Medicaid requirements and participate in a Patient Safety Organization. This memorandum seeks to address these issues.

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) was enacted July 29, 2005 (Public Law 109-41). This regulation allowed for the establishment of Patient Safety Organizations (designated organizations addressing patient safety) and outlined privileged and confidential status to materials voluntarily submitted by providers as a "patient safety work product." PSWP includes data, reports, records, memoranda, analysis, or written and oral statements assembled and developed for reporting to a Patient Safety Organization (PSO), and which have been submitted to a PSO that is approved and listed by the Department of Health and Human Services' (HHS') Agency for Healthcare Research and Quality (AHRQ). PSQIA also allows for the disclosure of PSWP under certain exceptions.

AHRQ published a final rule, titled *Patient Safety and Quality Improvement*, in the Federal Register on November 21, 2008 (73 FR 70732), which established "the requirements that entities must meet to become PSOs and the processes by which the Secretary will review and accept certifications and list PSOs," at 42 CFR Part 3. Further, the final rule clearly states that it "establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events" (73 FR 70732). The distinctions between what is, and what is not, protected information are noted in the final rule [emphasis added]:

> "The Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside but does not replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system. **Information is not patient safety work product if it is collected to comply with external obligations**, such as: state incident reporting requirements; adverse drug event information reporting to the Food and Drug Administration (FDA); certification or licensing records for compliance with health oversight agency requirements; reporting to the National Practitioner Data Bank of physician disciplinary actions; complying with required disclosures by particular providers or suppliers pursuant to Medicare's conditions of participation or conditions of coverage; or provision of access to records by Protection and Advocacy organizations as required by law" (73 FR 70742). Under one of the exceptions at 42 CFR 3.206(b)(8), providers may voluntarily disclose PSWP to their accrediting organizations, who in turn must keep the information confidential.

Since the QAPI CoP requires a hospital to "maintain and demonstrate evidence of its QAPI program for review by CMS" (42 CFR 482.21), such evidence may not be PSWP. This does not mean that hospitals must disclose PSWP to surveyors. Currently, there is no exception in the PSQIA, the Patient Safety and Quality Improvement Final Rule (73 FR 70796), or the Patient

Safety Organizations and Patient Safety Work Product requirements at 42 CFR Part 3 (https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-3) to permit disclosure to surveyors acting on behalf of CMS. Under one of the exceptions at 42 CFR 3.206(b)(8), providers may voluntarily disclose PSWP to their accrediting organizations, who in turn must keep the information confidential.

However, under the definition of PSWP at paragraph (2)(ii) of section 3.20, information assembled or developed by a provider for reporting to a PSO will no longer be considered PSWP if it is removed from a hospital's patient safety evaluation system (PSES), if it has not yet been reported to a PSO, and if its removal has been documented. There could be a situation, therefore, where a provider intends to report certain information to a PSO, subsequently decides not to report, and then removes that information from the PSES, thereby rendering it no longer PSWP. Such non-PSWP must be disclosed to surveyors since it no longer meets the definition of a PSWP. Moreover, by choosing to place evidence compliance with QAPI or other Conditions of Participation in its PSES, a hospital puts itself at risk of not being able to demonstrate its compliance with CMS' QAPI requirements.

Discussion:

On March 9, 2023, CMS released interpretive guidance for the hospital QAPI CoP in QSO-23-09-Hospital which provides the hospital community and surveyors the most current interpretation of the QAPI regulations.

The QAPI regulations require that the hospital's leadership (i.e., its governing body or organized group or individual who assumes full legal authority and responsibility for operations of the hospital, its medical staff, and administrative officials) establish expectations for safety throughout the hospital. Support for a culture of safety must flow from the governing body, medical staff, and administrative leadership of the hospital.

Hospitals must maintain and demonstrate evidence of their QAPI program, including the effectiveness of the program, to CMS upon survey. A hospital must be prepared to meet its obligation to provide surveyors access to QAPI program information as determined by federal and state surveyors without disclosing "patient safety work product," as that term is defined in 42 CFR Part 3, the regulations implementing the PSQIA. If there are concerns about the information requested by surveyors, please elevate that to the State and/or CMS.

When a hospital chooses to identify documents and materials as PSWP, surveyors should not demand disclosure of these documents or materials. However, hospitals will be expected to produce appropriate evidence of compliance that can be reviewed by the on-site surveyors. Hospitals that do not have a method of documentation to demonstrate compliance or that place information into a Patient Safety Organization may risk being cited for deficiencies and be subject to enforcement actions as a result. Examples of information that surveyors normally review and must be able to access include (but are not limited to): medical records; personnel records; training records; videos; staffing sheets; billing and discharge records; emergency department records and labs; interviews with staff and patients; unredacted QAPI program and governing body meeting minutes; grievance logs; and incident/accident logs. Further 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.

Following the release of this guidance, CMS will continue to engage with surveyors and external stakeholders to ensure that survey activities and QAPI assessments are performed thoroughly and consistently to protect all patients receiving care in hospitals. CMS would like to reinforce here that the evaluation of hospital QAPI materials serves as an integral part of the assessment of compliance.

Ultimately, it is the hospital's final decision as to whether to enter a relationship with a PSO and to create its PSES, including determining what information is placed within that system. In making such decisions, hospitals must consider how they will demonstrate compliance with the CoPs or other mandatory survey activities and findings of non-compliance. Upon request, the hospital should provide evidence to surveyors of its relationship with a PSO so that the survey team may verify that this relationship does exist. There is no prohibition under the PSQIA for hospitals to maintain duplicate systems, one consisting of patient safety work product within a protected patient safety evaluation system, and another to demonstrate compliance with local, State, or Federal requirements.

Contact:
For questions or concerns relating to this memorandum, please contact QSOG_Hospital@cms.hhs.gov .

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
Karen Tritz
Director, Survey Operations Group

/s/
David R. Wright
Director, Quality, Safety & Oversight Group