AQIPS | ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY

*PSOs and Healthcare Providers Advancing Patient Safety*

August 30, 2021

Transmitted Electronically: *www.reginfo.gov/public/do/ PRAMain*: "Currently under 30-day Review—Open for Public Comments"; Doris.Lefkowitz@AHRQ.hhs.gov

Agency for Healthcare Research and Quality
5600 Fishers Lane, Mailstop 06N100B
Rockville, Maryland 20857

RE: AHRQ Information Collection Activities; Proposed Collection; Comment Request, Notice 86 FR 41036 (July 30, 2021) Comment Period Extension; OMB Control Number: 0935-0143; ICR Reference Number: 202107-0935-005 (Comment period ends: September 30, 2021)

Dear AHRQ Clearance Officer:

The Alliance for Quality Improvement and Patient Safety (AQIPS)[1] appreciates the opportunity to comment on AHRQ's Information Collection Activities in relation to the AHRQ Common Formats, specifically the diagnostic safety format (CFER-DS Form). AQIPS supports efforts by AHRQ and the Patient Safety Organization (PSO) Community to improve Diagnostic Safety. Many PSOs have implemented innovative diagnostic safety programs as patient safety activities to assist clinicians improve the quality of patient care for the benefit of patients.

Patient Safety Organizations (PSOs) are a voluntary private sector self-improvement innovation program for all healthcare providers and all healthcare settings that were established under the Patient Safety and Quality Improvement Act (hereinafter The Patient Safety Act).[2] PSOs include for profit and nonprofit entities and as private sector organizations do not receive government funding for their activities. PSOs host a variety of data analysis and peer review programs to meet the quality improvement needs of their healthcare community. According to AHRQ in a recent draft report, PSOs are bringing robust quality improvement and peer review programs to specialties, settings

[1] AQIPS is the leading non-profit, national professional association composed of over 50 Patient Safety Organizations (PSOs) and their participating providers throughout the healthcare continuum and throughout the United States. AQIPS mission is to foster the ability of PSOs to improve the delivery of patient care through the privilege and confidentiality protections afforded in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, et seq.
[2] 42 USC 299b-21 et seq.

and modes of health care that traditionally faced high barriers to implementing such programs.[3] AHRQ's report that "[t]he 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."[4] In an evaluation of the effectiveness of PSOs, the vast majority of hospitals reported that PSOs are effective in improving safety culture and preventing medical errors.[5]

Under the Patient Safety Act, PSOs are required to engage patient safety activities, which include efforts to improve patient safety and the quality of healthcare delivery as well as to use patient safety work product to provide feedback and assistance to minimize patient risk.[6] Information collected (on a common format or other standardized format) by healthcare providers and reported to a PSO using the reporting pathway must be for the purpose of improving patient safety, quality of patient care or patient outcomes.[7] PSOs cannot collect identifiable Patient Safety Work Product for general research purposes except as provided under a specific disclosure permission under 42 C.F.R. § 3.206(b)(6). PSOs analyze reported information and develop feedback to disclose throughout the healthcare system to prevent harm from repeating in facilities across the nation. Congress designed the Patient Safety Act to break the silos that had been created due to the erosion of state peer review laws, and thereby create a national system of confidential sharing and learning with the goal of improving the quality and safety of patient care for the benefit of patients. PSOs can voluntarily report to the National Patient Safety Database (NPSD) at AHRQ as part of the learning system. In creating the NPSD, Congress envisioned a public-private partnership in improving patient safety and the quality of healthcare delivery between AHRQ and the PSO community.

The focus of AQIPS comments is the CFER-DS form and whether the collection of certain information is necessary for AHRQ's performance under the Patient Safety and Quality Improvement Act. However, we recognize that the CFER-DS Form is based on different burden and cost assumptions than the other common formats. For example, the AHRQ rulemaking assumes that the hospitals that report PSWP already have and are supporting the costs of a centralized patient safety event reporting system, which reduces the burden to submit information to the PSO and the PSO to the National Patient Safety Database (AHRQ). AHRQ estimates that 5% FTE of a patient safety manager at a facility will be spent to administer the Common Formats, which is approximately 100 hours a year. With respect to the CFER-DS Form, which is 15 pages long, the data collection is based on interviews and peer review by physicians and patient safety officers of information outside of the centralized patient safety event reporting system.

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[3] Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine, AHRQ (Feb. 2021) at 7.
[4] *Id.* at iii.
[5] OIG Report "Patient Safety Organization: Hospital Participation, Value, and Challenges" OEI-01-17-00420, Sept. 2019.
[6] 42 USC 299b-21(5) Patient Safety Activities.
[7] 42 USC 299b-21(7)(a)(i)(A).

**The proposed collection of some of the information in CFER-DS Form is unnecessary for AHRQ's proper performance under the Patient Safety and Quality Improvement Act, and the information will not have practical utility in conducting Patient Safety Activities.**

AHRQ's authority for developing the common formats for PSO reporting is found in 42 USC 299b-23, which provides in part, that AHRQ may determine common formats for reporting to the National Patient Safety Database of nonidentifiable patient safety work product. "The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities." The law is clear that the information reported to the National Patient Safety Database is nonidentifiable patient safety work product.

With respect to information reported from a provider to a PSO or from a PSO to the NPSD (AHRQ), the term patient safety work product means information that is collected or developed by a provider for reporting to a PSO and are reported to a PSO or are developed by a PSO for the conduct of patient safety activities and which could result in improved patient safety, healthcare quality or healthcare outcomes.[8] The term "nonidentifiable patient safety work product" means patient safety work product that is not identifiable patient safety work product.[9] The term "identifiable patient safety work product" means patient safety work product that—

(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 299b–22(e) of this title.[10]

Information about the reporter is also protected under the analysis pathway for creating Patient safety work product. In this regard, the term patient safety work product means information which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to a patient safety evaluation system.[11]

[8] 42 USC 299b-21(7)(a)(I).
[9] 42 USC 299b-21(2).
[10] 42 USC 299b-21(3).
[11] 42 USC 299b-21(7)(b)(ii).

## Some Information Requested in the CFER-DS Format is Not Patient Safety Work Product or is Not Necessary for PSO Patient Safety Activities.

Some of the information requested in the CFER-DS Form is not Patient Safety Work Product or is not relevant to the performance of patient safety activities and therefore is not permitted in a format for the collection of nonidentfiable patient safety work product for PSOs to conduct patient safety activities. Examples of information in CFER-DS that should not be collected under the Patient Safety Act include the following:

1. Information related to regulatory oversight is not Patient Safety Work Product. For example, question 1.3 asks when the final diagnosis was communicated to the patient. Many States require under State law that patients be notified of patient safety events, including diagnostic safety events, by their healthcare providers. Importantly, it is not within the PSOs legal authority to notify patients about diagnostic events to meet a hospitals state reporting requirement. The State laws require providers to report this information and require that the information remain confidential. Oversight activities are maintained by providers separately from activities related to reporting to the PSO and are not reported to the PSO. This type of regulatory oversight information is not part of a confidential learning system for the purposes of improving the quality of patient care. AQIPS and PSOs support the notification of patients about patient safety events and the compliance of all State laws. However, patient notification is an activity between a doctor and a patient, it is not a PSO activity and therefore should not be part of a common format for collection of nonidentifiable Patient Safety Work Product by PSOs.

2. Information about the patent and family that is collected directly from the patient and family is not patient safety work product. For example question 3.3 requests information concerning financial and time costs (e.g., resulted in additional health care co-pays, travel or childcare costs, time lost from work, school, usual activities); Other impact on patient's life, career, education, growth and/or development; Other impact on patient's family. AQIPS and our member PSOs support patient and family engagement. Indeed, AQIPS member PSOs include patient representatives in many analysis deliberations and some peer review activities under 42 USC 299b-21(7)(A)(ii). However, under the Patient Safety Act only information collected by healthcare providers is patient safety work product. Moreover, financial and economic information of any kind is not is not patient safety work product as it is not information that could improve the patient safety, healthcare quality or healthcare outcomes. PSOs do not conduct a cost benefit analysis on the events reported to them. PSOs are committed to minimizing patient risk. Information about economic and other impacts are more properly collected from claim and litigation information.

AQIPS members believe that patient engagement and informing the patient is vital and is a priority. AQIPS member PSOs include patient representatives in relevant activities. However, regulatory oversight and patient and family economic information is

not patient safety work product and therefore should not be collected on the common format. Information collected on the CFER-DS Form must be necessary for the PSO to complete its statutorily required functions and be confidential nonidentifiable patient safety work product. Importantly, confusion about the protections under the reporting pathway are a major problem that is a barrier to reporting by healthcare providers and PSOs. Because of the confusion concerning the protections under the reporting pathway identified by OIG in its report on the effectiveness of PSOs, the National Academy of Sciences (NAS) recommended that AHRQ communicate clear guidance about the legal protections afforded data submitted to PSOs and the NPSD, including privacy protecting procedures.[12] AQIPS agrees that the confusion about the confidentiality protections for information reported under the reporting pathway chills providers from conducting patient safety activities and reporting patient safety events to a PSO and chills PSOs from reporting to the NPSD. Collecting information in CFER-DS that is not patient safety work product will only exacerbate the present confusion and further chill reporting.

**Some of the Information Collected in the CFER-DS Form is Identifiable Patient Safety Work Product.**

The CFER-DS and information contained therein is identifiable patient safety work product and therefore the collection of this information may violate HIPAA and the Patient Safety Act. The Standard for nonidentification of Patient Safety Work Product can be found in 42 CFR § 3.212. Specific information collected in the CFER-DS Form - and when the information collected in the Form is read as a whole - could be used to reidentify the patient and the provider(s), which is contrary to the confidentiality protections of the Patient Safety Act. Specifically, the below information can be used to reidentify the patient and the provider(s).

1. Question number 4.5. Reporter information is specifically patient safety work product and cannot be disclosed. 42 USC 299b(7)(A)(ii).
2. Question number 1.2 the Date of final diagnosis can be used to identify the patient and the provider.
3. Sections 1 and 2. History of diagnosis – depending upon the circumstances and with the use of other information on the form may lead to identification or reidentification of patient and provider(s) information.
4. Question number 1.3 and section 3. Time period to report the incident to the patient and information from the patient/family can be used to reidentify the patient and provider particularly along with the date of the final diagnosis.
5. Question 4.0. AQIPS member PSOs are working to collect information that can promote health equity, including a patient's age, gender and race. However,

[12] National Academies of Sciences, Engineering, and Medicine 2021. *Peer Review of a Report on Strategies to Improve Patient Safety*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26136. The NAS committee referred to the OIG report that states: The PSQIA provides legal protection for health care organizations reporting PSWPs, but previous challenges found certain information was not protected (OIG, 2019).

combined with other information on the format this information can be used to identify the patient and provider(s).

6. Question number 3.3. Information collected directly from patient and family can be used to reidentify the patient and provider(s).

Reporting of common format information will be chilled if PSOs must worry whether a common format can be used to reidentify a patient or provider. Indeed, PSOs may be liable to their healthcare providers under their Patient Safety Act contracts if the PSO reports made to the NPSD are reidentified as to the patient or provider.

Thank you for the opportunity to submit comments on the CFER-DS form. Should you have any questions or require additional information, please contact me at pbinzer@allianceforqualityimprovement.org.

Sincerely yours,

Margaret ("Peggy") Binzer
Executive Director