DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare
Research and Quality

5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

SENT VIA ELECTRONIC MAIL

Margaret "Peggy" Binzer
Executive Director
Alliance for Quality Improvement and Patient Safety

September 15, 2021

Dear Ms. Binzer:

We thank you for taking the time to comment on the proposed information collection project "*Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Forms, and Common Formats*." We appreciate your support for efforts to improve diagnostic safety and your specific interest in the Common Formats for Diagnostic Safety (CFER-DS).

We have carefully reviewed your comments and find the basis for some to be unclear. We offer the following clarifications to address those that may be related to misunderstandings about the Common Formats generally and/or the CFER-DS version 0.1 Form. It should be noted that the CFER-DS has not been finalized for implementation (this will occur with version 1.0) and that changes may be made to the draft in version 1.0.

Your submission states that "the CFER-DS Form is based on different burden and cost assumptions than the other common formats." This is incorrect. For all Common Formats, "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."[1] We would also note that the CFER-DS can be implemented without using the CFER-DS Form.

Your comments suggest that the CFER-DS would differ from existing Common Formats by involving different data collection systems than the existing Common Formats. There is nothing in the CFER-DS to suggest that information must be collected in a specific way. For all Common Formats, users decide if and how to integrate the collection of specific data elements into their incident reporting systems and other existing work processes.

Your comments indicate a belief that all information collected in the Common Formats is, or must be, patient safety work product. This is not correct. Any provider may use the Common Formats, and providers are not required to work with a Patient Safety Organization (PSO) or collect the information as patient safety work product.[2] Those that choose to work

[1] 86 Fed. Reg. 41038 (Jul. 30, 2021).
[2] *See* https://www.pso.ahrq.gov/common-formats. "Any provider may use the AHRQ Common Formats, but Federal confidentiality and privilege protections are only available to providers and listed PSOs working together under the Patient Safety and Quality Improvement Act of 2005."

with a PSO may, but are not required to, use one of the Common Formats to collect the patient safety work product they report to the PSO.[3] In order for information assembled or developed by a provider – in any format – to be patient safety work product, it must meet the requirements[4] of the definition of patient safety work product in the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and its implementing regulation (Patient Safety Rule). Information would not meet the definition of patient safety work product solely on the basis that the provider gathered the information according to an AHRQ Common Format.

You asserted that "information collected on the CFER-DS Form must be necessary for the PSO to complete its statutorily required functions." While there is no such requirement in the Patient Safety Act, we anticipate that PSOs and the providers they work with will choose to use the CFER-DS for the purpose of conducting patient safety activities. The underlying premise for your assertion appears to be your opinion that some of the data elements in the CFER-DS are "not relevant" or "will not have practical utility" for conducting patient safety activities. You also appear to dismiss the importance of a patient-centered perspective when reporting patient harm data for patient safety improvement purposes. As the data elements in the CFER-DS were chosen with input from leading national experts in diagnostic safety improvement, tested by providers with an interest in this aspect of patient safety, and will be refined with input from the Expert Panel and members of the public, we expect that all of the data elements in the initial and subsequent versions of the CFER-DS will be both relevant and useful for local, regional, and national learning about improving diagnostic safety.

Your comments included various statements regarding information collected from a patient or patient's family that seem not to recognize that the patient (and/or the patient's family, where relevant) is the source of much of the information in patient medical records and other provider records. As mentioned above, there is nothing in the CFER-DS to suggest that information must be collected in a specific way. Furthermore, consistent with the statutory purpose for the Common Formats and AHRQ's authority, AHRQ neither prescribes nor limits the extent of patient/family participation in a provider's data collection for any Common Formats.

You incorrectly suggested that Question 1.3 asks whether the provider notified the patient of a diagnostic safety event, and characterized this item as asking for information related to regulatory oversight. Question 1.3 in fact refers to whether a diagnosis was communicated to the patient. It is completely unrelated to information that may be needed for regulatory oversight.

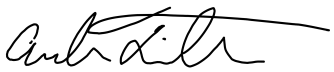
It would require technical assistance beyond the scope of this letter to address the apparent misunderstandings underlying your unfounded assertions that collecting some of the information in the CFER-DS (and, presumably, other Common Formats) "may violate HIPAA and the Patient Safety Act," and your suggestions that PSOs should "worry" about "reidentification" and potential liability. We want to assure PSOs, providers, patients, and other stakeholders that there are legal, procedural, and technical supports and safeguards

[3] 42 C.F.R. 3.102(b)(2)(i)(F), (b)(2)(ii), and (b)(2)(iii).
[4] *See* 42 USC 299b-21(7); 42 C.F.R. §3.20.

underlying the Network of Patient Safety Databases (NPSD) and use of the Common Formats. If a PSO and provider have established a reporting relationship that meets the requirements of the Patient Safety Rule and the HIPAA Privacy and Security Rules, there is no prohibition in the Patient Safety Act of a provider using the Common Formats – or any other format – to collect information for reporting to a PSO that may identify a patient, provider, and/or reporter. Information contributed by PSOs to the NPSD must first meet the non-identification standard in the Patient Safety Rule[5]. AHRQ has established the PSO Privacy Protection Center to ensure that "data are non-identifiable before transmittal to the NPSD for aggregation and analysis."[6] As you are aware, there are a number of methods used to achieve this. As AHRQ readies the CFER-DS for implementation, we will take steps to similarly ensure that any information submitted for inclusion in the NPSD meets the requirements of the Patient Safety Rule's non-identification standard.

We hope the above information has been helpful. Particularly as AQIPS is a membership organization of PSOs and related organizations, AHRQ appreciates this opportunity to ensure that all stakeholders have a clear and accurate understanding of the Common Formats and related requirements. As always, any PSO that has questions or would like to arrange for technical assistance with the AHRQ PSO team is welcome to contact us.

Thank you,



Andrea Timashenka, JD
Director, Patient Safety Organization Division
Center for Quality Improvement and Patient Safety

[5] 42 C.F.R. §3.212.
[6] *See* https://www.ahrq.gov/npsd/how-does-npsd-work/index.html.