To: IHA Members

From: Laura Brown, Deputy General Counsel

Date: April 18, 2023

Re: QAPI QSO and IDOH Survey Reminders

On March 9, 2023, the Centers for Medicare and Medicaid Services ("CMS") issued Quality Safety & Oversight ("QSO") Memorandum 23-09 on revisions to the State Operations Manual, Hospital Appendix A, regarding the interpretive guidelines for 42 CFR 482.21 on Quality Assessment & Performance Improvement ("QAPI") programs (hereinafter referred to as the "QAPI QSO").

This memorandum outlines highlights from the QAPI QSO and also provides reminders regarding the Indiana Department of Health's ("IDOH") survey process. Please note, this memorandum is provided as guidance only and does not constitute legal advice. IHA members are encouraged to review the entirety of the QAPI QSO with legal counsel.

I. QAPI QSO and Updated Interpretive Guidelines

The QAPI QSO makes several updates to Hospital Appendix A regarding the interpretive guidelines for 42 CFR 482.21 on QAPI programs. The QAPI QSO does not prescribe a particular QAPI program that all hospitals must use but notably outlines the following requirements for QAPI programs:

A) Evidence of Data Collection: The QAPI QSO underscores the need for a QAPI program to continuously collect data for all locations, services, and departments of a hospital, whether on or off-campus, that are covered under the hospital's Medicare provider agreement. While it is not expected that all departments and services be continuously engaged in large scale QAPI projects, all departments and services, including those provided under arrangement or contract, should provide evidence that there is continuous monitoring of the quality and safety of the services provided.

- Notably, the QAPI QSO also updates 42 CFR 482.21(b)(1) to require that the quality indicator data include "data related to hospital readmissions and hospital-acquired conditions."

B) Data Analysis: The QAPI QSO notes that such data collection should drive a QAPI program's decisions. In other words, a hospital should demonstrate that the quality indicators it has selected, along with the associated data, are used to monitor quality and safety, identify opportunities for quality improvement, and produce measurable improvement to the specific quality indicators (i.e., quantifiable data). The quality indicators selected should also reflect the hospital's specific patient population.

C) Implementation of Changes: The QAPI QSO states that surveyors should evaluate a hospital's success in its efforts to improve performance and quality and whether such improvements are sustained over time. As provided in the QAPI QSO, the focus of the QAPI assessment is "to determine whether a hospital has an effective, ongoing system in place for identifying problematic events, policies, or practices, and is taking actions to remedy them and then following up on these remedial actions to determine if they were

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effective in improving performance and quality." Linking the Agency for Healthcare Research and Quality's Culture of Patient Safety survey with a QAPI program, through which system change is implemented, may lend aid to such a requirement.

- The QAPI QSO notes that in establishing areas to improve performance, a hospital's prioritization process should take into account high-risk, high volume, and problem-prone areas. In deciding these areas, surveyors will look at the data to determine incidence, prevalence, and severity in supporting a QAPI program's choices.
- The QAPI QSO also notes that differentiation should be made between performance improvement activities and performance improvement projects – the former being continuous, ongoing functions, and the latter having a beginning and end date with up-front planning. Hospitals should maintain records of each performance improvement project completed within the previous six years, as well as a list of projects currently underway.

D) Governing Body Involvement: The QAPI QSO is specific that the governing body is responsible for specifying the frequency and detail of the data collection, which may include, but is not limited to, what data will be collected, what the data is intended to measure, in what areas of the hospital the data will be collected, and how frequently the various types of data will be collected. While the governing body need not have technical expertise in data collection, there must be evidence that the governing body has had an active role in the development and ongoing planning of the frequency and detail of the QAPI program's data collection. Such evidence may be documentation in the governing body's meeting minutes that it has reviewed and approved the frequency and detail of the QAPI program's data collection. The QAPI QSO specifically indicates that the meeting minutes may be requested to verify this requirement and hospital leadership / the governing body may be asked how the QAPI data has identified opportunities for improvement. Stoplight reporting and the inclusion of QAPI dashboards in the governing body's meeting minutes indicating presentation, review, discussion, and approval may lend aid to such a requirement. **IHA encourages each governing body to review this requirement and convene to ensure compliance.**

- The governing body should also be able to explain how the selection (i.e., number and scope) of the specific quality improvement projects is in alignment with the hospital's complexity and the scope of services it provides.
- AHA resources on quality discussions with governing bodies can be found here and here.

E) Surveys: If a surveyor identifies non-compliance, the QAPI QSO indicates that a surveyor may evaluate the QAPI program as a part of the non-compliance investigation. For example, if medication errors are determined to be very serious or widespread, the QAPI QSO directs surveyors to investigate the effectiveness of the QAPI program in handling medication errors. If there is evidence that the hospital is taking effective actions through its QAPI program to correct such deficiencies, then a citation of QAPI Condition of Participation ("CoP") deficiencies generally would not be appropriate, despite the individual lapses a surveyor might have observed. The QAPI QSO also notes that surveyors should avoid using the hospital's own QAPI program data and analyses as evidence of violations of other CoPs unless there is evidence of current non-compliance

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with the regulatory requirements – using the QAPI program as the basis for a deficiency citation of another CoP would be the exception, not the rule.

- Importantly, the QAPI QSO states that surveyors *may* review additional records to determine compliance with statutory and regulatory requirements, such as medical error reports and peer review information. **IHA has discussed this provision with IDOH due to the conflict of providing peer review information with Indiana Code § 34-30-15 *et al*., which specifies that peer review information is confidential. IDOH has confirmed that if any other documentation besides peer review information can be provided during such a review (i.e., to demonstrate that a hospital followed its policy and addressed an issue), then such alternative documentation will be acceptable.**

II. IDOH Survey Reminders

With the release of the QAPI QSO, IHA also wanted to provide a reminder on several items related to IDOH surveys. **Importantly, if there are any questions during an active survey, please do not hesitate to contact a member of the IHA team, specifically Andy VanZee, Karin Kennedy, Annette Handy, and/or Laura Brown, and IHA's team will be happy to engage IDOH to come to a resolution.**

A) IDOH Surveys: IDOH surveys hospitals for the following purposes: 1) Initial surveys, 2) recertification surveys, 3) validation surveys, and 4) complaint surveys. "Spot surveys" to determine compliance without a complaint are not conducted by the agency. However, please note, the complaint cannot be shared in the course of a complaint survey. During a survey, an entrance conference will be conducted first, followed by a review of records, interviews, and observations. An exit conference will conclude the survey.

B) HIPAA Compliance: As a reminder, the Health Insurance Portability and Accountability Act (hereafter referred to as the "HIPAA Privacy Rule") provides that protected health information ("PHI") allows Health Oversight Agencies to use PHI without the authorization of the subject of that information for health oversight activities that are authorized by law. Examples of health oversight activities include survey, inspection, complaint investigation, and other activities for which health information is necessary to determine compliance with program standards for entities subject to government regulations (*See* 45 CFR 164.512(d)). IDOH can provide the enclosed letter upon request should there be any concerns with compliance with the HIPAA Privacy Rule during an IDOH survey.

C) Patient Records: To enable a survey, patient records will be requested, but an extensive patient file can be broken out into pieces to facilitate a specific survey inquiry (i.e., the entirety of a 100-page patient record may not be necessary to facilitate the specific survey inquiry). Records may also be copied per 42 CFR 489.53(a)(13), which states, "CMS may terminate the agreement with any provider if CMS finds…[t]he provider or supplier refuses to permit copying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements."

IHA's team will continue to map the survey process with IDOH and plans to share additional resources in the coming weeks. If you have any questions regarding the QAPI QSO or IDOH's survey process, please do not hesitate to contact a member of IHA's team at any time.

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