



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Federal Update and Discussion: Section 1311(h) of the Affordable Care Act – Patient Safety Standards

Questions and Answers

Moderator:

Candace Jackson, RN

Program Lead, Hospital Inpatient Quality Reporting (IQR) Program
Hospital Inpatient Value, Incentives, and Quality Reporting (VIQR)
Outreach and Education Support Contractor (SC)

Speaker:

Nidhi Singh Shah, MPH

Health Insurance Specialist, Policy Lead for Marketplace Quality Initiatives,
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services (CMS)

May 3, 2016

2 p.m. ET

Question 1: Question regarding 81FR12203:pg12315 – does this apply to any size hospital or only hospitals 50 beds or larger?

This requirement applies to hospitals that have greater than 50 beds and that are contracting with Qualified Health Plans (QHPs) offered in the Marketplace.

Question 2: Where are the federally approved PSOs listed?

The Agency for Healthcare Quality and Research (AHRQ) website (<https://pso.ahrq.gov/>) lists the federally approved Patient Safety Organizations (PSOs).



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Question 3: **In Pennsylvania, Does the patient safety authority meet the patient safety requirements?**

As mentioned in the presentation, upon establishing these regulations we wanted to provide enough flexibility to stakeholders; therefore, CMS did not detail or provide an all-inclusive list of examples of what would meet the requirements. However, we did mention some examples, including robust state-based patient safety programs. Basically, if the hospitals do not contract with PSOs, it is up to the hospitals and issuers to ensure that they comply with QHP patient safety requirements. Hospitals would be responsible for making sure that state requirements for the state level patient safety authority involve hospitals that implement an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination. It is up to the hospital and QHP issuer to comply. CMS is not providing a list of every example that would meet these requirements.

Question 4: **If a hospital is located in a state where there is mandated incident reporting and confidentiality protections through state law, does this meet the requirements?**

Please see the response to question three. It would be up to the hospital and issuer to make sure that, if they do not contract with PSOs, they implement an evidence-based initiative to improve healthcare quality through the collection, management and analysis of patient safety events to either reduce all cause preventable harm or prevent hospital readmission or improve care coordination. If hospitals can demonstrate that they are involved with such a patient safety program or initiative, then they would comply.



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Question 5: HENs and QIOs are subject to yearly contract renewals, so if the HEN [that] the hospital is working with ends the approved contract, is compliance lost mid-year? What is the penalty for a hospital using a HEN or QIO that loses its contract approval per CMS in the middle of the year?

At this time, CMS can confirm that we intend to award Hospital Improvement Innovation Network (HIIN) awards before the end of FY2016, in concert with the natural end of the HEN 2.0 period of performance. If a hospital stops working at any point with a Hospital Engagement Network (HEN), Quality Innovation Network-Quality Improvement Organization (QIN-QIO), HIIN, etc. or modifies its patient safety program, there is no penalty; however, it is the responsibility of the hospital and QHP issuer to maintain ongoing compliance with the QHP patient safety requirements. In addition, although, for example an agreement with a HEN or QIO or PSO may end, we expect that patient safety initiative(s) would continue. In these cases, a hospital may have to provide different documentation to a QHP issuer to update information and maintain ongoing compliance with QHP patient safety requirements.

Question 6: Do State-based Marketplaces need to collect any documentation from QHP issuers?

There is no requirement that State-based Marketplaces (SBMs) collect information. However, we have provided flexibility in the law to state that, if a SBM chooses to request documentation from their QHP issuers regarding compliance with the standard, they may. So, in effect, it is up to the SBM.

Question 7: Can you elaborate more on who qualifies as a QIO?

The current QIN-QIO awardees are publically available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press->



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

[releases/2014-Press-releases-items/2014-07-18.html](https://www.cms.gov/releases/2014-Press-releases-items/2014-07-18.html). For additional information on the purpose and activities of the QIO program, please visit <http://www.qioprogram.org/>.

Question 8: So, if we submit data to q-net and Joint Commission we would meet this requirement, correct?

Again, the answer is yes, if the hospital demonstrates that those programs and initiatives improve health care quality through the collection, management and analysis of patient safety events that reduce all cause preventable harm, prevent hospital readmission, or improve care coordination. This applies whether it is by means of The Joint Commission's accreditation process or another method.

Question 9: I am confused about the statement made that contracts with a PSO are not subject to the protections and requirements in the PSO statute - can you clarify?

The documentation stating that a hospital is contracting with a PSO is not considered patient safety work product; therefore, that documentation is not subject to the confidentiality protections in the Patient Safety Act. We received several comments to our proposed regulation regarding hospital concerns about patient safety data confidentiality upon providing that PSO contract to a QHP issuer. We just wanted to clarify that the PSO contracts are not subject to those privileges and confidentiality protections.

Question 10: What are the implications for the CMS "Everyone with Diabetes Counts" and Immunizations programs?

The implication to these quality improvement activities is that they may offer one example to meet the QHP patient safety requirements. The point is that hospitals demonstrate that a patient safety initiative implemented through quality improvement is one that improves health care quality



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination.

Question 11: **For the 81 FR 12203 page 12316 - I just want to confirm that if a hospital is accredited by Joint Commission that would meet the CMS requirements?**

If a hospital can demonstrate that The Joint Commission accreditation involves an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination, then yes, the hospital and QHP issuer would meet these CMS requirements.

Question 12: **If we have a contract with the Partnership for Patients and they serve as our HEN, does that meet the requirement?**

Yes, if a hospital can demonstrate that their Partnership for Patients' HEN involves an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination, then yes, the hospital and QHP issuer would meet these CMS requirements.

Question 13: **So, if asked, we could present attestation of participation for last four years in the AHA HEN? If we aren't participating in PSO will we then be asked to present evidence of the safety initiative work we are involved in and reporting?**

Yes, a hospital attestation of working with a HEN is an example of documentation to demonstrate that the QHP contracted hospital implements an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination.



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Question 14: Do all CMS contracted HENs qualify to serve as a PSO?

CMS contracted HENs would not serve as a PSO. HENs and PSOs are distinct initiatives. The following website provides information about PSOs: <https://pso.ahrq.gov/>. And this website provides information about HENs: <https://partnershipforpatients.cms.gov/about-the-partnership/hospital-engagement-networks/thehospitalengagementnetworks.html>

Question 15: Will there be any requirements to report data collected by the HEN to CMS?

The data collection requirements related to patient safety efforts under the Partnership for Patients program are detailed extensively in the HEN 2.0 Statement of Work for current HENs in the field. Additionally, data collection requirements will be outlined in the upcoming HIIN Statement of Work, which shall be released as part of a formal Request for Proposals. Consistent with our previous policies and practices, the data collected under the Partnership for Patients program shall not be used for any regulatory compliance efforts; this data is intended to provide real-time information for quality improvement and patient harm reduction nationwide.

Question 16: Can you explain bullet one on slide 15: that is "PSO contracts do not meet the definition of "patient safety product"....?"

"PSO contracts do not meet the definition of patient safety work product" is intended to clarify that the actual agreement that states that a hospital is contracting with a PSO is not considered patient safety work product, as defined in The Patient Safety and Quality Improvement Act of 2005 (PSQIA). Therefore, a PSO contract is not subject to the protections and requirements in the statute.

Question 17: Is there a Q&A database being developed or a checklist to meet Affordable Care Act Patient Safety Standards?

No, there is no database or checklist being developed to meet patient safety standards in the Affordable Care Act.



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Question 18: **Is this applicable to all hospitals? How do I know if we are eligible and required to participate?**

The QHP patient safety standards apply to any hospital that has greater than 50 beds and that is contracting with a QHP offered in a Marketplace.

Question 19: **Does this apply to Critical Access Hospitals (CAHs)?**

No. Given that CAHs do not have greater than 50 beds, this regulation does not apply to CAHs.

Question 20: **Can you restate what is a "Qualified Health Plan"?**

A Qualified Health Plan, under the Affordable Care Act, is an insurance plan that is certified by the Health Insurance Marketplace, provides essential health benefits, follows established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts), and meets other requirements. A qualified health plan will have a certification by each Marketplace in which it is sold.

Question 21: **Is QIO the same as a PSO?**

No. A QIO is not the same as a PSO. QIOs and PSOs are distinct initiatives. The following website provides information about PSOs:

<https://pso.ahrq.gov/>. And, this website provides information about QIOs: <http://www.qioprogam.org/>.

Question 22: **Did I understand that Joint Commission accreditation qualifies as a contract for a patient safety initiative?**

If a hospital can demonstrate that The Joint Commission accreditation involves an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination, then yes, the hospital and QHP issuer would meet these CMS requirements.



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Question 23: If you are licensed for more than 50 beds, but your average daily census is less than 50 beds, do you fall under the rule?

Given that a hospital with a license for more than 50 beds may, at any point in time, be using more than 50 beds; then, yes, such a hospital, if contracting with a QHP offered in a Marketplace, must comply with these patient safety requirements.

Question 24: Can this form be used for staff education?

If “this form” refers to this transcript and webinar, then yes; these materials are intended for education and clarification purposes regarding QHP patient safety requirements.

Question 25: Does this only affect facilities that are 50+ beds?

Yes, these QHP patient safety standards apply to any hospital that has greater than 50 beds that is contracting with a QHP offered in a Marketplace.

Question 26: Can you please clarify again that, if a hospital undertakes patient safety and quality efforts pursuant to a state law, regulation, or policy, could this be counted toward meeting this requirement?

If a hospital participates with patient safety and quality efforts pursuant to a state law, regulation or policy and can demonstrate that this activity involves an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination, then yes, the hospital and QHP issuer would meet these CMS requirements.



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

Question 27: So, does participation with a HEN meet the requirements?

If a hospital participates with a HEN that involves an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination, then yes, the hospital and QHP issuer would meet these CMS requirements

Question 28: If a state requires reporting of all patient safety events, is this considered an exemption where the hospital is not required to contract with a PSO?

If a hospital must comply with state requirements to report all patient safety events and can demonstrate that this activity involves an evidence-based initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination, then yes, the hospital would meet the reasonable exception requirements and not need to contract with a PSO.