



# Hospital Inpatient Quality Reporting (IQR) Program

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

#### Presentation Transcript

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**May 3, 2016**

**2 p.m. ET**

**Candace Jackson:** Hello everyone. Welcome to our webinar. My name is Candace Jackson, and I will be your host for today's event. Before we begin, I would like to make a few announcements. This program is being recorded. A transcript of the presentation, along with the Q&As, will be posted to the Inpatient website, [www.qualityreportingcenter.com](http://www.qualityreportingcenter.com), within 10 business days. And, it will also be posted to *QualityNet* at a later date. If you registered for the event, a reminder email, as well as the slides, were made available to you about two hours ago. If you did not receive the email, you can download the slides at our Inpatient website, again, which is [www.qualityreportingcenter.com](http://www.qualityreportingcenter.com). And now, I'd like to introduce our guest speaker for today, Nidhi Singh-Shah. Nidhi joined the Center for Medicare & Medicaid Services in 2012 to work on the health insurance marketplace quality activities within the Center for Consumer Information and Insurance Oversight and now's in the Center for Clinical Standards and Quality. In her current role, she provides policy guidance and analysis

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to the leadership at CMS and the Department of Health in Human Services on priority initiatives, including areas of healthcare quality management, patient safety, quality rating system, and consumer experience surveys. At the end of today's presentation, there will be a Q&A session. Any questions that are not answered during the question and answer session at the end of this webinar will be posted to the Quality Reporting Center website within 10 business days. And now Nidhi, we'll begin our webinar. Nidhi, the floor is yours.

**Nidhi Singh Shah:** Thank you Candace, and thank you all for joining today's webinar. As Candace mentioned, my name is Nidhi Singh-Shah, and I work within CMS in the Center for Clinical Standards and Quality. At the Center for Clinical Standards and Quality, we have been working to implement and operationalize many of the quality related requirements in the Affordable Care Act.

There are several quality reporting requirements for health insurance issuers that offer plans in the marketplace. This afternoon, I'll be providing you the information on some recent updates regarding implementation of section 1311(h) of the affordable care act, which outlines qualified health plan patient safety requirements.

The three main objectives of today's webinar are: to gain an overview of the QHP patient safety standards; to gain clarification of recent amendments to the QHP patient safety standards that were finalized in 2017 HHS Payment Notice Final Rule; and, to have an opportunity to provide feedback and ask questions at the end of the presentation.

So, before I get to the details on what is on this slide, I wanted to mention that the Affordable Care Act, as you know, was passed in 2010. And, the primary goals of the numerous provisions in the law were focused on access, affordability, and quality of healthcare for all Americans. In the last six years, there has been historic reductions in the numbers of uninsured. And, in these early years of establishing health insurance marketplaces, we have worked towards stabilizing the marketplaces, increasing enrollment numbers of consumers buying QHPs, which are the

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plans that help insurance issuers offer in marketplaces, and ensuring access to network providers and affordable healthcare services. At the same time, we have phased-in several quality requirements across marketplaces. For example, QHP issuers are required to submit healthcare quality measure data to CMS that will be provided to consumers, so individuals can have information on the quality of plans available on the marketplace. Another crucial requirement for QHP issuers is outlined here in section 1311(h) and is the focus of today's webinar. This section of the law focuses on enhancing patient safety in marketplaces. It specifically states that, if a plan is contracting with the hospital that has greater than 50 beds, that hospital must meet certain patient safety standards, like using a patient's safety evaluation system and implementing comprehensive hospital discharge programs.

The law also goes on to state that the secretary of the Health and Human Services can establish reasonable exceptions to that patient safety organization requirement and can increase or decrease the 50 hospital bed threshold.

Now, as we were thinking of establishing regulations around these patient safety standards, we wanted to make sure we meaningfully aligned with national healthcare quality goals. The vision for the CMS quality strategy is to optimize health outcomes, by leading clinical quality improvement and health system transformation. You can see the six goals here. I won't go into them in detail, but you can see that one of the six goals includes goal number one, making care safer by reducing harm caused in the delivery of care. The culture of improving patient safety reflects a priority for CMS, along with being a national priority specified in the national quality strategy. Through programs and initiatives, CMS provides opportunities to improve the healthcare system by preventing serious medication events and eliminating healthcare associated infections and other preventable conditions. When developing the goals, we also came up with four foundational principles that apply to each and every goal, and guide the agency's action towards each of these goals, and you can find this in the center here. We felt that, unless these four foundational

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principles are explicitly incorporated into our agency's operational plan to achieve our goals, CMS will not succeed in driving change to improve the quality and cost of healthcare for all.

This next slide reiterates that the qualified help plan patient safety standards are built on the foundation of the CMS quality strategy and the national quality strategy for improvement in healthcare. The following goals of the CMS quality strategy, I just wanted to highlight because they support the implementation and intent of the patient safety standards. So, goal number one, making care safer by reducing harm, including specific objectives to improve a culture of safety, reduce inappropriate and unnecessary care and prevent harm. These objectives, which are all inherent in implementation of specific QHP patient safety standards across marketplaces. Goal number two talks about strengthening person and family engagement as partners in their care. Section 1311(h) also talks about patient centered education and counseling in a comprehensive discharge program. And goal number three, promoting effective communication and coordination of care. The idea of care coordination in a comprehensive hospital discharge program, as well as to improve patient safety.

Now in March 2014, we finalized standards to phase in the implementation of section 1311(h). Phase One implementation drew on Medicare standards and requires that QHP issuers in the initial two years, beginning January 1, 2015, ensure that certain of their contracted hospitals of greater than 50 beds are Medicare certified or are Medicaid only hospitals that are subject to the Medicare hospital conditions of participation standards. Operationally, what this has meant is that issuers have to collect and maintain CMS certification numbers for their applicable hospitals. All quality related reporting requirements for QHP issuers and marketplaces have been phased in. Our approach in the early years of the marketplace program is to minimize burden and align with effective quality recording initiatives. We've also drafted policies and guidance to try to maximize issuer and provider participation in

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marketplaces, so that people are able to access affordable quality healthcare.

So, in March of this year, we finalized the next phase of patient safety standards for QHP issuers. And, this is where we finalize the requirement for QHP issuers offering coverage through the marketplaces to track hospital participation with patient safety organizations. And, we also finalized providing an exception to the PSO requirement that QHP issuer may only contract with the hospital with more than 50 beds, if they implement an evidence-based initiative to improve healthcare quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination. We require QHP issuers to verify that their applicable contractor hospitals either have agreements with PSOs or have implemented an alternative. So for example, a hospital participating with a Hospital Engagement Network or a Quality Innovation Network, Quality Improvement Organization, they would be able to provide their issuers with appropriate documentation, hospital attestations or current agreements to the QHP issuer.

Next, I'd like to highlight a few clarifications that we included in the Final Rule, because we did receive several comments, and have been receiving questions around these areas. First, we clarified that, if a provider undertakes activities to improve patient safety and health care quality, but does not do so in conjunction with a patient safety organization, the patient safety and quality information involved in those initiatives would not be subject to the patient safety and quality improvement act privilege and confidentiality protection. So basically, contracting with one of the federally listed PSOs, which you can find on the Agency for Healthcare and Quality website, will provide those specific privilege and confidentiality provisions for patient safety work product; that, if a hospital chooses to meet this requirement using something other than a PSO, then those privilege and confidentiality protections do not apply.

The next clarification we wanted to highlight is that the PSO contracts, also known as patient safety act contracts, do not meet the definition of

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patient safety work product; and, therefore, are not subject to the protections and requirements in the PSO statute and regulations. So basically, there were questions around hospitals providing those PSO contracts to the issuer. And, we wanted to make sure that folks knew that those actual contracts, those agreements with the PSO, are not subject to those privilege and confidentiality protections. CMS does not intend to collect and publish data on the patient safety evaluation system, nor are we generally permitted to publish patient safety work product.

The third clarification that I would like to highlight is that the documentation requirement for plan years beginning on or after January 1, 2017, include examples that are intended to be broad. We provide examples of documentation, such as hospital attestations or current agreements to partner with the PSO or HEN or QIO. We also wanted to clarify that we do not provide an all-inclusive list of examples of how to meet these requirements, specifically to encourage flexibility and innovation for hospitals who are engaged in diverse initiatives to reduce patient harm and patient safety activities that are most appropriate for your diverse hospital populations.

To meet these QHP issuer patient safety standards, the onus is on the hospital and issuer to demonstrate compliance. And, if the option that is chosen, is the option that is other than contracting with the PSO, then those evidence-based initiatives could include a robust comparable initiatives, such as Joint Commission initiatives to accreditation or state based patient safety programs that would meet our legislative requirements. Again, the responsibility is upon the hospital and issuer to demonstrate compliance to the QHP issuer patient safety standards. Also, in our Proposed Rule, we sought comment on our consideration of requiring the use of agency for healthcare research and quality common format for reporting patient safety events. And, although we do not move forward in requiring the use of common formats, CMS continues to strongly support hospital tracking of patient safety events using the common formats, which are a useful tool for a hospital, regardless of what

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patient safety interventions are implemented for ongoing data-driven quality assessment.

Lastly, I wanted to provide you with a couple of resources. One is our marketplace quality initiatives website. Here you can find a link to the Final Rule that includes QHP patient safety standards. You can also view details of other quality reporting requirements in the marketplace. And, the second link is the link to our CMS quality strategy.

At this time, I will pause and try to answer some questions that you may have.

**Candace Jackson:** Thank you Nidhi. Before we go into the question and answer session, I would like to apologize for the power outage that we had that did interrupt the sound broadcasting of the webinar today. The transcript and the recording of this webinar will be posted to the [Quality Reporting Center](#) at a late – within 10 business days. And again, that website is [www.qualityreportingcenter.com](http://www.qualityreportingcenter.com). Now, we do have a few questions that have been submitted.

The first question: question regarding 81 FR 12203, page 12315, does this apply to any size hospital or only hospitals 50 beds or larger?

**Nidhi Singh Shah:** Thank you for that question. This requirement only applies to hospitals greater than 50 beds that are contracting with qualified health plans in the marketplace.

**Candace Jackson:** Our next question: where are the federally approved PSOs listed?

**Nidhi Singh Shah:** That would be on the agency for healthcare quality research and quality website. I can provide that link, I don't have it visibly with me right now, but I can provide that link.

**Candace Jackson:** Thank you. And then our next question: in Pennsylvania, does the patient safety authority meet the requirements for PSO?

**Nidhi Singh Shah:** So, thank you for that question. So, we did – when we were establishing these regulations, as I mentioned, we did not want to detail and provide an

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all-inclusive list of examples of what would meet the requirement, but we do mention state-based patient safety programs. So basically, it is up to the hospitals in Pennsylvania and issuers to make sure that – if there are state requirements for the state level patient safety authority, if that meets the requirements in this part of the law, then it would meet – then you would be able to comply. But it is, again, it's up to the hospital and issuer to comply with these requirements, and CMS is not providing a list of all the examples of what would meet.

**Candace Jackson:** Thank you for that response. Our next question: if a hospital is located in a state where there is mandated incident reporting and confidentiality protection through state laws, does this meet the requirements?

**Nidhi Singh Shah:** Again, my response would be the same as the question before. It would be up to the hospital and issuer to make sure that, for example, if the hospital is not contracting with a patient safety organization, then they would have to make sure that they are an – I'll just read the language from the law, which is “make sure that those hospitals are implementing an evidence-based initiative to improve healthcare quality through collection, management, and analysis of patient safety events to either reduce all cost preventable harm or prevent hospital readmission or improve care coordination.” So, if hospitals can demonstrate that they are involved with programs and initiatives that do this, then they would comply.

**Candace Jackson:** And our next question: HENs and QIOs are subject to yearly contract renewals, so if the HEN the hospital is working with NC approved contract is compliance lost midyear? And, the second part to this question: what is the penalty for a hospital using a HEN or a QIO that loses its contract approval for CMS in the middle of the year?

**Nidhi Singh Shah:** So, yes, we have been receiving questions regarding HENs and QIOs and contract and funding. And, right now, what we can say is that there is intention – CMS does intend to award new contracts by the end of this fiscal year. And so, there is no penalty; however, it is up to, again, the hospital to remain compliant with these QHP issuer patient safety standards. So, I would say that, if a hospital stops working midyear with a



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HEN or a QIO or modifies their patient safety program, it would be up to the hospital and issuer to maintain ongoing compliance.

**Candace Jackson:** Thank you. Our next question: Does state-based marketplaces need to collect any documentation from QHP issuers?

**Nidhi Singh Shah:** There is no requirement that state-based marketplaces collect information. However, we have provided flexibility in the law to state that, if a state-based marketplace chooses to request documentation from their issuers regarding compliance with the standard, that they may. So, it's up to the state based marketplace. And also, I just wanted to go back to the federal listing of the PSOs, I wanted to provide the link, it's <https://pso.ahrq.gov/listed>.

**Candace Jackson:** Thank you. And, our next question: can you be more elaborate on who qualifies as a QIO?

**Nidhi Singh Shah:** I guess I would have to ask further details around that question. What do you mean by who qualifies as a QIO? And, I can always – we're going to be receiving these questions after this webinar, and we can provide responses at a later date as well.

**Candace Jackson:** Thank you. And, our next question: so, if we submit data to QNet – *QualityNet*, and Joint Commissions, we would meet this requirement, correct?

**Nidhi Singh Shah:** Again, if the hospital demonstrates that those programs and initiatives, whether it's through Joint Commission accreditation or another method, if the hospital can demonstrate that those initiatives involved collection management and analysis of patient safety events and that either improve credit care coordination or prevent hospital grade admission or reduce all cause harm, then yes.

**Candace Jackson:** And, I'm not sure if you'll be able to provide a response for this next question, or not, but we will address it: what are the implications for the CMS, Everyone With Diabetes Counts, and Immunizations programs?

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**Nidhi Singh Shah:** Yes, I will probably have to get back to you with a response to that question.

**Candace Jackson:** Thank you. And our next question, and we do have time for one more question here: 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?

**Nidhi Singh Shah:** OK, so that clarification was basically to clarify that the actual agreement, that documentation that says that a hospital is contracting with the patient safety organization, that piece of documentation is not considered patient safety work product. So, that documentation, there's no – there are no confidentiality protections around that piece of documentation. Because we received comment in our regulation of hospitals concerned about providing that patient safety organization contract to an issuer, if an issuer asks for it – you know, concerned about confidentiality with patient safety data. So, we just wanted to clarify that that PSO contract would not be subject to those protections.

**Candace Jackson:** Thank you. And, that concludes our presentation for today. I would like to thank Nidhi for presenting this information to us, and I hope that everyone did find it beneficial. Again, we will be posting the Q&As to the [Quality Reporting Center](#) website at a later date. So, if your question did not get answered on the call today, it will be answered when those Q&As are posted. Again, we would like to thank you for your participation and hope that you have a good day. Thank you.

**END**