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December 18, 2015

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***Re: CMS 9937-P, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017.***

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, Notice of Benefit and Payment Parameters for 2017. This letter focuses on the proposed patient safety standards for Qualified Health Plan (QHP) issuers. Specifically, we comment on CMS's proposals for the second phase of regulations implementing the patient safety requirements in section 1311(h) of the Affordable Care Act (ACA).

**Patient safety is hospitals' first priority.** America's hospitals are committed to ensuring that patients receive safe, high-quality care. Hospitals participating in the Medicare program have internal, ongoing, data-driven quality assurance and performance improvement programs that measure, track and analyze quality indicators. They also take advantage of an extensive number of patient safety initiatives offered through improvement-focused organizations. For example, many hospitals have joined patient safety organizations (PSOs), which have strong potential to provide a deeper understanding of the underlying factors that contribute to avoidable errors in care and suggest strategies for ameliorating the risk. In addition, hospitals often participate in patient safety and quality improvement projects coordinated by the Partnership for Patients Hospital Engagement Network (HEN), the Agency for Healthcare Research and Quality (AHRQ), The Joint Commission, medical specialty societies, state hospitals associations, quality improvement organizations (QIOs), the Centers for Disease Control



and Prevention, and more. While more work remains, we know that these and other efforts by hospitals to make care safer are paying off.<sup>1</sup>

We appreciate CMS's objective to strengthen the standards for section 1311(h) **and we generally support the agency's framework for phase two, which provides two options for compliance.** We agree that hospitals should be able to either join a PSO or engage in other evidence-based initiatives to improve quality. **However, CMS's proposals related to discharge planning are duplicative of its other proposals and would increase burden without adding value.**

We outline our recommendations for each option and ask several clarifying questions below. **As the agency finalizes its proposal, the AHA urges CMS to ensure that mechanisms for compliance are as efficient and consistent as possible for hospitals.** For whichever option a hospital chooses, it should be able to document its compliance the same way for each QHP issuer. We also note that a 30-day comment period for this rule, which spans numerous holidays and coincides with the release of other major regulations, poses challenges for stakeholders in providing analysis and input. Therefore, we suggest that CMS continue to work with stakeholders, as allowed, as it finalizes these proposals.

## **BACKGROUND**

Section 1311(h) of the ACA describes three conditions for hospitals and health care providers to meet, starting Jan. 1, 2015, in order to contract with a QHP. First, a QHP may contract with a hospital with more than 50 beds only if the hospital uses a Patient Safety Evaluation System (PSES) as described in Part C of title IX of the Public Health Service Act. This reference means that a hospital must have an agreement with a PSO established by the Patient Safety and Quality Improvement Act of 2005 (PSQIA). Second, a QHP may contract with a hospital with more than 50 beds only if the hospital has mechanisms in place to ensure comprehensive discharge planning. Finally, the language of this section states that QHPs may contract with a health care provider only if the provider implements quality improvement mechanisms that the Secretary of Health and Human Services (HHS) may require.

The ACA also provides considerable discretion to the Secretary in how these conditions are implemented. Specifically, the law allows HHS to make reasonable exceptions to any of the three conditions and to adjust the number of beds for the hospital requirements.

The initial phase of implementation for section 1311(h), effective for plan years beginning on or after Jan. 1, 2015, is based on compliance with the Medicare hospital Conditions of Participation (CoPs) for quality assessment and performance improvement and discharge planning. Thus, currently applicable hospitals must provide QHPs with their CMS Certification Numbers to demonstrate that they meet the CoPs.

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<sup>1</sup> Zeroing in on the Triple Aim. American Hospital Association. Issue Brief, April 2015.

In the proposed rule, CMS would increase the requirements that hospitals would need to meet in order to contract with QHP issuers. However, the agency would allow two options to implement the more stringent requirements. The proposed regulations for phase two, which would apply to plan years beginning on or after Jan. 1, 2017, would require hospitals of more than 50 beds to either (1) have an agreement with a PSO listed by the AHRQ and a mechanism for comprehensive person-centered hospital discharge; or (2) implement other evidence-based initiatives to reduce harm and improve quality.

## **PROPOSALS FOR PHASE TWO**

As noted above, the AHA supports CMS's framework of allowing two options for QHP issuers and hospitals to comply with section 1311(h) beginning for plan years on or after Jan. 1, 2017. Below we provide comments on each option.

### **Option One – PSO Agreements and Patient-centered Discharge Policies**

Under the proposed first option, hospitals would need to provide documentation to a QHP issuer that they are engaging in two separate types of activities. First, a hospital with more than 50 beds would need to verify that it has an agreement with a PSO created by PSQIA and listed by AHRQ.

The AHA supported the passage of PSQIA and believes PSOs can be an essential tool to foster safety. For example, today PSOs are sharing ideas about how to prevent falls in hospital settings; identifying potential hazards when using electronic health records; and convening “safe tables,” through which health care providers candidly share experiences about adverse events and lessons learned. As the PSO field continues to develop and the value of participating is further demonstrated, we believe PSOs have the potential to dramatically enhance patient safety.

**We support CMS's approach for option one, which would encourage participation in AHRQ-listed PSOs. However, we do not support CMS's proposed method of documentation, which would require hospitals to share their PSO agreements with QHPs.** CMS states that it expects the documentation to “reflect implementation of PSO activities, such as PSOs and hospitals working together to collect, report and analyze patient safety events.” We are concerned that the kind of documentation CMS envisions may violate the prohibitions in the PSQIA that prevent hospitals and PSOs from sharing patient safety work product (PSWP) and analyses with those outside the PSO. Whatever documentation mechanism is adopted, CMS should clarify that it will not require the submission of information that could compromise the confidentiality or privileged nature of PSWP or data submitted to a PSES. Instead, CMS could require hospitals to inform QHPs in writing, during contract negotiations, of the name of the PSO with which they have an agreement. In addition, whatever documentation CMS deems to be acceptable should be consistently accepted by all QHP issuers.

**The AHA also requests that CMS provide a process for hospitals to follow in case a PSO is de-listed by AHRQ.** If a PSO is de-listed, hospitals working with that PSO could either join another AHRQ-listed PSO or engage in one of the other opportunities allowed under option two, within a specified time-frame. Given that opportunities to join ongoing improvement projects may be limited (for example, there may be specified enrollment periods for various quality initiatives), hospitals could need considerable time to implement an alternative. We suggest that hospitals have at least a year to research, negotiate and implement alternatives.

Under the first option, CMS also proposes that the QHP issuer would need to verify that the hospital implements a mechanism for comprehensive person-centered hospital discharge. **However, the agency is already addressing the need for person-centered discharge planning through a separate proposed rule updating the Medicare CoPs for discharge planning.** CMS published in the Nov. 3 *Federal Register* a separate proposed rule that would expand current Medicare CoPs regulations by requiring hospitals to implement robust and patient-centered discharge planning processes for all inpatients as well as several categories of outpatients. Specifically, that proposed rule would require hospitals to provide an evaluation based on at least eight specific criteria, including the patient's goals and treatment preferences, and develop a discharge plan for each applicable patient. In addition, CMS would require hospitals to provide discharge instructions to patients discharged to home, transmit information containing 21 separate elements to a receiving facility when a patient is transferred, and implement post-discharge follow-up processes, among other requirements.

When finalized, we believe these changes to the CoPs will be more than sufficient to meet the discharge-planning patient safety requirements in section 1311(h) of the ACA. **Thus, we believe that QHP issuers will not need to collect additional information related to discharge planning for any hospital that participates in Medicare and that requiring documentation would be an added, unnecessary burden.** If CMS believes documentation is absolutely necessary, QHPs should be able to simply collect CMS Certification Numbers from their contracted hospitals, which demonstrates that hospitals are subject to the CoPs for discharge planning.

### **Option Two – Evidence-based Alternatives to PSOs**

As an alternative to the first option, hospitals could implement other evidence-based initiatives to reduce harm and improve quality. Specifically, CMS proposes to allow a hospital to implement other “evidence-based initiatives to reduce all-cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events.” For example, CMS states that QHP issuers could comply with the law if their contracted hospitals participate as part of a HEN or work with a QIO. The agency suggests that hospitals could provide copies of an agreement with a HEN or QIO to demonstrate compliance.

The AHA supports CMS's use of the exception language in the ACA to provide flexibility in how to meet the standards. While the AHA supports PSOs, the PSQIA and its corresponding AHRQ regulations always envisioned that PSO participation would be voluntary. **In addition, we believe flexibility is especially important as challenges to the breadth of PSQIA's legal protections are being brought in the courts, including one case that the Supreme Court has been asked to review. We believe it would be contrary to both the intent and the letter of the PSQIA if CMS created a situation in which hospitals are required to utilize a PSES for which confidentiality and privilege protections are reduced or removed.**

We also agree with the suggested activities for phase two of HEN and QIO participation. However, as far as we know, HEN funding is not scheduled to be extended beyond 2016. Further, we think the proposed regulatory language for this option at section 156.1110(a)(2)(ii) could be interpreted to exclude some of the initiatives CMS would want to consider under option two. Read literally, that language suggests that all acceptable initiatives must address all four required components: 1) all-cause preventable harm, 2) readmissions, 3) care coordination and 4) improved quality, through the analysis of patient safety events. That level of comprehensiveness will be difficult to find in any single initiative. For example, we are not sure that all PSOs, the Quality Innovation Network (QIN)-QIO projects or other leading patient safety improvement projects will include all four of these components. Alternatively, an AHRQ-coordinated project that reduces hospital infections also may have the effect of reducing readmissions, but it may not directly improve care coordination from one setting to another or address "all-cause" preventable harm, a term that is not clearly defined in the rule.

We believe it is important for hospitals to engage in initiatives in which they collect and analyze quality or safety data, implement evidence-based solutions, track progress and encourage a culture of safety. Hospitals also need flexibility to target their resources and initiatives to identified patient safety issues that are priorities for their organization. We suggest that CMS slightly alter the proposed regulatory language, so that QHPs could verify that a hospital:

- (ii) Implements evidence-based initiatives to reduce preventable harm, prevent hospital readmission, or improve care coordination. Initiatives must involve the collection, management and analysis of data on quality or safety, the implementation of solutions to improve care, and a method for tracking progress.

**For option two, hospitals should be able to participate in any of the initiatives described below or similar activities.** For documentation purposes, a hospital could inform QHPs in writing, during contract negotiations, of its participation in one of the following activities, and identify the specific entity with which it is working:

- Participation in a HEN, if the HEN program continues for the 2017 plan year and beyond. As we understand it, not all HENs have formal contracts, thus CMS's proposal for hospitals to provide a copy of an agreement may not work.
- Participation in an initiative of a QIN-QIO. As with the HENs, since CMS is already aware of the nature and value of QIN-QIO activities, hospitals should not be required to provide QHP issuers with the QIO agreement.
- Participation with The Joint Commission's Center for Transforming Healthcare on a Targeted Solution Tool for falls, hand hygiene, handoff communications, or safe surgery. The Joint Commission's Targeted Solutions Tools are evidence-based tools that guide hospitals through a step-by-step process to measure performance, identify the barriers to excellent performance, and implement proven strategies tailored to a hospital's particular barriers.
- Participation in an AHRQ project to reduce harm. We believe hospitals also should be able to participate in AHRQ-funded projects similar to the Comprehensive Unit-based Safety Program (CUSP), which significantly reduced central line-associated blood stream infections (CLABSIs).
- Implementation of a robust, system-wide patient safety analysis and improvement system in multi-hospital organizations. Some health care systems have implemented comprehensive, system-wide patient safety programs that include collection of multiple types of patient safety event data; benchmarking of that data both internally and externally; and implementation of evidence-based strategies to address problems and improve care. We believe health care systems with more than two hospitals should be able to demonstrate that they are working to address a safety or quality improvement issue, if the project involves the following elements: collection and analysis of data; research or generation of ideas about how to improve care; the testing of those ideas, and adopting the successful solutions. Hospitals opting for this mechanism could be asked to provide a letter attesting to their participation in the program and briefly explaining the nature of the project.
- Participation in certain PSO or safety analysis and improvement program created through or required by state legislation or regulation. AHA recommends that CMS allow participation in a PSO or safety analysis and improvement program *created through state legislation or regulation* to be a qualifying activity for compliance with section 1311(h) of the ACA, especially if it is mandatory. In particular, we are aware of mandatory state programs in Pennsylvania and Connecticut. For example, Pennsylvania law requires hospitals to report adverse events and near misses to an independent state agency, the Pennsylvania Patient Safety Authority, which acts similarly to a PSO. Connecticut requires hospitals to work with state-registered and state-defined PSOs, which can be either private or public organizations. **CMS should review the pertinent laws or regulations for**

**these states to determine that they meet the criteria under option two and exempt their hospitals from the documentation requirement in those states in the final rule.**

Further, we urge CMS to consider that projects may have various start and end dates, as well as specific enrollment periods, and these timeframes are unlikely to coincide precisely with plan years. Therefore, we ask CMS to build flexibility into the final rule, so that during the contract negotiation process, a hospital may attest to the fact that it is already or will start to take part in a patient safety activity during the relevant plan year. For example, a plan year could begin on Jan. 1, while an initiative that addresses an identified safety priority in a hospital may begin in March. Alternatively, CMS could base compliance on a hospital's previous year's activities.

### **Incorporation of Future Initiatives**

In the final rule CMS also should outline the process for how it will approve additional initiatives in the future. As time goes on, new initiatives that fit the parameters of the statutory intent and CMS's objectives may be created.

## **COMMON FORMATS**

**The AHA does not support CMS mandating the use of the AHRQ Common Formats.** In the proposed rule, CMS states that it is considering whether to require QHP issuers to ensure that their contracted hospitals as described in section 1311(h) are standardizing reporting of patient safety events with the use of the AHRQ Common Formats. The AHRQ Common Formats may be a useful construct for data collection for some organizations, but for many, they may not be the most useful vehicle for understanding what contributes to patient safety events or the effectiveness of various proposed ways to make care safer. The focus of hospitals, other providers and of CMS should not be on whether the organization is making use of a particular tool, such as the AHRQ Common Formats, but rather on whether care is getting safer.

Further, to ask the plans to verify that the AHRQ Common Formats are being used implies that they would have to look at data that are submitted to the PSOs, but federal law prohibits such data from being shared outside the PSOs.

## **TIMELINE FOR QHP AND HOSPITAL COMPLIANCE**

**We ask CMS to clarify that its timetable for the effective date for data collection for phase two is at least Jan. 1, 2017.** CMS proposes that phase two requirements would apply for plan years beginning on or after January 1, 2017. We interpret this to mean that QHP issuers would collect information from hospitals to comply with section 1311(h) of

the ACA no sooner than Jan. 1, 2017. However, QHP issuers may have certification and filing deadlines for 2017 that occur earlier.

Hospitals that are not already part of a PSO, HEN or QIO project will need sufficient time to determine which option it should take to comply with the standards for phase two. The decision process will include researching the options; obtaining internal approval, including the approval of leadership, feedback from staff and departments that will be involved in the initiative, and necessary budget approvals; and negotiating the agreements with various patient safety improvement organizations. Therefore, CMS should not require QHP issuers to have the relevant documentation in place as to how each of its contracted hospitals will meet the requirements of section 1311(h) before Jan. 1, 2017. **Hospitals should have a year from the date the rule is finalized to ensure that the arrangements to comply with section 1311(h) are in place.**

Thank you again for the opportunity to comment. If you have any questions, please contact me or Nancy Foster, vice president of quality and safety policy, at [nfoster@aha.org](mailto:nfoster@aha.org), or Evelyn Knolle, senior associate director of policy, at [eknolle@aha.org](mailto:eknolle@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President