



**American Hospital
Association**

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Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Re: CMS 9954-P, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015, Proposed Rule, December 2, 2013, Comments Specific to Section 1311(h), related to patient safety and quality improvement.

Dear Ms. Tavenner:

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 related to the *Patient Protection and Affordable Care Act (ACA)*; *HHS Notice of Benefit and Payment Parameters for 2015*. For this letter, our comments are limited to the proposals to implement section 1311(h) of the ACA relating to new patient safety standards. We have submitted separate comments related to the reinsurance program provision.

We appreciate CMS's thoughtful approach to implementing section 1311(h), which describes several new patient safety and quality improvement requirements for certain hospitals and health care providers that wish to contract with qualified health plans (QHPs) in the new Health Insurance Marketplaces. **Overall, we are pleased with CMS's plan to phase in these requirements over time. We support CMS's proposal to connect compliance to selected Conditions of Participation (CoPs) in phase one and to initiate future rulemaking before implementing more robust requirements in the second phase.**

CMS faces a number of challenges in implementing this section, and we recognize that the questions that CMS poses for how these ACA requirements should work in the second phase will require more contemplation, analysis and input by the stakeholder community than is achievable within a 30-day comment period. We appreciate CMS's objective to move the needle forward on patient safety while avoiding duplication with the extensive number of successful patient safety initiatives already underway. Hospitals have never worked harder to ensure that



patients receive safe, quality care. Among other achievements, thousands of hospitals have reduced readmissions, hospital-acquired infections, early elective deliveries and other adverse events through the Hospital Engagement Network improvement model. In addition, hospitals across the nation are undertaking improvement projects in collaboration with the Agency for Healthcare Research and Quality (AHRQ), statewide collaboratives, Quality Improvement Organizations, medical specialty societies and hospital accreditation organizations such as The Joint Commission.

We describe below our understanding of and recommendations for phase one. In addition, we offer insights about how CMS might initially approach phase two in order to achieve a more comprehensive implementation of these ACA patient safety goals. We look forward to continued discussions about the best course of action for the longer term.

BACKGROUND

The language of 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 is generally understood to mean that a hospital must have an agreement with a federally designated Patient Safety Organization (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 provision does not apply to hospitals with 50 or fewer beds.)

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

In the proposed rule, CMS expresses concern that “implementing all of the requirements described in section 1311(h) by Jan. 1, 2015 could result in a shortage of qualified hospitals and providers available for contracting with QHPs.” Specifically, CMS questions whether enough PSOs exist to accommodate all hospitals subject to the PSES condition, and whether hospitals and QHPs would have sufficient time to comply. For these reasons, CMS outlines **two phases** for implementation of the QHP contract conditions. The first phase would provide a short-term framework for hospitals to comply with the PSES and discharge planning provisions. The second phase would focus on how both hospitals and health care providers can meet all of the requirements under this section in a more comprehensive way. CMS envisions that this second phase will require future rulemaking.

COMMENTS ON PHASE ONE

In the first phase of implementation for hospitals, from 2015 to at least 2017, CMS would connect compliance to certain Medicare Conditions of Participation for hospitals (CoPs). Specifically, CMS proposes that a QHP issuer would be able to contract with a hospital with more than 50 beds only if the issuer verified that the hospital is Medicare-certified or has a Medicaid-only CMS Certification Number (CCN). CMS articulates that this verification would essentially confirm that the hospital is subject to the CoPs for quality assessment and performance improvement (QAPI) and discharge planning. To document compliance, QHP issuers would collect from applicable hospitals information including, but not limited to, a CCN.

CMS proposes to apply the standards in phase one to hospitals, as defined in section 1861(e) of the *Social Security Act*, that are Medicare certified, and to Medicaid-only hospitals with a Medicaid-only CMS Certification Number (CCN). We ask CMS to explain in more detail what it considers to be a section 1861(e) hospital, including the types of hospitals. We understand that CMS intends for this provision to apply only to hospitals that are subject to the CoPs for QAPI and discharge planning, which is broader than general acute care hospitals.

We agree with CMS's approach for phase one. We believe the QAPI and discharge planning CoPs provide a good place to start in meeting the objectives of the ACA. These standards require hospitals to have effective processes in place to assess quality and help patients transition smoothly to the next care setting. In addition, many hospitals already are meeting more rigorous criteria for QAPI through The Joint Commission (TJC) accreditation requirements. Further, and as we discuss below, the discharge planning CoPs are accompanied by extensive surveyor guidance that provides a very comprehensive framework for discharge planning.

We support CMS's proposal for allowing hospitals to demonstrate compliance by providing their CCNs. We believe that providing a CCN should suffice in demonstrating compliance for any hospital that has a CCN. However, the proposed regulatory language would allow QHPs to collect information *other than* a CCN to demonstrate that a hospital is subject to the CoPs for QAPI or discharge planning. **If the goal is to ensure that the hospital is subject to the CoPs, then the CCN is all that is required. In addition, we question if requiring hospitals to supply CCNs to health plans is duplicative, since CMS would already have this information. It would be more efficient for CMS to share this data with QHPs.**

We understand that CMS plans to apply these standards *only* to hospitals that are Medicare-certified and to hospitals with a Medicaid-only CCN. We question whether the proposed regulatory text is perfectly clear that hospitals that do not participate in Medicare or Medicaid would not be subject to this provision and would have no restrictions on QHP contracting. Facilities that are new construction hospitals, and some hospitals undergoing a change of ownership, may be temporarily without a CMS certification number. We urge CMS to clarify that these hospitals would not be subject to the requirements under proposed section 156.1110 until they acquired a CCN.

For these hospitals, the current types of contract provisions already imposed by health plans should suffice. If, for some reason, CMS chooses to apply the proposed requirements to such hospitals, we encourage CMS to consider provisional acceptance of compliance, which can be accompanied by an application for a provider agreement, a previous provider agreement, or possibly documentation of accreditation.

At the very least, we urge CMS to ensure that the information QHPs collect to ascertain hospital compliance with section 1311(h) is consistent among all QHPs. Otherwise, hospitals could face varying information collection requirements from different QHPs in order to comply with the ACA, adding additional burden and possibly limiting patient choice. That scenario would be unwarranted given that CMS's objectives can be met by the sharing of CCNs. We urge CMS to ensure that the documentation process does not cause delays or restrict access to hospital care.

COMMENTS ON PHASE TWO

CMS does not outline concrete expectations for the second phase of implementation, but says it is "considering requiring QHP issuers to ensure that their contracted hospitals have agreements with PSOs and comprehensive hospital discharge programs, and that their health care providers implement health care quality activities." CMS will issue further direction related to section 1311(h) in future rulemaking. For now, the agency requests comment on the following:

- What core aspects should be included in hospital patient safety programs?
- What should a comprehensive hospital discharge planning program require for each patient?
- What health care quality improvement activities should be implemented by health care providers?
- How can QHP issuers track patient safety information such as hospital agreements with PSOs?
- What specific, comparable activities could be included as reasonable exceptions to these patient safety standards?

Section 1311(h) places a special emphasis on PSO participation. PSOs play a vital role in helping hospitals and other care providers improve patient safety through their incident reporting, analysis and data-sharing mechanisms. The AHA is familiar with several member hospitals and state hospital association partners that have established PSOs and are using data collection and analysis to successfully address patient safety needs. Further, the health care field is beginning to realize the full potential of what PSOs can ultimately achieve. The success of the voluntary Aviation Safety Reporting System demonstrates the promise of the health care PSO model, which enables hospital employees to confidentially report adverse events and near misses and allows others to learn from analyses of these patient safety reports.

We believe that participation in PSOs should be included in a list of options of how to comply with the PSES condition. As currently required, participation in a *federally-designated* PSO should remain completely voluntary, because PSQIA establishes a framework for PSO

participation that is voluntary. In 2008, AHRQ, which oversees the implementation of PSQIA, issued a final rule that restricts mandatory participation in federally-designated PSOs. Thus, any entity that operates a federal, state, local or tribal patient safety reporting system is generally precluded from federal PSO designation if providers are required to report data to that entity by law or regulation. AHRQ even excluded voluntary accrediting organizations from federal PSO designation because of what it called the “mandatory nature” of reporting data to an accrediting organization if accreditation is required by third parties such as payers. Similarly, if CMS required hospitals to have an agreement with a federal PSO in order to contract with a QHP, it would undermine the voluntary nature of federal PSO participation as envisioned by PSQIA.

At the same time, AHA believes it is vitally important to 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 this section of the ACA. State programs in Pennsylvania, Connecticut and Minnesota have demonstrated their effectiveness for several years. To require federal PSO participation *on top of* voluntary or mandated participation in state-organized PSOs/PSESs would be duplicative and could even create challenges in keeping data confidential and privileged.

Rather than creating specific mandates, CMS should recognize multiple patient safety activities that are considered to be effective in reducing adverse events. CMS could develop criteria for evaluating the effectiveness of specific patient safety activities, such as PSO participation. CMS could then allow hospitals to meet the conditions of section 1311(h) by engaging in a qualified activity. Such criteria could include an evaluation of whether the activity:

- Helps a hospital establish a just culture or a patient safety culture, which includes protecting reporters of adverse events.
- Uses data collection and analysis as a core component of improvement, such as root cause analysis (which may be protected).
- Uses evidence-based practices, where applicable.
- Provides measureable results.
- Provides mechanisms in which information on hazards and advice on safety improvement strategies can be shared with providers.
- Is supported by a hospital’s leadership.
- Is voluntary in nature (with the exception of state-based PSOs/PSESs).
- Does not limit improvement to a single area of medicine, such as PSOs that focus solely on anesthesia or breast health.

We think this approach makes sense because it ensures that each hospital would take part in a robust patient safety effort *that has many of the same components of PSO participation*. At the same time, this framework avoids conflicts with state level requirements, duplication with other patient safety initiatives, and mandatory PSO participation that undermines the intent of PSQIA. In addition, it will allow CMS to carefully analyze how a more rigorous set of standards would apply to different types of hospitals, with unique safety concerns, other than general acute care hospitals.

CMS'S SPECIFIC QUESTIONS

Below, we outline our answers to some of the specific questions posed by CMS in the proposed rule.

- What core aspects should be included in hospital patient safety programs?

Patient safety improvement is a multi-pronged effort that includes gathering and analyzing data to establish priorities, implementing specific improvements, tracking progress and maintaining improvement. Effective patient safety programs begin with a just culture where employees, patients and families feel free to raise concerns or report problems. These programs include robust data collection and analysis, including root cause analysis, measurement and monitoring. They also include leadership support. At the same time, good patient safety programs have processes in place for reporting, analyzing and responding to adverse events, near-misses and serious complaints, such as agreements with PSOs.

- What should a comprehensive hospital discharge planning program require for each patient?

The AHA believes the framework provided by the CoPs and corresponding surveyor guidance, along with the considerable emphasis placed on discharge planning by hospitals as they seek to reduce readmissions, enables hospitals to meet the ACA discharge planning objective as described in section 1311(h).

A strong discharge plan ensures that the patient will experience a smooth care transition to the next care setting and helps avoid post-hospital complications as well as readmissions. Effective discharge planning assures that as patients leave the hospital, they and/or their caregivers have a good understanding of the patient's medical condition(s), what and how medications should be taken, how the patient should be cared for at home, if that is where the patient will be, and what follow-up care will be needed, if any.

As part of the discharge planning process, hospitals conduct medication reconciliation with patients and make sure prescriptions are filled, offer education and counseling about the patient's condition, arrange follow-up care with post-acute providers, and contact the patient after discharge to monitor progress and answer questions. This last step can include visiting post-acute care settings such as nursing homes to ensure that the patients are receiving the proper follow-up care.

These are a few of the types of activities hospitals are already undertaking as part of their obligations to meet the CoPs for discharge planning. The requirements under the CoPs establish a framework in which all inpatients are screened in order to identify those who will need a discharge plan (if the hospital does not already develop a discharge plan for all patients). The CoPs further require hospitals to develop and offer a discharge plan to

each patient identified as needing a plan as well as patients (or their doctors or family members) who request a discharge plan. The hospital must involve the patient in developing the discharge plan, which must be completed on a timely basis and reassessed as needed. Among other requirements, the CoPs require counseling of patients and family members (or other interested parties) as needed to prepare them for post-hospital care and appropriate referrals by the hospital for follow up care.

In addition to the CoPs, CMS has issued extensive and detailed guidance for surveyors that lays out expectations for comprehensive discharge planning. To highlight the comprehensiveness of this guidance, we share a few of these expectations below:

- Hospitals must assess what the patient will need in the next care setting and help the patient meet his or her post-acute care needs. For example, the surveyor guidance requires hospitals to review what kind of medical equipment patients will need or if their homes need modifications. They must assess whether the patient has someone who can care for them, as needed, and if someone can be trained by the hospital to care for the patient at home.
- Hospitals should review whether the facility at which the patient resided prior to inpatient hospital admission has the capability to care for him or her.
- Hospitals must have knowledge of the abilities and capacities of many types of service providers in the area that provide post-hospital care in order to develop a realistic discharge plan.
- Throughout the guidance, CMS emphasizes medication reconciliation and proper, thorough communication with the next care provider.
- The hospital is expected to discuss with the patient/family/support persons the ability to pay out of pocket for services.
- The hospital must include discharge planning as part of the QAPI process and review discharge plans in closed medical records to assess their effectiveness.

Therefore, the thoroughness of the CoPs and discharge planning surveyor guidance, as well as the emphasis hospitals are placing on discharge plans as they seek to avoid penalties under the Hospital Readmissions Reduction Program, are sufficient to meet the discharge planning activities envisioned in the ACA. We caution that creating a new or separate mechanism for meeting additional discharge planning requirements could be duplicative and inefficient.

- How can QHP issuers track patient safety information such as hospital agreements with PSOs?

Whatever tracking mechanism CMS adopts, it should be uniform among all QHP issuers, so that hospitals will not have to provide different information to multiple issuers. For example, CMS could maintain a list of patient safety activities it believes are effective in promoting patient safety, including participation in specific PSOs recommended by AHRQ, which QHPs could track.

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- What specific, comparable activities could be included as reasonable exceptions to these patient safety standards?

As discussed above, we believe that CMS should develop specific criteria to evaluate whether patient safety activities can meet the expectations of these ACA patient safety requirements. These activities could include, for example, QIO projects, HEN activities, specific private-sector projects such as The Joint Commission's (TJC's) Center for Transforming Healthcare or the use of TJC's Targeted Solution Tool, depending on how they are structured.

- What "reasonable exceptions" should the Secretary establish?

As noted above, the AHA believes that participation in a state-based PSO or safety analysis and improvement program should be a qualifying activity for compliance with section 1311(h). For example, hospitals in Pennsylvania, Connecticut and Minnesota already participate in functioning state-level PSO frameworks. We believe it would be duplicative and burdensome to impose additional standards for hospitals in such states.

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

Sincerely,

/s/

Rick Pollack
Executive Vice President