



December 21, 2015

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

Subject: CMS–9937–P, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Proposed Rule (Vol. 78, No. 231), December 2, 2015

Dear Acting Administrator Slavitt:

On behalf of the California Hospital Association (CHA) and our more than 400 member hospitals and health systems, as well as the CHPSO (formerly the California Hospital Patient Safety Organization), one of the first and largest not-for-profit patient safety organizations (PSOs) in the nation, we are pleased to submit comments on the *CMS-9937-P Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017* proposed rule, which further implements provisions of the Affordable Care Act that require certain patient safety and quality improvement requirements in order to contract with a qualified health plan (QHP) through the health insurance exchanges. **The comments addressed in this letter are limited to Subpart D §156.1110 establishment of the patient safety standards for QHP issuers.**

CHPSO was established by CHA to lead efforts toward eliminating preventable patient harm and improving the quality of health care delivery in hospitals. CHPSO has established itself as one of the largest and most successful PSOs in the nation, with more than 300 members in nine western states. CHPSO's initiatives include providing a collaborative and privileged environment where hospitals can share data and best practices; analyzing adverse outcomes and developing corrective actions to prevent reoccurrence; helping manufacturers design safer equipment; developing education materials; and serving as a resource for national and international patient safety initiatives.

CHPSO accomplishments over the past year include:

- Continuing its leadership in convening “safe tables” — meetings of clinicians from groups of hospitals — in which providers can candidly share experiences with each other, to learn from each other and ensure that lessons learned in one organization are shared with others in order to best protect patients from harm.
- Phasing-in hospitals’ participation in event reporting and waiting for incident report system vendors to automate the process, rather than asking for manual data entry. This simple process requires no special software or knowledge at the participating organization, resulting in over 880,000 individual reports of unsafe conditions, close calls and safety incidents, providing a rich database of experience.
- Mining data from the reports, leading to many publicly-issued patient safety alerts and detailed articles.
- Working with manufacturers to address device design practices that have led to patient safety issues, as solutions to many of healthcare’s safety challenges require the coordinated effort of clinicians and those that design the equipment clinicians use.

As you know, *To Err is Human* included recommendation 5.2, “The development of voluntary reporting efforts should be encouraged.” Congress responded by passing the Patient Safety and Quality Improvement Act of 2005 (PSQIA), establishing PSOs. *To Err is Human* followed its recommendation with the following call to action: “Voluntary reporting systems are an important part of an overall program for improving patient safety and should

be encouraged. Accrediting bodies and group purchasers should recognize and reward health care organizations that participate in voluntary reporting systems.”

The ACA requirement for PSO participation is an important step in implementing this recommendation. CHA and CHPSO believe that the regulatory framework used to implement this section of law should strongly encourage hospital participation in federally qualified PSOs, and we appreciate the Department of Health and Human Services’ (HHS) efforts to encourage hospital participation.

Among other requirements, Section 1311(h) lays out a condition that a QHP may contract with a hospital with more than 50 beds only if that hospital utilizes a patient safety evaluation system as described in the PSQIA. The ACA also allows the Secretary to create “reasonable exceptions” to this requirement.

The initial phase of implementation effective for plan years beginning on or after Jan. 1, 2015, is based on compliance with the Medicare Hospital Conditions of Participation for quality assessment and performance improvement and discharge planning. Currently, hospitals must provide QHPs with their CMS certification numbers to demonstrate that they meet those requirements. CHA and CHPSO supported this phased approach to implementation to give hospitals additional time to contract with PSOs and establish robust patient safety evaluation systems.

The proposed regulations for phase two under Subpart D §156.1110 would apply to plan years beginning on or after Jan. 1, 2017 and would require hospitals to either:

- implement a patient safety evaluation system and a mechanism for comprehensive person-centered hospital discharge; or
- implement other evidence-based initiatives to reduce harm and improve quality.

For those electing to work with a PSO, the proposed rule would require QHP issuers that contract with a hospital with more than 50 beds to verify that the hospital utilizes a patient safety evaluation system as defined in the current regulations for PSQIA and PSOs listed by the Agency for Healthcare Research and Quality. Alternatively, 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, QHP issuers could comply with the law if hospitals participate through the Partnership for Patients initiative as part of a hospital engagement network (HEN) or work with a quality improvement organization (QIO)/quality improvement network (QIN).

CHA and CHPSO generally support the regulatory framework proposed for phase two, with one exception. Currently, the vast majority of hospitals are certified under the Medicare CoPs, and as such, are already required to establish policies and procedures for patient-centered hospital discharge. Further, CMS is currently revising those discharge planning CoPs, rendering the additional requirement in §156.1110 unnecessary and duplicative of existing requirements. We urge CMS to remove “and a mechanism for comprehensive person-centered hospital discharge” from the federal regulatory text.

In addition, we appreciate CMS efforts to align the alternatives with existing HEN and QIO/QIN quality improvement efforts. However, such efforts are time-limited and may sunset, giving rise to other important CMS initiatives. CHA and CHPSO urge CMS to allow the list of qualifying alternatives to be informed by additional stakeholder input on an annual basis to ensure that important opportunities for alignment are not missed.

To demonstrate compliance, CMS proposes that a QHP issuer collect information from contracted hospitals, such as a copy of the current agreement to partner with a PSO, HEN or QIO. The documentation would need to reflect the implementation of a PSO and discharge planning activities or other patient safety initiatives.

We do not believe it is appropriate for QHPs to have access to copies of confidentially negotiated contracts between hospitals and other entities, including PSOs or other qualified partners. Rather, we urge HHS to require QHPs to obtain from the hospital an annual attestation on conformance with these requirements. In addition, the acceptable documentation should be consistently accepted by all QHP issuers.

Annual attestation is most important for those hospitals that initially choose not to participate in a federally qualified PSO or establish a patient safety evaluation system, as the alternatives are often time-limited and dependent on external funding. For example, many QIO/QIN initiatives are limited to only a certain number of hospitals, due to limited CMS funding. Throughout the year, and over the course of many years, hospitals will likely move from one initiative to another or to PSO participation as they seek to continually improve performance and improve patient care. Hospital attestation allows for additional flexibility and will limit the administrative burden on both QHPs and hospitals.

CHA and CHPSO believe strongly that the PSOs are a critical component in all quality improvement and safety initiatives in hospitals, and we urge HHS to encourage participation in federally qualified PSOs. PSOs, like CHPSO, carry out a variety of patient safety activities with the goal of improving patient safety and the quality of health care delivery. PSOs are able to collect, aggregate and analyze patient safety events and information that is protected under privilege and confidentiality standards. The patient safety evaluation system provisions set forth in the ACA and implemented in regulation align with the Triple Aim and the goals laid out in the National Quality Strategy.

Establishing a nationwide learning system requires broad participation. Several states, such as Pennsylvania, have reporting systems consistent with a learning system and include comprehensive reporting encompassing no-harm events and near misses, a non-punitive environment and confidentiality. **We believe those select state-established systems that meet the recommendations of *To Err is Human* should not be considered comparable to PSO participation, as those systems do not use the Common Formats and cannot contribute to the Network of Patient Safety Databases, but should qualify as evidence-based initiatives to reduce harm and improve quality under the currently proposed regulatory framework. By recognizing those systems as alternatives to PSO participation, hospitals in those states would be spared duplicate reporting. However, this exception should be only for those systems already in place as of Jan. 1, 2016, as proliferation of this exception would limit the data sharing, reducing the potential benefit of the PSO program.**

We appreciate the opportunity to comment on this proposed rule. If you have any questions, please contact Rory Jaffe, executive director, CHPSO, at rjaffe@chpsso.org or (916) 552-7568, or Alyssa Keefe, vice president federal regulatory affairs, CHA, at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/S/
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Vice President Federal Regulatory Affairs
California Hospital Association

/S/
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CC: William Munier, MD, MBA, Agency for Health Care Research and Quality