

Qualified Health Plans: CMS Maintains Commitment to PSOs and January 1, 2017 Participation Deadline in Proposed Rule

On November 20, 2015, CMS released a [Proposed Rule](#)¹ that significantly impacts Patient Safety Organizations (PSOs) and hospitals with more than 50 beds. The PSO community has closely watched CMS' interpretation of Section 1311(h) of the Affordable Care Act, which initially required hospitals with more than 50 beds to meet certain patient safety standards by January 1, 2015 in order to contract with insurers that sell Qualified Health Plans in Federally-facilitated Exchanges (QHP Issuers). Included in these standards is a requirement for a comprehensive hospital discharge program and use of a Patient Safety Evaluation System (PSES), which means the collection, management, or analysis of information for reporting to or by a PSO.²

Phase 1

In March of 2014, [CMS codified 42 C.F.R. § 156.1110](#), delaying the PSES compliance deadline until at least January 1, 2017. In the interim, CMS has permitted QHP Issuers to contract with hospitals with greater than 50 beds if the hospital is either Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN). CMS deemed this interim period as "Phase 1" but made clear its intent to issue "Phase 2" regulations after reassessing PSO development and the Health Exchange market.³

Phase 2

On November 20, 2015, CMS issued the Proposed Rule that addresses benefit and payment parameters for 2017, including patient safety standards for QHP Issuers. For plan years beginning on or after January 1, 2017, the Proposed Rule would require QHP Issuers to verify that their contracting hospitals with greater than 50 beds comply with patient safety standards in one of two ways:

- (1) By utilizing a PSES as defined in 42 C.F.R. § 3.20 and implementing a mechanism for comprehensive person-centered hospital discharge to improve care coordination and healthcare quality for each patient;

or

- (2) By implementing evidence-based initiatives to reduce all cause preventable harm, prevent hospital readmissions, improve care coordination, and improve healthcare quality through the collection, management, and analysis of patient safety events.

If finalized, QHP Issuers must document that their contracting hospitals comply with the above patient safety standards. The Proposed Rule suggests this may be accomplished by QHP Issuers maintaining a copy of the hospital's participation agreement with a PSO under approach 1, or a copy of the hospital's participation agreement with a Hospital Engagement Network (HEN)⁴ or Quality Improvement Organization (QIO)⁵ under approach 2. CMS indicates that it "expects" that hospitals will opt for participation with PSOs, but it seeks to recognize the broad

¹ The Proposed Rule is scheduled to be published in the Federal Register on December 2, 2015, at which time it will be available at <https://www.federalregister.gov/articles/2015/12/02/2015-29884/patient-protection-and-affordable-care-act-benefit-and-payment-parameters-for-2017>.

² 42 C.F.R. § 3.20.

³ 79 Fed. Reg. 13814 (Mar. 11, 2014).

⁴ HENs work at the regional, State, national, or hospital system level to help identify solutions already working and disseminate them to other hospitals and providers. There are currently 17 HENs nationwide. See <https://partnershipforpatients.cms.gov/about-the-partnership/aboutthepartnershipforpatients.html>.

⁵ QIOs are groups of health quality experts, clinicians, and consumers organized to improve the care delivered to Medicare beneficiaries by reviewing providers' quality concerns and offering solutions to improve quality. See <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs/>.

impact that HENs and QIOs are making to reduce patient harm by offering an alternate path to compliance with Section 1311(h). Although it offers this alternative, CMS indicates that it will “continue to monitor the status of the PSO program and other patient safety initiatives and will develop additional requirements or guidance, if needed, to support effective patient safety strategies and harmonization of evidence-based standards and requirements.”⁶ It should also be noted that the Patient Safety and Quality Improvement Act’s privilege and confidentiality protections would not extend to providers who elect to participate in a HEN or QIO instead of a PSO.

Notably, CMS did not propose to delay the January 1, 2017 compliance deadline or the 50-bed threshold. If hospitals wish to comply via participation with a PSO, they will need to begin working fairly quickly towards either participation with a PSO or creation of their own PSO. CMS also included language touting the benefits of [AHRQ’s Common Formats](#), which provide common definitions and reporting formats to help providers uniformly report patient safety events nationwide. There is no proposed requirement for PSOs to implement Common Formats, but CMS clearly favors their use and announced that AHRQ anticipates a release of “Common Formats Version 2.0” in the future.

CMS will accept comments on the Proposed Rule through December 21, 2015. If you would like assistance in commenting on the Proposed Rule, evaluating your options for compliance with Section 1311(h), or if you have questions regarding PSO formation, strategy, or participation, please contact B. Page Gravely, Jr. (pgravely@hdjn.com), Molly A. Huffman (mhuffman@hdjn.com), or Andrew G. Schutte (aschutte@hdjn.com) by email or phone at (866) 967-9604. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm’s website at www.hdjn.com.

⁶ See <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-29884.pdf> at p.247.

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