September 8, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1631-P
P.O. Box 8013
Baltimore, MD 21244-8013

[Submitted online at: http://www.regulations.gov/#!documentDetail;D=CMS-2015-0081-0002]

Re: CMS-1631-P QCDR Reporting Options and Requirements under the PQRS

Dear Administrator Slavitt:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) are writing to comment on the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016” proposed rule regarding the reporting options and requirements for qualified clinical data registries (QCDRs) under the Physician Quality Reporting System (PQRS).\(^1\) The Coalition is a group of more than 20 medical societies and other physician-led organizations that sponsor clinical data registries that collect identifiable patient information for quality improvement purposes to help participating providers monitor clinical outcomes among their patients. We are committed to advocating for policies that enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of such outcomes. Over half the members of the Coalition have qualified as QCDRs and most of the others are working toward that goal.

The Coalition commends the Centers for Medicare & Medicaid Services (CMS) for its continued dedication to promoting quality of care through the PQRS and other quality incentive programs. We also welcome this opportunity to comment on the proposed changes in the CY 2016 Physician Fee Schedule that implicate QCDRs under the PQRS. In particular, this Comment asks that CMS 1) allow QCDRs to report on PQRS measures groups, 2) remove the requirement that eligible professionals (EPs) using QCDRs report on 50 percent or more of patients from all patients.

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payers, not just Medicare, and 3) allow QCDRs more flexibility in developing evidence-based sampling strategies for QCDR-specific measures.

This Comment also addresses CMS’ proposal to require vendors submitting quality data measures under the PQRS to retain all data submitted to CMS for a minimum of seven years, and the proposal that seems to require QCDRs to collect documentation from EPs as the method of verifying the accuracy of Tax Identification Numbers (TINs) and National Provider Identifiers (NPIs). Both of these requirements are unduly burdensome to QCDRs and seem unnecessary for PQRS reporting purposes.

1. CMS Should Allow QCDRs to Report on PQRS Measures Groups and Eliminate the Requirement that EPs Using QCDRs Report on 50 Percent of Patients from All Payers

In 2012, Congress directed CMS to adopt a QCDR reporting option for the PQRS under the American Taxpayer Relief Act (ATRA) of 2012 (codified at section 1848(m)(3)(D) of the Social Security Act, 42 U.S.C. § 1395w-4). In implementing this directive, CMS promulgated a rule allowing an EP to satisfactorily participate in the PQRS for purposes of avoiding the 2017 payment adjustment if the EP reports on nine QCDR measures across three NQS domains for at least 50 percent of the EP’s patients, across all payers. Unlike other reporting options, QCDRs may report on up to 30 non-PQRS measures, enabling specialist EPs to qualitatively participate in the PQRS when there otherwise might be few measures they can report.

The Coalition supports continued use and expansion of the QCDR reporting option as part of the PQRS. Currently, however, QCDRs are only allowed to report on individual measures instead of measures groups. By contrast, EPs can report on measures groups through PQRS qualified registries. Measures groups are defined in the PQRS rule at 42 CFR § 414.90 as “a subset of six or more PQRS measures that have a particular condition or focus in common.” For qualified registries, measures groups address the reporting needs of specialty EPs by allowing them to create a composite set of measures specific to a condition or specialty that an EP may report in lieu of selecting individual measures. EPs that report on a measures group as opposed to individual measures need only report on one measure group for a twenty-(20)-patient sample, the majority of which must be Medicare Part B fee-for-service patients, for a twelve-month reporting period.

The Coalition supports CMS’ proposal to maintain the measures group reporting requirements for the 2018 PQRS with respect to PQRS qualified registries. However, the measures groups reporting option, as currently written, should be extended to EPs participating in the PQRS through QCDRs. EPs using the QCDR reporting option should also be able to report on a single measure group, instead of just through individual measures. Allowing QCDRs to report on measures groups would be less burdensome and would also align two PQRS reporting options for specialty EPs to enable them to participate in the PQRS in a way that is targeted to their specialty so they can best demonstrate the quality of care they provide. The Coalition therefore respectfully requests that CMS expand the measures group reporting option so that EPs reporting...
through QCDRs may receive credit for reporting individual measures or through measures groups.

In addition, the Coalition requests that CMS remove the requirement that EPs reporting through QCDRs report on at least 50 percent of patients across all payers, and instead limit the requirement to reporting on just Medicare patients. QCDRs are currently the only reporting mechanism in the PQRS that must satisfy this requirement, which can lead to confusion for EPs, particularly given that PQRS qualified registries only need to report measures for 50 percent of all Medicare patients. To better align the PQRS reporting requirements, the Coalition respectfully requests that CMS change this requirement for QCDRs.

In addition, the Coalition requests that CMS allow QCDRs more flexibility to define evidence-based sampling strategies as part of the development of QCDR-specific quality measures. This change would allow QCDRs to report a larger variety of measures to CMS and more measures related to patient-reported outcomes and patient satisfaction consistent with consumer demand.

2. CMS’ Proposal that Appears to Require QCDRs to Collect Documentation to Validate TINs and NPIs Is Burdensome and Unnecessary

For the 2018 PQRS payment adjustment, CMS proposes to require QCDRs to include a list of specific requirements as part of the data validation strategy for verifying the accuracy of EP data that QCDRs must submit to CMS. These requirements would include an indication of “the method the entity will use to verify the accuracy of each [TIN] and [NPI] it is intending to submit (that is, National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation).”\(^2\) CMS appears to expect QCDRs to collect NPI and tax documentation from EPs to satisfy this requirement. Previously, CMS has only requested that QCDRs adopt this method as part of a satisfactory validation strategy submitted to CMS outlining how it intends to verify that each EP has successfully met individual measures and that their data are true, accurate and complete.\(^3\)

The Coalition asks CMS to clarify whether in specifically asking for information on the method QCDRs use to verify the accuracy of each TIN and NPI, the agency is also asking QCDRs to collect NPI and tax documentation as the exclusive means of verifying a provider’s NPI and TIN. The Coalition finds this requirement as currently written to be unclear and would oppose any requirement that QCDRs collect EP NPI and tax documentation as part of a data validation strategy. Provider verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements.

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\(^2\) 80 Fed. Reg. at 41818.
3. CMS’ Proposal to Require All Data Submission Vendors to Retain Data Submitted for at Least Seven Years Is Burdensome and Unnecessary

For the 2018 PQRS payment adjustment, CMS proposes to require all entities submitting PQRS quality measure data also to submit the contact information of each EP and in addition “retain all data submitted to CMS for the PQRS program for a minimum of seven years.”\textsuperscript{4} CMS has previously only required vendors to retain “signed documentation that each holder of an NPI whose data are submitted to the qualified clinical data registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on beneficiaries to CMS for the purpose of PQRS participation.”\textsuperscript{5} Requiring vendors, including QCDRs, to submit EP contact information is burdensome and unnecessary given that CMS already maintains contact information for each EP participating in the PQRS, and QCDRs often do not have the required contact information for individual EPs.

In addition, requiring vendors to retain all data submitted as part of the PQRS for seven years is particularly burdensome given the nature of how this data is actually stored. For example, if a data storage vendor is bought or sold, a QCDR would have to reevaluate whether it wants to keep data with the new vendor or coordinate the transfer of the data to a different entity, a scenario that is more likely to occur in a seven-year time frame. Alternatively, if a QCDR uses a distributive model registry instead of storing data in a single location, the storage of the PQRS data for seven years could become that much more complex and difficult to manage. The seven-year data retention time frame is too long given the potential for these changes in ownership and the nature of how data is actually stored.

CMS’ proposed data retention requirement imposes a greater burden than other data retention requirements under federal law. HIPAA, for example, merely requires that covered entities maintain documentation such as policies and procedures for six years and does not impose data retention requirements for protected health information. Likewise, the look-back period for Medicare recovery audits is only three years from the date a claim is paid. CMS’ current proposal for PQRS data to be retained for seven years is out of step with these other federal laws. For these reasons, the Coalition respectfully requests that CMS reduce the data retention requirement to a more manageable time frame of three years.

Conclusion

The Coalition appreciates this opportunity to comment on the proposed CY 2016 Physician Fee Schedule Rule, particularly as it pertains to the need for flexibility in reporting options for QCDRs, and the burdensome and unnecessary proposed TIN and NPI verification and records retention requirements for QCDRs and other vendors. We encourage CMS to expand the data reporting option for QCDRs and reconsider its proposals regarding TIN/NPI validation and the

\textsuperscript{4} 80 Fed. Reg. at 41819.
\textsuperscript{5} 78 Fed. Reg. at 74469.
seven-year data retention requirement. Questions regarding this comment may be submitted to Robert Portman via email at rob.portman@ppsv.com or telephone at (202) 872-6756.

Sincerely,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
AMERICAN ACADEMY OF OPHTHALMEOLOGY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN JOINT REPLACEMENT REGISTRY
AMERICAN COLLEGE OF SURGEONS
ANESTHESIA QUALITY INSTITUTE/AMERICAN SOCIETY OF ANESTHESIOLOGISTS
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
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