Lantana
CONSULTING GROUP

October 30, 2015

To: Centers for Medicare & Medicaid Services, Department of Health and Human Services

RE: Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models (80 FR 59102, "the October 1 RFI")

To whom it may concern:

Lantana Consulting Group (Lantana) appreciates the opportunity to comment on the **Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models.** Our comments focus on those areas of particular relevance to our expertise with Health Level Seven (HL7) Clinical Document Architecture (CDA), Consolidated Clinical Document Architecture (C-CDA), Quality Reporting Document Architecture (QRDA), and the National Quality Forum Quality Data Model.

Lantana's work focuses on interoperability where we see specifications not as an end in and of themselves, but as a means to an end — that end being a data-driven healthcare system. Lantana's mission is to transform healthcare through health information. Lantana principals and employees have served as primary authors for CDA, Continuity of Care Document (CCD), C-CDA, QRDA, and electronic Clinical Quality Measure (eCQM) specifications.

Lantana would like to offer suggestions for your consideration on the questions related to the **Quality Performance Category** (Section II.A.3).

A. Reporting Mechanisms Available for Quality Performance Category

Should we maintain all PQRS reporting mechanisms noted above under MIPS? If so, what policies should be in place for determining which data should be used to calculate a MIPS EP's quality score if data are received via multiple methods of submission? What considerations should be made to ensure a patient's data is not counted multiple times? For example, if the same measure is reported through different reporting mechanisms, the same patient could be reported multiple times.

Comment:

We understand there are challenges to aligning reporting mechanism such as differing measure lists, varied measure formats (e.g., eCQM vs. paper-based), and multiple reporting specifications (e.g., QRDA vs. QCDR XML). We recommend a short-term/long-term and approaches. Once the short-term approach is addressed, the long-term road could be implemented.

In the short-term, continue to allow individual eligible professionals (EPs) and group practices to use multiple mechanisms for reporting. During the short-term, develop reporting criteria that standardize the number of measures needed in the performance scoring process. These measures should represent information across multiple quality domains, including a minimum number of outcomes-based measures, and should remove reporting redundancies.

In the long-term, consider using fewer acceptable reporting mechanisms to create simple and efficient processes that align reporting mechanisms to the measures and reduce the chance for patient data to be counted multiple times.

Harmonizing reporting mechanisms and measures will reduce the burden on participating providers and will standardize the quality data received from multiple reporting mechanisms.

Should we require that certain types of measures be reported? For example, should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?

Comment: We recommend increasing the number of outcomes-based measures rather than process measures. In the short-term, assigning more weight to outcomes-based measures is reasonable. Consider setting a minimum number of outcomes-based measures to be developed per year for EPs and for specialties that lack outcomes-based measures.

Should we require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender?

Comment: Yes. EPs reporting quality measures under the CMS EHR Incentive Programs for Meaningful Use are required to report with QRDA (I and III) which support stratification. Standardizing on QRDA across programs will support uniform stratification.

B. Data Accuracy

What should CMS require in terms of testing of the qualified registry, QCDR, or direct EHR product, or EHR data submission vendor product? How can testing be enhanced to improve data integrity?

Comment: Testing and validation can be improved across the submission process. We see room for improvement in each of these areas:

- All submission standards must be defined with sufficient rigor to support automated validation using scripts and readily available tools as well as custom solutions.
- Test scripts and cost-free validation tools that correspond to submission standards and reflect CMS internal test requirements must be accessible by all stakeholders during system design and development.
- CMS should require that files are validated before submission, regardless of the sender. Senders are advised to validate at the source to improve data integrity.
- CMS should create a qualifications review that includes a requirement to validate files on receipt and reject files that do not pass validation.
- CMS should provide education, training, and FAQs on the validation tools and processes.

CMS should consider reviewing existing data submitted. This review may identify the causes of bad data and gaps in the submission process. For example, the XML specifications (e.g., QRDA, registry XML specification, etc.) may need to be tightened and validation rules and checking mechanisms may be needed during key parts of the submission process.

Should registries and qualified clinical data registries be required to submit data to CMS using certain standards, such as the Quality Reporting Document Architecture (QRDA) standard, which certified EHRs are required to support?

Comment: Yes. Data standards reduce data integrity problems by providing a consistent and automated means to extract data. Creation of validation tools that aligns with data standards improves the quality of data submitted. We recommend:

- Harmonization and standardization of reporting mechanisms, including standardizing the reporting format for registries and Qualified Clinical Data Registries (QCDRs). Registries and QCDRs are using their own XML specifications, which adds to the burden on providers, on system developers, on IT staff, and adds challenges to sharing and reusing data submitted through multiple mechanisms.
- Incorporation of QRDA into registry and QCDR requirements as the single reporting standard. Some of the measures used by registries and QCDRs are paper-based; these may pose challenges to using QRDA unless they are retooled as eCQMs.

Should CMS require that qualified registries, QCDRs, and health IT systems undergo review and qualification by CMS to ensure that CMS' form and manner are met? For example, CMS uses a specific file format for qualified registry reporting. The current version is available at: https://www.qualitynet.org/imageserver/pqrs/registry2015/index.htm. What should be involved in the testing to ensure CMS' form and manner requirements are met?

Comment: Yes. We recommend a three-part approach for review and qualification so CMS can ensure form and manner of reporting are acceptable:

- Evaluate registry data for conformance to the Registry XML specification and the QCDR XML specification.
- Identify common error types found in the historic data. This will provide guidance for development of requirements.
- Develop for registries and health IT systems a pre-submission evaluation tool that validates the file format and submission requirements. If this tool allows a system to perform an automated test, the burden for the vendors will decrease.

What feedback from CMS during testing would be beneficial to these stakeholders?

Comment: We recommend aligning testing with submissions to produce:

- Meaningful error messages to pinpoint specific data issues
- A list of common errors (those identified during review of historic data) and solutions

What thresholds for data integrity should CMS have in place for accuracy, completeness, and reliability of the data?

Comment: Accuracy, reliability, and completeness should be rigorous to eliminate cheating. Inaccuracy should be grounds for rejection.

For example, if a QCDR's calculated performance rate does not equate to the distinct performance values, such as the numerator exceeding the value of the denominator, should CMS re-calculate the data based on the numerator and denominator values provided?

Comment: CMS should reject submissions with gross errors. Gross errors are easy to detect before submission and the data provider should resolve these prior to submission.

Should CMS not require MIPS EPs to submit a calculated performance rate (and instead have CMS calculate all rates)? Alternatively, for example, if a QCDR omits data elements that make validation of the reported data infeasible, should the data be discarded? What threshold of errors in submitted data should be acceptable?

Comment:

- No. CMS should require submission of performance rate. It's an easy calculation.
- Yes. Data should be discarded.
- Obvious errors such as the numerator exceeding the denominator should be unacceptable.

If CMS determines that the MIPS EP (participating as an individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet our data integrity standards, how should CMS assess the MIPS EP when calculating their quality performance category score? Should there be any consequences for the qualified registry, QCDR or EHR vendor in order to correct future practices? Should the qualified registry, QCDR or EHR vendor be disqualified or unable to participate in future performance periods? What consequences should there be for MIPS EPs?

Comment: CMS should develop a "3-strikes" data integrity policy. CMS would temporarily disqualify a MIPS EP who struck out or consider other penalties to encourage data integrity.

C. Use of Certified EHR Technology (CEHRT) Under the Quality Performance Category

Under the MIPS, what should constitute use of CEHRT for purposes of reporting quality data?

Comment: We recommend that MIPS use the same CEHRT reporting mechanisms as PQRS.

Instead of requiring that the EHR be utilized to transmit the data, should it be sufficient to use the EHR to capture and/or calculate the quality data? What standards should apply for data capture and transmission?

Comment: QRDA I and III should be used for transmission, eventually switching to FHIR-based standards. We recommend better alignment of the standards for data capture with the quality reporting standards. We do not recommend a standard for data capture – data capture should be responsive to user demands for ease of use and workflow support, it is an area ripe for innovation and disruption and should not be constrained by government requirements, as long as the required data can be transmitted in standard form.

Thank you for the opportunity to respond to this RFI. Please let us know if you have any questions regarding our suggestions.

Sincerely,

Liora Alschuler, Chief Executive Officer