Consumer-Purchaser
DISCLOSURE PROJECT
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April 8, 2013

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore MD, 21244

RE: CMS-3276-NC: Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs

Dear Ms. Tavenner:

The Consumer-Purchaser Disclosure Project represents a collaboration of leading consumer, labor, and employer organizations committed to improving the quality and affordability of health care through the use of performance information to inform consumer choice, provider payment, and performance improvement. We appreciate the opportunity to respond to the Request for Information (RFI) on the use of non-federal qualified clinical data registries in federal reporting programs for eligible professionals (EPs). In addition, we are including comments on the implementation of section 601(b) of the American Taxpayer Relief Act of 2012, which allows for physicians who are successful participants in clinical registries to also be considered successful participants in the PQRS program.

Electronic clinical registries are typically used by clinicians to manage patients with chronic conditions or, in surgical specialties, to benchmark performance against their peers. In addition to their role in care management and quality improvement, registries can serve as a rich source of data for performance measures in accountability programs, such as public reporting and payment. Below are key criteria that should guide the use of registries in federally-sponsored accountability programs to ensure that they meet the needs of consumers and purchasers. We strongly believe **program sponsors of accountability programs (e.g., CMS and other purchasers/payers) should retain responsibility for determining the qualifying criteria** to protect against the inherent conflict of interest of those registries that are sponsored by representatives of participants in those programs. These criteria should address the

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following areas: performance measures, data quality and interoperability, accountability and quality improvement, and other requirements.

Performance Measures

Measures that are used in accountability programs should include those that are relevant and meaningful to purchasers and consumers. Specifically, accountability programs should include measures that assess appropriateness, clinical and patient-reported outcomes, patient safety, patient experience, coordination of care, and cost and resource use. For more information, refer to *Ten Criteria for Meaningful and Usable Measures of Performance*. Additionally, NQF endorsement should be preferred for measures used in accountability programs in order to ensure that the measures meet national standards and have been approved through a nationally recognized multi-stakeholder consensus process. Furthermore, registries can also serve as test beds for innovative measures prior to NQF submission and endorsement if the measures are developed by trusted entities such as NCQA, Minnesota Community Measurement, or professional organizations with advanced clinical registries. And registries may contain a mix of measures that include some measure that are useful for quality improvement and care management but are not suitable for accountability.

Data Quality and Interoperability

First and foremost, data should be accurate and complete. Having quality controls, including a validation process, is important to ensuring data integrity. Second, registries should electronically interface with other data sources, including both EHRs and other sources of data not included in the EHR (e.g., imaging, product bar code, other settings); they should also be able to transmit data electronically to third parties (e.g., vendors, CMS). For instance, a surgeon's private practice EHR may not be integrated with the EHR at the hospital where she practices, but both the surgeon's and hospital's EHRs can supply data to the registry. **A critical element of this requirement is for EHR vendors to adopt the data and interoperability standards being developed by ONC/HHS**. Additionally, registries should use standards for common data elements, such as LOINC codes for laboratory data and NCPDP standards for pharmacy data. Finally, **the denominator populations for registry-produced measures should include all clinically relevant patients under the provider's care, regardless of insurance status.** Once the provider is using an EHR and that EHR is able to transmit data electronically to the registry, there is no reason why they should not be submitting data on all their patients.

Accountability and Quality Improvement

Registry-based measures can be important tools not solely for research and quality improvement, but also for holding EPs accountable by linking the measures to public reporting and payment programs. However, **accountability programs should not give credit (i.e. financial incentives) for participation**

alone, except as a temporary step in a staged process. A possible staging scheme for reaching full accountability (payment and public reporting) might be as follows:

- Stage 1: Physicians and other providers get credit for participation if they 1) submit data on a substantial proportion of their patients to the registry and 2) if the registry provides data back to the provider that can be used for improvement and care management.
- Stage 2: Once the registry has sufficient data, it privately reports measures at the individual clinician, small practice group, and/or hospital levels against benchmarks. Registry permits EPs to publicly report their performance if they so choose.
- Stage 3: Registry publicly reports the performance measures of interest to consumers and purchasers at the individual clinician, small practice group, and hospital levels for all the relevant participants.

Clinicians from a technical specialty, e.g., proceduralists, should not get credit for group performance. To meet consumer and purchaser needs, they should be required to report at the individual clinician level. Additionally, numerators and denominators for accountability measures should be made publicly available to facilitate use in multiple programs (e.g., regional public reports), not just those that are federally based.

Registries should have a commitment to performance improvement – not just to performance measurement. Registries should therefore have a process for timely communication of results to support care management and improvement. We also believe that using registry measures in accountability programs will enhance the priority and pace of improvement.

Other Requirements

Registries used for accountability should meet certain other requirements, including:

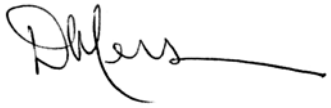
- Governance by a multi-stakeholder board that includes meaningful representation by consumers and purchasers.
- Demonstration of organizational stability, maturity and achievement (e.g., in existence for a minimum number of years, established infrastructure).
- Adequate penetration of potential participant population, e.g., X% of EPs already submitting data to the registry.
- Transparent as to purpose and sponsorship of registry, governance, size, data handling capabilities, success with QI, etc.
- Evidence of reasonable fees that are used only to cover the costs of maintaining the registry.

Furthermore, qualified registries should not be limited to national registries operated by professional societies. This would preclude other entities such as strong local/regional registries and regional reporting and improvement collaboratives from participating.

In closing, qualification of registries for use in payment and public reporting accountability programs should be guided by the above criteria to ensure that they meet the needs of consumers and purchasers**.** Failure to do so would undermine the very intent of such accountability programs. In the appendix, we respond to specific questions asked in the RFI. Most of those answers reflect our comments above, but in some places include more specific information.

We appreciate the opportunity to respond to this RFI and look forward to continuing to engage with you on this important issue. If you have any questions, please contact either one of us.

Sincerely,



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Appendix

High-level questions	
Question	**Response**
Are there examples of other non-federal programs under which eligible professionals report quality measures data?	There are many non-federal quality reporting programs that go well beyond the reporting requirements for PQRS and Meaningful Use, such as those sponsored by Wisconsin Collaborative for Healthcare Quality, Minnesota Community Measurement, and California Joint Replacement Registry. This is an excellent opportunity to raise the bar for federal programs and reward advanced programs while reducing the collective effort for participation by "deeming" high quality registry programs. This also presents an opportunity to drive a higher bar in non-federal programs since many are interested in being qualified.
What would be the benefits and shortcomings involved with allowing third-party entities to report quality data to CMS on behalf of physicians and other eligible professionals?	The potential benefits include: more efficient data collection and reporting processes, leaving more time for improvement; an efficient and effective method for CMS to engage a significant pool of EPs, a challenge of PQRS; and it could provide a partner for testing and refining measures prior to NQF endorsement. Furthermore, third-party entities are likely able to extract data from EHRs and electronically report the data for all the EP's patients, not just a sample. By including all patients, performance measures would become more accurate and could be reported at a more granular level, e.g., at the individual clinician level. A successful model of using third party entities is in the hospital setting; QualityNet provides data to both CMS and The Joint Commission.
What entities have the capacity to report quality data similar to those reported under the PQRS, Value-based Payment Modifier, and/or EHR Incentive programs? If these entities were to report such data to CMS, what requirements should we include in the reporting system used by such entities, including requirement to ensure high quality data?	In principle, any entity that is organized by a physician specialty organization or a multi-stakeholder regional reporting/improvement collaborative could have this capacity. Essential requirements for performance measures, data quality and interoperability, accountability and quality improvement, and others are included in the body of the cover letter.

How should our quality reporting programs change/evolve to reduce reporting burden on eligible professionals, while still receiving robust data on clinical quality?	These CMS programs have generally not been robust drivers of quality improvement, despite the fact that many have been in effect for quite a few years. We believe that after a year of internal reporting, a measure should be a candidate for accountability. Both PQRS and Meaningful Use have been slow in ramping up their performance reporting. For example, since 2007 PQRS has only required individual participants to report on three measures of their own choice, many of which lack evidence of improving outcomes. Use of already established registries is likely to reduce the burden of data collection for EPs. However, when discussing the effort required to collect measures, there should be a broader focus on costs and benefits. Some measures drive greater improvement, and thus are worthy of more effort required to collect them. Additionally, there is rarely discussion of the burden placed on consumers and purchasers who must make important decisions without meaningful information.

Questions regarding reporting requirements for entities that report via a registry under the PQRS for 2014 and subsequent years or the EHR Incentive Program if registry reporting is established as a reporting method for that program in future years	
Question	**Response**
What types of entities should be eligible to submit quality measures data on behalf of eligible professionals for PQRS and other EHR Incentive Program? What qualification requirements should be applicable to such entities?	The focus should not be on the type of entity, but rather any entity that is capable and agrees to abide by a set of requirements to participate. Qualification requirements should include those outlined in the body of the cover letter and described below.
What functionalities should entities qualified to submit PQRS quality measures data possess?	Qualified entities should demonstrate the following minimum requirements in the first year of the program: multi-stakeholder governance; infrastructure for electronic patient-level data collection/storage, ability to conduct measure calculation, ability to undergo audit/validation, ability to integrate data from other sources, ability to transmit data electronically, and commitment to public reporting. In addition, some level of ONC certification is important to ensure standardization across qualified entities.

What criteria should we require of entities submitting quality measures data to us on behalf of eligible professionals?	1. Demonstration that they can meet the functionalities listed above 2. Requirements for timeliness of data – e.g., data complete for prior quarter within X days of close of quarter 3. Ability to maintain data security and integrity 4. Agreement to undergo data audits
Should reporting entities be required to publicly post performance data?	Yes, reporting entities should be required to publicly post performance data. Additionally, specialists should be required to report individual clinician results, although not necessarily in the first year if a reliability threshold (due to sample size) is not met.
Should we require an entity to submit a yearly self-nomination statement to participate in PQRS?	CMS should annually review the performance of the entities that are approved, but should use a streamlined process for renewal that is not unnecessarily burdensome.
Should data submission timelines for these reporting entities be modified so that the submission timeframes for these quality reporting programs are aligned? How much time are reporting entities outside of PQRS afforded to submit quality measures data? What challenges do reporting entities face in reporting data according to current timeframes?	A key objective for CMS should be use of reporting entities to streamline reporting for PQRS and the EHR Incentive Program. These entities should have the capability to gather and report a full range of data/measures to CMS electronically. Furthermore, they should be able to meet reasonable timelines, e.g., data complete for prior quarter within X days of close of quarter. Those that have this capability should be able to meet any reasonable timeline established by CMS.
What oversight should be in place to ensure that data is submitted and calculated properly by entities?	Entities should be required to undergo a thorough audit for data integrity and measure coding prior to approval. Thereafter, a less intensive audit should be required on a periodic basis.

Questions regarding selection of measures related to registry reporting under PQRS for 2014 and subsequent years and for the EHR Incentive Program if registry reporting is established as a reporting method for that program in future years	
Question	**Response**
Should we require that a certain proportion of submitted measures have particular characteristics such as being NQF-endorsed or outcome- based?	The primary requirement should be for information that would enable CMS and the general public to identify high-value providers within specific clinical specialty areas. The measures should therefore be consumer and purchaser-relevant and should include appropriateness, patient safety, clinical and patient-reported outcomes, patient experience, coordination of care, and cost and resource use. Additionally, NQF endorsement is preferred for measures used in accountability programs.
Should we require that the quality measures data submitted cover a certain number of the six national quality strategy domains?	We agree that CMS should require performance measures that cover all six national quality strategy domains. This contributes to understanding the breadth of the provider's performance.
To what extent would third-party entities struggle to meet reporting for measures currently available under PQRS and the EHR Incentive Program?	To be a qualified entity, an organization should be able to demonstrate that is does not have difficulty reporting the current measures. At the same time, those with strong electronic interchange capabilities with EHR-enabled EPs should be able to report a more robust set of clinical quality measures than currently required by these CMS programs.

Questions regarding registry measures reporting criteria	
Question	**Response**
How many measures should an eligible professional be required to report to collect meaningful quality data? If we were to align reporting criteria with reporting requirements for other non-federal reporting programs, in future years, should we propose to require reporting on a different number of measures than what is currently required for the PQRS in 2013 and the EHR Incentive Program under the Stage 2 final rule, or should the non-federal reporting programs align with CMS criteria?	CMS should step up its requirements for EP performance reporting. Eventually, we expect to see a comprehensive set of measures collected and reported by these federal programs. It is not the number of measures that is important, but rather whether the measures collectively are an adequate reflection of the EP's performance. The measure set should be parsimonious—e.g. reporting composite measures rather than individual process measures. But the measure set should also be comprehensive in its inclusion of measures in the categories of highest importance to consumers and purchasers, such as appropriateness, patient safety, clinical and patient-reported outcomes, patient experience, coordination of care, and cost and resource use. From an effort standpoint, the number of measures is less relevant when using EHRs or other electronically available data to populate the registry. Currently, some non-federal reporting programs are more robust than the federal reporting programs. Rather than lowering the standards for non-federal reporting programs, the federal programs should raise their standards to better align with the non-federal programs.
For PQRS, should eligible professionals still be required to report quality measures data on a certain percentage of their applicable patients, or should we require that eligible professionals report on a certain minimum number of patients rather than a percentage?	CMS should raise its standards for PQRS in recognition of EPs who have adopted electronic health records. Those EPs should be able to report data based on <u>all</u> their patients who meet denominator criteria, and CMS should tighten its requirements accordingly. By eliminating sampling, CMS would ensure that reporting is unbiased and, in some areas at least, sufficiently robust to enable accurate reporting at the individual clinician level.