Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3276-NC
Mail Stop S3–02–01
7500 Security Boulevard
Baltimore, Maryland  21244-1850

April 8, 2013

Via Electronic Mail & Overnight Mail

Re: CMS-3276-NC Medicare Program: Request for Information (RFI) 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

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments to CMS regarding the “Request for Information (RFI) 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” published on February 7, 2013 in the Federal Register.

AdvaMed supports CMS’s efforts to improve the quality of health care in the United States and welcomes the opportunity to provide recommendations on the use of clinical quality measures (CQMs). As health care delivery systems are dynamically evolving, we are aware of the increasingly complex nature of measuring quality accurately and providing this information so that it is non-biased, relevant and accurate.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed’s members produce the majority of the health care technology purchased annually in the United States and a significant share purchased annually around the world. AdvaMed members
range from the largest to the smallest medical technology innovators and companies. AdvaMed has a longstanding interest and engagement in healthcare quality improvement issues. AdvaMed is a member of the National Quality Forum (NQF) and is an active participant in the NQF-convened Measure Applications Partnership, AQA Alliance, the AMA’s Physician Consortium for Performance Improvement (PCPI), and other coalitions and organizations seeking to improve health care quality.

AdvaMed is committed to the principles of evidence-based medicine. Patients, providers, manufacturers and other stakeholders share an interest in taking steps to ensure that there is adequate and accurate information to guide health decision-making concerning the effectiveness of medical interventions. Registries are one mechanism that may be appropriate for gaining additional information about medical interventions and if designed and executed properly, can provide useful information about pre-defined clinical questions. AdvaMed supports efforts to allow doctors to opt out of other quality-reporting requirements if they participate in an approved registry. AdvaMed has the following comments and recommendations regarding the following specific questions put-forth in the Request for Information regarding 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:

**General Comments:**
AdvaMed supports section 601 (b) of the American Taxpayer Relief Act of 2012, which provides for treating an eligible professional (EP) as satisfactorily reporting data on quality measures if the EP is satisfactorily participating in a qualified clinical data registry.¹ Allowing doctors to substitute participation in an approved registry for other quality-reporting requirements will encourage doctors and other providers to participate in registry data gathering. In addition, numerous medical specialty groups, providers and industry already utilize or plan to develop clinical-data registries; and the PQRS itself has evolved to offer multiple reporting mechanisms, including registries for purposes of reporting PQRS quality measures data. The number of eligible professionals that participate in PQRS via registry reporting has continued to increase over the past several years. This is especially important since, as mentioned in the RFI, eligible professionals using the registry-based reporting mechanism, historically have been more successful at meeting the criteria for satisfactory reporting of the PQRS data than through the claims-based reporting mechanism. Responses to specific questions follow.

**Question:** What requirements should be included in the reporting system used by entities, including requirements to ensure high quality data?

**Recommendation:** Ensuring the capture of high quality accurate data is essential to the success of reporting clinical quality data via registries. Registries must comply with all research ethics, applicable laws and regulatory requirements including those governing

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¹ A “qualified clinical data registry” as established by the Secretary must provide mechanisms for transparency of data, risk models, and measures; requires submission of data with respect to multiple payers; provides timely performance reports to participants at the individual level; and supports quality improvement initiatives.
data privacy and informed consent. It is essential that patient privacy be protected by this process which includes linking of databases.

All confidential manufacturer, physician, and hospital data must be safeguarded. To this end, AdvaMed recommends that each entity have a “data governance committee” that is responsible for all details concerning data submission, validation of data and data integrity and security. In addition, CMS should encourage standardization of data elements and definitions for the registries by providing a framework of certain elements to be included, leaving some of the more disease-specific detailed data elements up to the individual registries. CMS can also review the criteria of their registry qualification process on a periodic basis to account for changes, recommendations and future feedback. These recommendations will help to ensure that that registries and electronic health records can function in harmony.

AdvaMed believes that it is important to have standards and transparency in terms of methodology for data statistical analysis and reporting. Furthermore the follow-up compliance rate and completeness should be taken in to consideration to produce meaningful reports. AdvaMed also recommends that all qualified clinical data registries, which collect data on the same clinical procedures, use the same risk-adjustment model to the maximum extent practicable, but still allow eligible registries to employ varying risk-adjustment methods to glean the most meaningful data from the registry. Also, entities need to ensure that the risk-adjustment of registry data is appropriate and validated prior to public reporting.

**Question:** What types of entities should be eligible to submit quality measures data on behalf of eligible professionals for PQRS and the EHR Incentive Program? Examples might include medical board registries, specialty society registries, regional quality collaboratives or other entities. What qualification requirements should be applicable to such entities?

**Recommendation:** AdvaMed recommends that CMS move gradually and slowly in designating any qualified clinical registries that would serve as a substitute for reporting of quality measures for CMS national programs. Factors that CMS should consider in designating registries as qualified under Section 601(b) should include, but not be limited to: sponsorship by national medical board registries or specialty society registries, or by not-for-profit entities that are committed to serving the health and well-being of the public, or by independent entities with device industry participation. In addition to sponsorship, CMS should consider the purpose of registries to be designated as qualified. Such registries should have as their focus the collection of national data on specific health care conditions and health care outcomes and assist in the development of quality measures that will improve health outcomes. c. As the goal should be to provide extensive national data, state registries, which would be extremely restricted in the extent of the data being captured, should be precluded from being designated as qualified entities.
AdvaMed supports the “registry qualification process” as outlined in the CY 2013 Physician Fee Schedule Final Rule, as applicable to all entities wishing to submit quality measure data for PQRS. To become qualified for a particular reporting period, a registry would be required to:

- Submit an acceptable “validation strategy” to CMS by March 31 of the reporting year the registry seeks qualification.
- Perform the validation outlined in the strategy and send the results to CMS by June 30 of the year following the reporting period.
- Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the registry’s receipt of patient specific data from the eligible professionals and group practices.
- Provide CMS a signed, written attestation statement which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete.
- Agree to verify the information and qualifications for the registry prior to posting and furnish/support all of the services listed for the registry on the CMS Website.
- Provide at least 1 feedback report to participating eligible professionals and group practices for each program year in which the registry submits data on PQRS quality measures on behalf of eligible professionals and group practices.
- Not be owned or managed by an individual, locally-owned, single-specialty group.
- Participate in all ongoing PQRS mandatory support conference calls and meetings hosted by CMS for the program year in which the registry seeks to be qualified.
- Comply with a CMS-specified secure method for data submission, such as submitting the registry’s data in an XML file through an identity management system specified by CMS or another CMS-approved method, such as use of appropriate Nationwide Health Information Network specifications, if technically feasible.

Regarding the CMS disqualification process, AdvaMed believes that it is important for registries to submit correct data once it is qualified to submit data on behalf of its eligible professionals. However, we do not believe that immediate disqualification is always warranted if an error occurs. AdvaMed believes that developing a QC and QA process may be more productive than simply disqualifying registries. It is important that CMS recognize that registries are dependent on the data they receive from eligible professionals. In cases where a registry has submitted inaccurate data, CMS should allow the registry an opportunity to correct their mistakes and rectify any processes leading to data submission errors. In addition, alternative processes such as placing a registry on probationary status may be useful for CMS to consider. AdvaMed recommends that CMS consider carefully the negative consequences of disqualifying a previously qualified registry and use this authority with caution.
**Question:** What oversight (for example, checks or audits) should be in place to ensure that data is submitted and calculated properly by entities?

**Recommendation:** AdvaMed recommends that all data which is entered into the registry be reviewed to verify appropriate formatting and identify appropriate fit. Statistical analysis should be employed to seek out trend and performance outliers. This should be followed by a *manual* verification process. It is our understanding that currently CMS requires only an attestation in lieu of requiring auditing of data. AdvaMed recommends that each entity submitting data institute a detailed auditing process as part of their standard operating procedures and these auditing processes be consistent across entities. Additionally, if eligible physicians find errors as a result of auditing, they should have the opportunity to correct these errors. Entities should consider employing a review process prior to final publication consisting of input provided by statisticians and methodologists to be reviewed by a committee of EPs for face validity or commentary prior to distribution of reports. This type of mechanism may help hasten the acceptance and subsequent positive practice changes by EPs.

**Question:** Should we require that a certain proportion of submitted measures have particular characteristics such as being NQF-endorsed or outcome-based?

**Recommendation:** AdvaMed encourages the use of NQF-endorsed quality measures. NQF has long recognized that measurement and reporting are key to improving health and health care. The NQF endorsement process provides for rigorous vetting of submitted measures that examine in-detail the following measure considerations: (1) impact of the Measure including addressing disparities and gaps that the measure addresses; (2) the quality, quantity and consistency of the evidence supporting the development of the measure; (3) reliability and validity testing of the measure; (4) feasibility and usability of implementing measures and subsequent reporting with considerations of unintended consequences.

Long-term clinical outcomes are often not captured with NQF-endorsed measures. Both process and outcomes measures are important, but outcome measures capture the consequence of treatment protocols and are crucial to medical decision making. Qualified registries should have the objective/goal of collecting data that can be used for developing appropriate outcome measures. Tracking quality improvement over time and understanding the appropriate length of an episode of care are essential in providing accurate information for patients and providers. To date, most quality measures are “process” measures, rather than “outcomes” measures. They are necessary, but not sufficient in many cases to capture the full benefits of advances in medical technologies. For patients who receive the benefits of an advanced medical technology, a higher quality outcome may be realized over a multi-year period. For example, an implantable device that needs to be replaced or adjusted every 10 years, rather than every 5 years would provide higher quality for the patient, but would not be captured by existing quality measures. Quality organizations such as the NQF, PCPI and others are quickly moving to emphasize the importance of including quality outcome measures in their portfolios for all medical specialties.
AdvaMed welcomes the opportunity to present these comments on the Request for Information regarding 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. We would be pleased to answer any questions regarding these comments. Please contact Steven Brotman at (202) 434-7207 or sbrotman@advamed.org if we can be of further assistance.

Sincerely,

[Signature]

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