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Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3276-NC
P. O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; 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; CMS–3276–NC

Dear Acting Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) 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 AMA applauds the agency for issuing an RFI on the important topic of identifying, developing, and promoting the use of meaningful approaches for the evaluation of physician quality measure reporting and improvement. In addition, we would like to take this opportunity to acknowledge CMS' efforts to alleviate regulatory reporting burdens on physician practices. Physicians are seeking opportunities for avoiding payment penalties, while at the same time trying to evaluate new delivery reform models that rely on accurate and timely data for improving quality and lowering costs. **Recognizing these realities, the AMA urges CMS to balance two primary goals:**

1) **The short term goal of allowing physicians the opportunity to successfully engage in quality measurement and improvement activities that result in avoiding payment penalties and/or qualifying for an incentive; and**

2) **The long term goal of moving away from pay for reporting policies towards pay for performance models predicated on the use of timely data capture and evaluation for improving quality and lowering costs**.

We strongly recommend that CMS adopt a scaled approach to reporting so that a variety of physician quality measure reporting activities are eligible for a number of Medicare physician performance programs including PQRS and EHR meaningful use. Such an approach will enable the agency to best balance the aforementioned short and long term goals.

"Deeming" Quality Measurement and Improvement Activities

The AMA recommends that CMS create a mechanism so that physicians and other health care provider organizations are able to meet the federal data reporting requirements under a number of Medicare programs through their active participation in other "deemed" quality measurement and improvement activities. In its simplest form, the U.S. Department of Health and Human Services via CMS would "deem" medical specialty registry participation, medical board certification, Regional Heath Care Quality Collaborative participation, successful completion of an accreditation program (e.g., The Joint Commission [TJC], National Committee for Quality Assurance [NCQA]), measure reporting through an EHR, and other quality related activities as meeting CMS' data requirements, and thus be eligible for any applicable financial incentive, while avoiding payment penalties. This approach facilitates a more streamlined and efficient process through single data submission that meets the CMS quality reporting requirements, while also supporting meaningful quality improvement activities already adopted by many physicians throughout the country. In addition, we believe that "deeming" a variety of quality measurement and improvement activities would enable CMS to work effectively with external stakeholders and make it feasible to expand the scope of truly relevant quality data collection, even for very small specialties or patient populations.

In order to make this concept operational, CMS should develop guidance and standards for physicians and other health care provider organizations to qualify under the "deemed" status. **The AMA recommends that CMS adopt baseline standards based on input from physicians and other stakeholders that encourage a variety of quality measurement and improvement activities while not setting the bar so high during initial years as to exclude any activities or organizations with an established record of achievement.** To begin work on establishing standards, the AMA recommends that CMS initially build upon its current processes for "qualifying" registries, while also considering the following important concepts: benchmarking of performance data; inclusion of comparative feedback reports to physicians involved in the "deemed" quality measurement and improvement activity; education outreach by the "deemed" activity to help participants understand their performance information; and transparent descriptions of risk adjustment and attribution techniques. More specific standards for evaluating eligible activities for "deeming" will be

necessary after the initial years, especially as CMS moves towards full implementation of public reporting policies. Development of these future standards should include input from affected stakeholders, including physician organizations.

In addition to the aforementioned recommendations for "deeming" quality measurement and improvement activities, we have the following responses to specific questions contained in the RFI.

1) General Questions:

How are the current reporting requirements for the PQRS and the reporting requirements in 2014 for the EHR Incentive Program similar to the reporting requirements already established for the ABMS boards or to other non-federal quality reporting programs? How are they different? In what ways are these reporting requirements duplicative and can these reporting programs be integrated to reduce the reporting burden on eligible professionals?

As mentioned above, the AMA recommends that physicians receive reporting credit through meaningful participation in a variety of quality measure data activities, including board certification (e.g., satisfying Part IV Maintenance of Certification). The AMA urges CMS to promote flexibility in its performance programs by allowing physicians to report through their medical boards, registries, accreditation activities (e.g., TJC), CQM reporting in EHRs for demonstrating meaningful use, or other state/local/regional quality improvement activities.

We recommend that CMS take into consideration varying EHR capabilities and how physicians' use of EHR functionality impacts quality measurement and improvement activities.

Are there examples of other non-federal programs under which eligible professionals report quality measures data?

There are many examples of non-federal programs under which physicians report quality measure data. These include: Ongoing Professional Performance Evaluation (OPPE) utilized by pathologists; Maintenance of Certification by a variety of medical specialty boards; accreditation tools and programs by TJC; NCQA certification programs; participation in clinical patient registries; Bridges to Excellence programs which measure the quality of care delivered in provider practices; and others.

With regard to medical board certification activities, we urge CMS to protect physicians who have been provided lifetime Maintenance of Certification (grandfathered) from financial penalties associated with Medicare programs (e.g., PQRS, Meaningful Use). This approach is consistent with the AMA's recommendation that, during these transition periods,

physicians who face hardships, such as physicians at or near retirement age, should be protected from burdensome requirements and financial penalties.

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?

There are several significant benefits for allowing third-party entities to report quality data to CMS on behalf of physicians and other eligible professionals (EP). Such an approach provides the following benefits: reduces measurement burden; represents an efficient and effective method for CMS to engage a large percentage of EPs in a region/state; and, with time, provides CMS with access to validated data, thus creating a partner for testing and refining measures prior to widespread deployment. Initially, some shortcomings may arise around the ability of third-party entities to accurately and meaningfully report quality measure data and/or results to CMS on behalf of physicians. For example, any data and/or results reported to CMS for the PQRS program have to be as accurate as possible because the performance information will be posted on Physician Compare and be included in the Value Modifier calculation. We are in a period of transition where more physicians are using EHRs and starting to share data through other activities, e.g. registries. However, until we have robust and tested data exchanges, it is important to have a supplemental process that allows practices to review and correct information extracted from the EHR or third party data activity. To help address some of these potential shortcomings, third-party entities should ensure the accuracy of their data collection, validation, and reporting processes.

Moreover, collectors of quality (as well as cost) data should be responsible for appropriately using and disclosing the data. Before these data are publicly reported by CMS or any other entity (including the collecting entity), **the quality data activity should have an established infrastructure with requisite experience and expertise in the realm of secure collection/storage of patient-level data, performance measurement, and public reporting, including safeguards to ensure that the data is valid, comprehensible, and subject to effective methodologies for risk-adjustment and attribution of care. Physicians should also have the opportunity for review and appeal of the data prior to public reporting. In addition, protections should be implemented to ensure that any performance report or data used as the basis for the report will not be subject to discovery or admission as evidence in judicial or administrative proceedings without the consent of the physicians.**

How should the CMS quality reporting programs change/evolve to reduce reporting burden on eligible professionals, while still receiving robust data on clinical quality?

CMS' establishment of a "deeming" approach will help address measure burden, as physicians will be able to participate in one quality data collection activity and be recognized by CMS for satisfying a number of Medicare performance programs. We strongly

recommend that physicians be provided with options to report on their quality measurement and improvement through a variety of activities.

The AMA also believes it is critical that the measures and format for reporting measures under the PQRS, meaningful use, and value-base modifier (VBM) programs be aligned. This requires: setting common program objectives; aligning the measures, establishing a common format for reporting, and testing the common "measures" and "reporting format" to see if they can be implemented in an EHR system; piloting the measures in an actual clinical environment once system testing is completed to provide real world results and feedback in a selected and controlled environment; and evaluating results of pilot testing to determine that the results meet the original program's objectives. Moreover, CMS should work to standardize its timelines for reporting in these various programs. As it stands, the timelines, as well as reporting deadlines vary, creating much confusion for physicians who are trying to participate consistently and get credit across all Medicare performance programs. Without these alignment efforts, there will be a significant chilling effect on the progression of accurate, efficient, and meaningful Medicare quality performance reporting through technology.

In addition, while CMS has outlined a general framework of how the PQRS Group Practice Reporting Options (GPRO) and Accountable Care Organizations (ACOs) quality reporting will align with the EHR Incentive Program, many details still need to be clarified. Specifically, the AMA urges CMS to recognize current GPRO and ACO quality measure data collection activity through the web portal as satisfying reporting requirements for the EHR Incentive Program.

2) Reporting requirements for entities that report via a registry under the PQRS or the EHR Incentive Program if registry reporting is established as a reporting method in future years:

Should reporting entities be required to publicly post performance data?

It is premature to impose such a requirement. The necessary processes and safeguards required to make public reporting meaningful for physicians, patients, and the public require time and resources. Requiring the public reporting of performance data to become a "deemed" activity would prevent many meaningful measurement and improvement activities from counting for participation in CMS performance programs. Rather, CMS should provide the necessary lead time through a scaled approach in rulemaking that establishes criteria for moving toward accurate and meaningful public reporting of performance information. The AMA communicated the necessary safeguards for how to report performance information in comments submitted to the agency in response to the implementation of the Medicare Qualified Entity Program (http://www.ama-assn.org/resources/doc/washington/medicare-data-release-sign-on-08aug2011.pdf). We encourage CMS to review these comments in order to lay out a path for posting performance data.

Should CMS require an entity to submit a yearly self-nomination statement to participate in PQRS?

We do not recommend that entities be required to submit a yearly self-nomination statement in order to participate in PQRS. Rather, similar to the current processes for qualifying registries under the PQRS program, CMS should only require an initial letter of intent, followed by a completed application. CMS should also consider a three or more year deeming period, similar to what TJC has adopted for its accreditation programs (e.g., TJC accreditation is at least every 39 months). By eliminating additional administrative burdens, potential "deemed" entities would be able to focus on the development, testing, and use of methods that strengthen their activities around quality measurement and improvement. Further, CMS should "deem" entities that meet the initial deeming requirements (exclusive of public reporting).

What should be included in the data validation plan for these reporting entities?

Reporting entities should establish and provide documentation of a data validation plan. Certain leading practices should be considered in developing this plan. This includes, but is not limited to, an automated validation process that enables comparisons of the data to the source, as well as an approach for how the entity would handle missing data fields. Oversight by an audit committee, which should include practicing physicians and patient representation, is essential to help ensure integrity of the validation model. The current CMS PQRS Validation Plan Protocol also includes items such as verification of an entity's tax identification number and its ability to send an accurate QRDA or XML file, as well as a process for completing a detailed audit.

If CMS provided a reporting option for PQRS and/or the EHR Incentive Program through such entities, what specification should CMS use to receive the quality data information (for example, Quality Reporting Document Architecture [QRDA] 1 or 3, XML, other)?

If third party entities are provided a reporting option for PQRS and/or the EHR Incentive Program, they should also be provided clear guidance for what specification standard is required for CMS to receive the quality data information. Additionally, the AMA recommends that regardless of which standard is designated to be used for the reporting of quality data information, that the standard be applied across all CMS programs, and be consistent with the EHR certification program.

Should data submission timelines for these reporting entities be modified so that the submission timeframes for these quality reporting programs are aligned? For example, PQRS qualified registries are required to submit quality measures data once, within 2 months following the reporting period. 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?

Although a consistent submission timeline will help promote alignment, not all third-party quality data collection activities will be ready for immediate data transition to CMS. Therefore, the AMA urges the adoption of a scaled approach with regard to how and when CMS requires the submission of quality data from "deemed" activities.

What oversight should be in place to ensure that data is submitted and calculated properly by entities?

Not all third-party quality data collection activities will be immediately ready to transmit data to CMS. To ensure that all current quality measurement activities, which have proven meaningful to physicians and patients, have an opportunity to obtain CMS "deeming," the AMA recommends that, for initial participation, third-party entities/activities not be required to transmit data to CMS. Rather, these "deemed" entities should have, at a minimum, a year or longer (depending on their current infrastructure) to create, develop, and implement sound data collection and transmission processes. Such a transition period is essential if physicians and these various quality data collection activities have to move from pay for reporting models to an accountability model. As has been stated by several medical specialty society registry stewards, it can take years to collect and analyze data in an accurate, timely, and robust fashion. **Therefore, it is essential that CMS build in a realistic timeframe into any "deeming" status program.** With time, as already demonstrated by some registry stewards, additional modules can be built that can pull explicit data from EHRs and feed them into a registry for developing meaningful and timely quality performance reports.

In addition, physicians should not have to report on their entire patient population to be considered successful participants in a third-party quality data reporting activity. Rather, reporting on a sample number of patients should be sufficient for qualifying purposes. Sampling methodology should be clearly defined and scientifically valid.

Overall, we encourage CMS to establish realistic standards for "deeming" given that not all third-party quality data activities are starting from the same point in their data capture, calculation, and reporting. CMS should be focused on building upon and capturing the significant quality improvement efforts already underway by physicians nationally as well as local initiatives.

3) 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:

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

The AMA is concerned with any approach taken by CMS that would require the use of and reporting on overly prescriptive quality measures. Measures being considered for use in a

CMS program should have gone through the following steps during their development, including: having multi-disciplinary input on development, being subject to a public comment period, addressing known gaps in care of a particular population, ensuring its processes link to outcomes, and including testing. Measures developed pursuant to these recommended steps, such as specialty-developed measures, as well as NQF-endorsed measures should be considered.

The AMA recommends that measures move toward a consistent definition within regulatory requirements. This would include clear guidance which defines process vs. outcome measures across all programs.

Should CMS require that the quality measures data submitted cover a certain number of the six national quality strategy domains?

Physicians should not have to meet all of the six national quality strategy domains. Rather, the AMA recommends that all physicians report on one or two national quality strategy domains for initial program years. Because different measures fall within the various domains, it is unlikely that an individual physician would have measures applicable to their given specialty across *all* domains.

To what extent would third-party entities struggle to meet reporting for measures currently available under PQRS and EHR Incentive Program?

As mentioned earlier in our comments, not all third-party quality data collection activities will be ready for immediate data transition to CMS. To ensure that all current quality measurement activities which have proven meaningful to physicians and patients are given a real opportunity to meet CMS' "deeming" status, the AMA recommends that for initial participation, third-party entities/activities not be required to transmit data to CMS.

4) Registry measures reporting criteria:

Any new reporting policies for the PQRS and EHR Meaningful Use programs should be meaningful but not overly prescriptive and there should be a transition period so that registries and other third-party data activities (e.g., board certification, accreditation, and local regional collaborative participation) can evolve and be assessed. Registries, along with other third-party quality data collection activities, should have the initial flexibility to tailor measures to a given population that they are trying to measure.

If CMS proposes revised criteria for satisfactory reporting under PQRS and for meeting the CQM component of meaningful use under the EHR Incentive Program, how many measures should an eligible professional be required to report to collect meaningful quality data?

The number of quality measures a physician should report on should be left to the users of the system to determine. The measures reportable will depend on the maturity of an entity's quality data capture activity. The ultimate goal is that measures reported should create a complete picture of the care provided that supports performance improvement at the local level.

If CMS were to align reporting criteria with reporting requirements for other non-federal reporting programs, in future years, should the agency 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?

The AMA supports the goal of aligning public and private sector quality measurement activities. It is important to recognize that CMS does not have the authority to make non-federal programs align with their criteria. Further, there is currently no single set of reporting criteria for federal programs. It is important that CMS work to identify harmonized reporting criteria within its programs, while taking into consideration private sector measurement and data collection activities.

For PQRS, should eligible professionals still be required to report quality measures data on a certain percentage of their applicable patients, such as 80 percent, for 2014 and subsequent years? Or, should CMS require that eligible professionals report on a certain minimum number of patients, such as 20, rather than a percentage?

The AMA does not support a requirement for reporting quality measures data on a certain percentage or number of the professional's patients. We support a statistically valid sample size and no public reporting for physicians who do not have enough patients in the measure to meet this sample size.

The AMA strongly urges CMS to avoid the development and implementation of a one-size-fits-all data reporting system in the early stages of this program. The intention behind section 601(b) of the "American Taxpayer Relief Act" is to provide physicians with greater flexibility to report on (i.e., via a variety of reporting vehicles including specialty-led registries) and get credit for their quality improvement activities relevant to their practice and patients.

Conclusion

The AMA urges CMS to adopt a "deeming" approach for the recognition of quality data reporting activities across all of the Medicare physician performance programs. Any new CMS program that "deems" activities for quality measurement and improvement should not mirror overly prescriptive reporting approaches initially adopted for PQRS and the EHR meaningful use programs. There should also be a transition period so that these types of

"deemed" activities (e.g., registry use, accreditation, board certification, regional collaborative participation, etc.) can evolve and be accurately assessed by CMS. In addition, these activities should support the ability of third-party activities to focus on a patient population of greatest need for improvement based on the specialty or local population.

The addition of "deeming" status for participation in CMS performance programs (e.g., PQRS, EHR meaningful use, VBM) will make a significant contribution toward reducing the burden of measurement associated with data submission in response to national initiatives and voluntary measurement organizations at a state/regional/local level, while significantly expanding the scope of participation by physicians in Medicare programs. It is important to recognize that quality measurement and improvement activities are resource intensive. To date, the financial burden of these resources (e.g., staff and expenditures) has fallen directly on the physicians and other health care organizations that participate in these activities. Moving forward, the Medicare program should invest in an infrastructure that supports the development and implementation of performance measures. This infrastructure should also enable an integrated data system that enhances knowledge of performance within the health care system to inform shared decision making and performance improvement activities.

The AMA stands ready to work with the agency on improving its performance programs, making them meaningful for physicians, their patients, and the health care system. If you need further information, please contact Jennifer Meeks, Assistant Director of Federal Affairs, at jennifer.meeks@ama-assn.org or at 202-789-4688.

Sincerely,

James L. Madara, MD