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April 8, 2013

Marilyn Tavenner, MHA, RN
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-3276-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to http://www.regulations.gov

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**

Dear Administrator Tavenner:

The American Nurses Association (ANA) welcomes the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) Medicare Program Request for Information (RFI) cited above. The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses through its constituent/state nurses associations, organizational affiliates, specialty nursing associations, and individual members. Registered nurses (RNs), including advanced practice registered nurses (APRNs), are the largest group of healthcare professionals serving in multiple direct care, care coordination, and administrative leadership roles across all healthcare settings.

As eligible professionals (EPs), APRNs will be held to the standards set by CMS as reported through the Physician Quality Reporting System (PQRS), the American Board of Medical Specialties (ABMS), and through other venues that monitor and report the quality of care provided by EPs. ANA submits this response to CMS' RFI on behalf of the nation's RNs, including APRNs. The policies for which this RFI collects information will affect all of these constituents.

Comments on Background:
The RFI gives a very good overview of the background information necessary to understand the request. Most particularly, ANA appreciates the concise and informative treatment given to Maintenance of Certification (MOC). Although other professional certification/recertification programs exist, the American Board of Medical Specialties (ABMS) recertification model merits consideration as an exemplar for addressing quality of clinical practice. Additionally, CMS gave an excellent overview of the Physician Quality Reporting System (PQRS) and the challenges currently faced by eligible professionals (EPs) seeking to report on the quality of their practices through any of several reporting venues. Finally, CMS elucidated the interactions between

qualified clinical data registries and certified electronic health record (EHR) technologies (CEHRTs).

At the end of section A.4. (p. 9058), CMS stated, "The Secretary is required to establish a process to determine whether an entity meets the requirements to be a qualified clinical data registry. The process can involve a determination by the Secretary or the Secretary can designate one or more independent organizations to make such determination, or both approaches can be used." ANA believes that such a determination would be very valuable to all clinicians, vendors, and other interested parties and suggests that the Secretary expeditiously publish a draft of the proposed process for public comment. ANA offers to assist in the development process if the qualifying requirements have not yet been determined.

CMS outlined several questions for which it seeks information. ANA directs its comments toward those questions that we can respond to in a meaningful way.

Responses to high level 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 reporting burden on eligible professionals?

> ANA is aware that duplication of data entry costs money, expends valuable time, and causes errors. CMS should consider any reasonable recommendations that will decrease duplication.
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> The American Association of Nurse Anesthetists' (AANAs') and ANA concur on the following comments.
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> Advanced Practice Registered Nurses (APRNs), including Certified Registered Nurse Anesthetists (CRNAs), Nurse Practitioners (NPs), and Certified Nurse Midwives (CNMs) are eligible professionals for reporting to the PQRS program. APRNs report through the PQRS program using the claims-based reporting option, as this is currently the only reporting option available. Since APRNs are not eligible to participate in the EHR incentive program, they should not be penalized in Medicare payment or in eligibility for PQRS for not having and using certified EHR systems.
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> The ANA and AANA are concerned that ABMS boards will be similar to the AMA Relative Value Update Committee (AMA-RUC), which has rejected multiple requests for inclusion of our nursing organizations in its processes. If medical societies are to advise CMS on issues vital to other practitioners, but prohibit the inclusion of all EPs affected by their rules, the validity of the entire process is called into question.

++ 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 requirements to ensure high quality data?

> ANA is not aware of other programs that report such data. Should such entities exist, CMS could ensure high quality data by setting standards consistent with those set for data submission to PQRS and with CEHRT criteria. Those standards should follow a "less is better" approach that allows innovation to flourish while requiring high quality data submissions. In support of these high standards, CMS should institute self-policing by the organizations accepting data. CMS should also conduct random audits of the data stores compared to the data submitters' records to ensure high data quality. CMS should conduct these audits using a contractor with considerable skills and experience in this area.

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

> ANA recommends that CMS maintain an open dialogue with all clinicians, including EPs, registered nurses, pharmacists, social workers, physical and occupational therapists, and providers of complementary and alternative medicine. While most of these clinicians are not direct reporters to PQRS, their care has an influence on perceived and actual quality of care. Many of them provide inputs to EPs' PQRS reports. The outcomes of those reports (e.g., receipt of incentive payments, decreases in payments to the practice) affect these clinicians' practices. Because of these and other factors, non-EP clinicians' inputs to the drivers of quality will give a broader view of reporting burden, data necessary to report, and will inform CMS' decisions to change/evolve reporting practices to improve the efficiency and effectiveness of reporting practices. Lastly, receiving direct aggregate data uploads from organizations that collect data on behalf of clinicians will facilitate reducing the data collection burden on the clinician and will provide robust data on clinical quality overall.

Responses to 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:

++ 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.

> The existing reporting structure, as elucidated in the background of the RFI, includes all of the entities that would report on behalf of physicians. It is not clear whether CMS includes in its definition of specialty society registries those organizations that collect data on behalf of non-physician EPs, such as Certified Registered Nurse Anesthetists. AANA and similar organizations could support the practices of their members by collecting and submitting quality measures data. Beyond addition of such specialty organizations to the existing definition, ANA suggests that CMS limit reporting to the

extant group, as broader reporting structures could increase the likelihood of poor data quality due to the variations implicit in collecting data from multiple, disparate sources.

What qualification requirements should be applicable to such entities?

CMS could set qualification requirements for entities submitting quality data to include only entities that represent the interests of EPs for whom they submit data. For instance, recognized specialty organizations would include only those that provide bona fide specialty certifications and/or credentials (e.g., AANA, American Board of Internal Medicine). Additionally, organizations with a vested interest in the quality of care provided by EPs, including regional health information organizations (RHIOs), must meet predefined criteria set by the Department of Health and Human Services (HHS) in order to represent their participants in that role and be deemed by CMS as qualified data submitters. CMS should limit data submission to only those entities.

++ What functionalities should entities qualified to submit PQRS quality measures data possess? For example, for CQMs that can be electronically submitted and reported under PQRS and the EHR Incentive Program, should an entity's qualification to submit such measures be based on whether they have technology certified to ONC's certification criteria for CQM calculation and/or electronic submission?

ANA recommends that CMS remain cognizant of the financial and resource burdens placed on EPs who endeavor to represent their practices through the submission of quality-related data. Increasing the certification criteria for CQM submission will increase the costs and could increase the time required to make submission. These added burdens have the potential to reduce the EP’s perception of value of data submission and could ultimately reduce the quality of care as EPs shift time from patient care to data submission.

++ What criteria should we require of entities submitting quality measures data to us on behalf of eligible professionals? Examples might include transparency of measures available to EPs, specific frequency of feedback reports, tools to guide improvement efforts for EPs, ability to report aggregate data, agreement to data audits if requested, etc.

Entities submitting quality measures data should be held to a high standard consistent with those required of the EPs for whom they submit data. Such entities should be open to review and audit at random, have transparent transactions, and provide error-free reporting to EPs and CMS. Entities should provide quality reports to EPs in a sufficiently robust and understandable manner that recipients can easily compare their quality to that of other similar EPs and against reasonable performance benchmarks. Methods of reporting could include tools such as dashboards. Timing of such reports should be sufficient to allow EPs to adjust and improve their performance—either through changes in practice or through reasonable investments in training, personnel, supportive technologies, or other structures and processes—before the next reporting period. As appropriate, and in exchange for reasonable fees, entities should provide EPs with evidence-based recommendations for effective methods of improving their practices to

meet or exceed reported benchmarks. Additionally, these entities should report to CMS at regular intervals and without error at the individual EP, practice entity, and aggregate levels based on such parameters as geographical region, type of specialty, and type of provider.

++ Should reporting entities be required to publicly post performance data?

Data reported to CMS should be publicly reported to all interested parties at an aggregate level. Specific EP-level data should be available to those same parties by request, unless legal or safety reasons prevent such reports.

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

Entities should submit a self-nomination statement prior to the first reporting period for which they will submit data. If approved to submit data, those entities should be considered satisfactory data submitters for subsequent reporting periods. Submission of annual statements would add to the bureaucratic burdens for CMS, the entity, and for all EPs for whom the entities submit data. If the entities pass random audits, it is unlikely that annual statements would add significant value. A mechanism to self-identify elected transition from participant to non-participant status merits consideration.

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

ANA recommends that CMS require reporting entities to submit to random annual audits focusing on data quality.

++ 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 two months following the reporting period.

ANA recommends alignment of timelines to reduce the reporting burden and to increase the consistency and comparability of data submissions across agencies and programs. Data submission offsets among agencies and programs mean that reporters collect data at multiple intervals encompassing various periods for submission to disparate organizations. Additionally, alignment of timelines will allow all involved parties to plan for resource allocations and set expectations for receipt of and use of report findings. Such coordination enables easier comparisons of data and information by interested parties.

++ What oversight (for example, checks or audits) should be in place to ensure that data is submitted and calculated properly by entities?

ANA recommends the implementation of random annual audits encompassing 1% of the data submitted. This is consistent with current and effective CMS' practices in oversight

of durable medical equipment providers through the Evaluation and Oversight of Qualified Independent Contractors. Additionally, EPs and the entities submitting data on their behalf should be required to sign a legally binding statement of attestation supporting the validity and accuracy of the data submitted. Periodicity of submission of such attestation statements must not be a burdensome requirement.

Responses to 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:

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

NQF endorsement is an important consideration in that it sets standards for the quality of the data submitted; however, NQF endorsement does not ensure that the data represent the breadth of the clinical practice space. Further, NQF endorsement is an expensive and onerous proposition for the stewards of quality measurement data. Other methods, such as consensus among representatives of a consortium of specialty societies representing a certain area of practice should be sufficient for CMS to consider a quality measure as acceptable. For instance, a quality standard for cardiovascular outcomes might be agreed upon by a consortium of representatives from the American College of Cardiology, the American College of Cardiovascular Nurses, and the American Board of Physical Therapy Specialties, and other professional society stakeholders. In the absence of a NQF endorsed standard, such a consortium should be an acceptable resource for such a measure.

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

The national quality strategy domains are reasonably comprehensive of quality expectations of EPs. For this reason, ANA recommends that EPs report at least one measure representing each domain in their quality measures data.

Responses to Questions regarding registry measures reporting criteria:

++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?

ANA recommends that CMS remain cognizant of the financial and resource burdens placed on EPs who endeavor to represent their practices through the submission of quality-related data. Increasing the certification criteria for CQM submission will increase the costs and could increase the time required to make submission. These added burdens have the potential to reduce the EP's perception of value of data submission and

could ultimately reduce the quality of care as EPs shift time from patient care to data submission.

++ 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 we require that eligible professionals report on a certain minimum number of patients, such as 20, rather than a percentage?

ANA recommends that EPs report on a percentage of patients instead of on a specified number. The reason for this recommendation is that the burden of reporting on a percentage will remain consistent among providers of various sizes. If CMS chose to use a minimum number of patients, small providers would bear a disproportionate burden of reporting on an over-representative sample of patients, while large providers would experience comparatively little burden to report on an under-representative sample of their patients.

Conclusion

ANA appreciates the opportunity to respond to this RFI. If we can be of further assistance or if you have any questions or comments please contact Darryl W. Roberts, PhD, MS, RN at darryl.roberts@ana.org or 301-628-5081.

Sincerely,

Marla J. Weston, PhD, RN, FAAN
Chief Executive Officer

cc: Karen A. Daley, PhD, MPH, RN, FAAN
President