April 8, 2013

Submitted Via http://www.regulations.gov

The Honorable Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445—G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS 3276-NC 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 Acting Administrator Tavenner:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recent request for information on quality measurement and reporting under Medicare (78 Federal Register 9057, February 7, 2013). Our comments focus on the Agency’s request for information regarding clinical data registries and the new authority established under Section 601(b) of the American Taxpayer Relief Act of 2012 (ATRA).

ASCO is the national organization representing over 30,000 physicians and other health care professionals specializing in cancer prevention, diagnosis and treatment. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans. ASCO has devoted substantial resources and efforts over more than a decade to the development and promotion of its clinical data registry, the Quality Oncology Practice Initiative (QOPI) and associated quality assurance initiatives that promote quality, value and care coordination in the day-to-day delivery of oncology care. QOPI’s goal is to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. QOPI assures less variability in practice patterns within and between oncology practices
in order to promote quality, value and care coordination in the day-to-day delivery of oncology care.

ASCO is pleased that CMS is taking steps toward qualifying clinical data registries for federal reporting. Improving the quality, value and coordination of care provided to patients with cancer is especially relevant to the Medicare program. Cancer is a leading cause of morbidity and mortality among Medicare beneficiaries, as over 60 percent of all cancer diagnoses in the United States occur in individuals who have reached the age of 65. The challenges facing the oncology community are unique, and generalized programs used to evaluate quality of medical care typically lack sufficient detail to evaluate and improve the quality of oncology care.

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ASCO provides the following initial observations and recommendations in response to the request for information:

- **Section 601(b)** is intended to ensure that the Medicare program promotes quality, value and coordination of care by harnessing the evidence-based performance measures and clinical data registries already established by a number of national medical specialty societies.

- When promulgating rules and guidance, CMS should use the ASCO Quality Oncology Practice Initiative (QOPI) as a model for the type of clinical data registry that qualifies under Section 601(b). ASCO played a leading role in working with Members of Congress to support Section 601(b), and QOPI is one of the mature, pre-existing clinical data registry programs that policymakers envisioned when drafting and enacting this legislative provision.

- QOPI satisfies the four criteria described in Section 601(b), including transparency, multiple payers, timely performance reports and quality improvement initiatives.

- CMS should not limit the clinical quality measures used by clinical data registries to the measures endorsed by the National Quality Forum (NQF). Similarly, CMS should respect the autonomy of recognized registries to determine the unit of analysis and reporting (e.g., provider-level or practice-level) and other methodological approaches that are most appropriate for meaningful quality improvement in that specialty.

- CMS should qualify specialty-specific clinical data registries under Section 601(b) as quickly as possible, allowing specialties with mature programs in existence to begin satisfying the PQRS requirements through a clinical data registry in 2014.

Below are more specific comments in response to the request for information.

**Eligible Entities**

Congress enacted Section 601(b) to harness the evidence-based performance measures and clinical data registries already established by a number of national medical specialty societies.
These registries promote high quality, high value health care services in ways that are not feasible using the more limited measure sets and generalized focus of PQRS. CMS should leverage the innovative, specialized clinical data registries and quality assurance programs developed by national medical specialty societies that will have the highest likelihood of success. Physicians will embrace quality improvement programs that are developed by their own specialty societies, and these initiatives will have direct relevance to their day-to-day practice in promoting meaningful improvements in the care delivered to their patients.

In particular, adopting the clinical data registries developed by national medical specialty societies will—

- promote provider reporting on the breadth and depth of quality measures required for a meaningful quality assessment;
- lead to the timely adaptation of specialty quality measures, reflecting the evolution of scientific evidence and clinical practice guidelines;
- promote high quality and efficient care;
- encourage a culture of quality improvement regardless of geographic location, patient demographics, practice size or corporate and contractual relationships; and
- foster significant improvements in quality, care coordination and cost savings by engaging physician specialists in defining quality, value and care coordination.

For these reasons, we urge CMS to focus initially on established clinical data registries promulgated by national medical specialty societies. In future years, after CMS gains experience with clinical data registries, there may be opportunities for CMS to look beyond the programs developed by national medical specialty societies.

**Criteria for Clinical Data Registries**

ASCO is one of a limited number of organizations able to offer a response to the request for information from the perspective of a convener of a long-standing, comprehensive clinical data registry program initiated and maintained specifically for the purpose of improving cancer care. ASCO and our members have devoted significant resources toward developing, building and adapting an infrastructure that includes: a web-based entry portal, developing EHR-reporting capabilities, a defined methodology for sampling and participation, a defined process for testing/piloting new measures, and training and help desk support.

ASCO’s QOPI is a meaningful quality improvement program developed by and for oncologists to drive practice improvement. Whereas oncology specific measures in PQRS are very limited, QOPI offers more than 150 quality measures that span multiple diseases and domains of cancer care, and QOPI measures rapidly evolve to reflect the pace of science and emerging clinical consensus. The QOPI program provides meaningful, actionable data in the form of quality reports to participants within four weeks of data submission. QOPI offers tools and resources to
support practice improvement based on QOPI measures and enable dedicated quality improvement collaborations.

We urge CMS to use QOPI as a model for how a well-established clinical data registry can meet the four criteria that Congress provided for consideration within the statutory language. Section 601(b) directs the Secretary to consider whether an entity:

1. Has in place mechanisms for the transparency of data elements and specifications, risk models, and measures
2. Requires submission from participants with respect to multiple payers
3. Provides timely performance reports to participants at the individual participant level
4. Supports quality improvement initiatives for participants.

The latter is an especially important distinguishing factor for improvement-oriented registry programs. Registry programs should provide or promote clinical tools, continuing medical education, educational modules, clinical practice guidelines, and focused practice improvement initiatives directly related to the registry measurement areas.

In addition to the criteria that are set out in the statute, ASCO urges CMS to consider the additional functionalities for qualified registries listed below:

- Operation consistent with privacy and data protection laws.
- Inclusion of a sufficient number of quality measures to promote meaningful performance improvement. At minimum, each reporting entity should report 10 quality measures to serve as an alternative to PQRS. Qualified registries should identify and transparently describe the measures that are considered by that registry to be appropriate for meeting federal reporting requirements; however, the registry may also implement other measures that are not designated for federal reporting (e.g., measures in testing, measures implemented for other reporting programs).
- Quality measures may be reported at the provider or group/practice level, at the discretion of the clinical registry, as most appropriate to promote quality improvement based upon the individual measure specifications. To ensure meaningful measurement and quality reporting, it is imperative that CMS refrains from requiring provider-level measurement as the only alternative.
- Quality reporting is rapid and actionable, and includes benchmarking.

ASCO also recommends that CMS consider the guidance on how to define a clinical data registry found in a report promulgated by the Agency for Healthcare Research and Quality (AHRQ) entitled *Registries for Evaluating Patient Outcomes*. In this report, AHRQ describes alternative core functions of registries that are directly applicable to Section 610(b).
Measure Development

Under the statute, it is clear that endorsement by NQF is not a prerequisite to the use of clinical measures by a clinical data registry, and that CMS should encourage the use of measures that promote robust, evidence-based approaches to the improvement of care without limiting specialty-specific registries to measures that have been submitted to or endorsed by NQF. Importantly, the statute will now allow for clinical registries to add, modify and adapt evidence-based quality measures on a timely basis.

CMS should consider the following requirements for measures of a clinical data registry that are designated for use for federal reporting:

- Measures must be developed using a transparent, multi-stakeholder, and consensus-based process, including public posting and opportunity for review of complete specifications and analytics. Measures must be tested prior to inclusion in the clinical registry.

- Outside of the ten or more measures implemented in the registry for federal reporting, measures may be reported to providers as part of the registry but not considered part of the federal reporting measure set. This will allow societies to use registries to test and implement measures that are not considered ready or appropriate for the federal set.

- Recognized registries must report on a minimum of one outcome measure in the federal reporting set by 2016. Patient reported outcome measures should also be encouraged.

- Recognized registries must report on value-focused measure(s) in the federal reporting set (e.g., measures developed from ABIM Choosing Wisely items).

Registries must be transparent regarding which of the six national domains are included in registry quality measure sets, but should not be required to include a specific number in any one domain. While registries can strive to cover as many of the six domains as possible, they should not guide selection of measures for specific registry programs.

Additionally, CMS should not limit participation under Section 601(b) to entities that have qualified to provide registries under PQRS. The current PQRS registry reporting is subject to most of the limitations of PQRS, and Section 601(b) is intended to provide an alternative that complements but does not replicate PQRS.

Reporting

In 2014 and 2015, the focus of recognized registries should be on improving health care, and encouraging uptake among providers. Thus, public reporting of performance data should not be tied to participation in these registries until 2016 at the earliest. This phased approach also allows for additional measure vetting and testing which is needed prior to public reporting of measure data.

During 2014-2015, registry quality reporting to participating eligible providers (EPs)/groups should include individual and/or group data, along with comparative aggregate and/or
benchmarking data. As required by the ACA, physicians must participate in public reporting by 2016. Therefore, in 2016 or later, these quality reports to EPs/groups could be augmented by public reporting. Recognized registries should have two options to meet public reporting requirements: 1) create and maintain a public reporting site as a component of the registry, and publicly post measure performance; 2) submit measure data to CMS in a format and timeline that permits CMS to populate the Physician Compare website. Option 1 does not require any measure data or raw data submission to CMS. If option 1 is implemented by a specific qualified registry, the Physician Compare website can provide a link to that registry’s public reporting site for relevant providers.

**Data Submission and Validation**

Recognized registries - especially existing specialty society registries - should have the flexibility to use the registry data submission timeframes that are determined most appropriate for quality improvement. It is reasonable to require that a minimum level of participation occurs by the due date assigned by CMS to allow recognition of participation in federal programs.

As noted above, recognized registries should transmit information to CMS regarding participation, not measure data. Participation information can be sent according to CMS formatting specifications.

It is reasonable to require a third party audit of the reliability, accuracy and completeness of data submitted to the registry. Results of this audit should be made publicly available. Specialty societies may select their own third party auditor and determine specific audit methodology.

**Self-nomination**

Specialty society registries should complete an initial self-nomination using a feasible and streamlined process. Yearly self-nomination should not be required for recognized registries; rather, these registries should be required to submit annual reports to CMS or another entity regarding changes to the program. It is important that providers - who must devote time and resources to participation – are able to rely on registry programs from year to year. This is especially important for providers in ambulatory and private practice settings.

**Alignment with Other CMS Reporting Programs**

As noted in the RFI, there is an existing and increasing alignment of the PQRS program with the EHR Incentive Program clinical quality measure (CQM) reporting, the Value Based Modifier Program, and public reporting. While this alignment is highly desirable overall, it does introduce additional complexity to the implementation of 601b. A reasonable approach is to provide additional opportunity for registries to meet federal reporting requirements over several years.

- 2014 and 2015: Registries that meet criteria are recognized as alternatives to PQRS reporting. Participants in these programs receive the benefits of participation and avoid the penalties for non-participation associated with PQRS. Registries able to accept data from EHRs are recognized as alternatives to EHR Incentive CMQ reporting.
Registries performing either/both of these roles would provide confirmation of participation to CMS via standardized report formats (e.g., NPI, TIN; not measure performance or raw data)

- 2016: The registry may publicly report on a website maintained by the registry, or transmit measures data for public reporting to CMS. If a recognized registry participates in public reporting, Physician Compare will direct the user to the registry public reporting site.

- 2017: By 2017, CMS is required to apply a value-based modifier to all physicians participating in Medicare. Physicians should have the option of allowing specialty registries to send quality measures to CMS to be used for the purpose of the value-based modifier calculation. The specialty registries should not be required to calculate the value-based modifier.

**Patient Protection and Reporting Safeguards**

Section 601(b) reflects the recognition by Congress that data reporting and measurement are critical for improving the quality and safety of care and containing the cost of care. ASCO is highly supportive of federal recognition and promotion of specialty society registries as a means of achieving these public policy objectives. Shifting from federal reporting programs to reporting to such registries does, however, highlight a need for regulatory measures that protect patients and do not unnecessarily burden quality improvement. When promulgating rules and guidance, CMS should provide confirmation and clarification on several key points.

First, CMS should confirm that providers and groups that report quality data to a qualified clinical data registry are carrying out health care operations (as defined by the HIPAA rules) and not engaging in research (as defined by the HIPAA rules or the Common Rule). It is important to clarify that providers and groups do not need to obtain approval from an institutional review board (IRB) before reporting data to the registry. Such a statement would be consistent with guidance from the HHS Office of Human Research Protection.

Second, CMS should confirm that aggregation and analysis of quality data within the registry, for example to derive regional, national, or other benchmarks, is also not considered research under the HIPAA rules or the Common Rule. These are classic health care operations which should not require approval or waiver by an IRB or individual patient consent or authorization.

Third, and more broadly, the Common Rule should not apply to any qualified registry activities where the registry complies with the HIPAA privacy and security rules in its stewardship of protected health information. The HIPAA rules are much more protective of identifiable patient information than the more general requirements of the Common Rule. Therefore, the Common Rule should be applicable only when registry data are used in clinical trials or other research activities that involve intervention with patients.

Fourth, CMS should take whatever steps it can within its regulatory authority to ensure that participation in a medical specialty society data registry is recognized as a peer review or patient
safety activity. Provider participation is essential to realize the potential of clinical data registries for improving quality, value, and coordination of care. Providers should have confidence that data they share for self-improvement will not be used against them in private lawsuits. Information in a qualified registry should be protected from discovery in federal and state actions without provider consent. Ultimately, public reporting is the appropriate means of achieving transparency and accountability.

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Thank you for the opportunity to submit comments on this proposed rule. If you have any question or would like to request assistance from ASCO on any issued involving the care of individuals with cancer, please contact Kristen McNiff at 571.483.1631 or kristen.mcniff@asco.org.

Sincerely,

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