January 27, 2016

Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

Re: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs [CMS-3323-NC]

Dear Acting Administrator Slavitt:

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs. The College is the largest medical specialty society and the second-largest physician membership organization in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

1) Why eMeasurement cannot Be Fixed with Incremental Changes to Certification:

While ACP appreciates the ability to provide feedback on this critically important issue, we are concerned that the Centers for Medicare and Medicaid Services (CMS) is asking for piecemeal feedback rather than feedback on more fundamental problems with electronic measurement. Electronic Clinical Quality Measures (eCQMs), or eMeasures, seemed like a good idea when they were first considered, and we still believe that they can play an important role in facilitating improvements in healthcare delivery. In 2010, ACP published a position paper that discussed in great detail the benefits of electronic health record (EHR)-based quality measurement. ([EHR – Based Quality Measurement & Reporting: Critical for Meaningful Use and Health Care Improvement - https://www.acponline.org/advocacy/where_we_stand/assets/ehrs.pdf])

ACP has fully supported CMS efforts to bring the technology to maturity. Unfortunately, experience over the last few years has clearly demonstrated that eMeasurement is not
yet working well enough for our healthcare system to depend on it as a tool for accurately measuring quality and value of care. For the near term, we have only a small set of available measures that have been determined to be of high quality, to be truly evidence based, and to use only data elements that are accurately collected in the course of care delivery by most physicians and other clinicians. These are the only measures that should be in use by quality programs today.

In this Request for Information (RFI), CMS proposes a range of minor enhancements to a certification process with the intent of fixing what is wrong with eMeasures. Unfortunately, the problems with eMeasures cannot be fixed via the certification process. Instead, we have to fix the measure development process and the measures themselves, as the move to value-based care is predicated on meaningful, reliable, accurate, and actionable measures and measurement. Therefore, CMS is being unrealistic to expect that more certification will make up for defective measures and processes. More specifically, the problems with the eCQMs fall into several categories:

a) Structural issues;

b) Data collection approaches/expectations;

c) Measure upkeep based upon new evidence; and

d) Expectations of a predictable cycle for updates.

We believe that basic structural problems with eMeasures are the source of much of what is currently wrong with eCQMs. Those structural problems include: a focus on quality measurement per se, rather than quality measurement as infrastructure to support quality improvement; faulty, infeasible, and/or imprecise measure logic; and lack of consistent attention to what may reasonably be captured in an EHR using normal or even enhanced care workflows. Many problems that have been identified with measurement, such as date/time inconsistencies among different data sources, cannot be fixed through the certification process no matter how the test scripts are designed.

Unlike measures obtained from manual records abstraction, eMeasures are by definition a measurable output from health information technology (health IT), most frequently from EHR systems. As such, eMeasure logic and eMeasure specifications must begin with data elements that are defined in most EHRs. Further, depending on the measure and specialty/scope of practice of the clinician, these data elements should reasonably be expected to be routinely collected during the course of care delivery. Therefore, CMS should only approve eCQMs that meet stringent requirements for data elements that are readily available in common EHR systems, and that are reasonably collected during the course of care delivery (rather than relying on data that currently are non-existent since they are not routinely collected or may be part of the narrative rather than in structured fields). Many of the current problems with eCQMs would disappear if CMS strictly enforced this requirement. We might not have as many measures with this approach, but we would have accurate reporting of the measures remaining.
Additionally, there are issues related to measure upkeep. The ecosystem of measurement is not static; as there is an expectation that at a minimum, measures will evolve either with or shortly after clinical guidelines change. Per this certification proposal, the only way to keep up-to-date with regular (possibly annual) updates to existing measures and to accommodate new measures would be an annual certification process. This might be possible for the small number of specialty-specific EHRs; but for the much larger market of multi-specialty EHRs, it is simply not a reasonable expectation. Additionally, EHR systems are incredibly expensive and complex – it also is not feasible to expect that EHR users could regularly change EHRs in order to ensure that they are using the most up-to-date measure set.

Furthermore, the CMS eCQM management process is predicated on enforcing a predictable annual cycle of activity. As we have seen, a predictable annual cycle is not currently possible. Groups need sufficient time with the measures to perform their responsibilities effectively. Sources of change include changes to standards, value sets, measures, and tooling, as well as the need to identify and fix errors that are found in all of these components throughout the process.

While it is reasonable for clinicians and hospitals to expect to be able to report on any available measure, it is clearly not feasible nor scalable with the existing approach to eCQM certification. And with the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the situation is likely to worsen, as there is a clear expectation that the number of measures available for reporting under MACRA may grow to several times the number of measures currently available.

2) A Recommendation for the Near Term:

The ACP urges CMS to focus immediately on evolving all of the current quality measurement programs, including the Physician Quality Reporting System (PQRS), the Value-Based Modifier Program (VM), and Meaningful Use (MU), to truly align in preparation for the Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) programs. This includes identifying and adopting a core set of measures (perhaps in line with a recent Brookings Institution recommendations and considering a set of measures expected to be identified through an America’s Health Insurance Plans (AHIP) coalition that is currently underway).

3) A New Approach to eMeasure Construction and Certification:

Measure-by-measure certification can never accomplish the goals that CMS has set. We need to take a radically different approach to achieve our shared goals.

a) Adopt new and more functional standards

Once relevant and available data elements have been identified, the content of these elements must be standardized. All eMeasures must conform to a standard model composed of standard constructs, including standard structures, vocabularies, expression language, and value sets that reflect real-world practice. With measures built in this manner, they can then be deconstructed into a library of
components or data building blocks; which can then easily be re-used to efficiently evolve existing measures as well as building new ones. (See recommendation “d” below for a specific path forward.)

b) **Certify functions instead of measures**
With eMeasures developed in this manner, vendors can certify against the underlying components rather than the current approach of certifying against each version of each individual measure. New measures that consist entirely of components already used in other measures would not have to be certified. For new measures that include a new component, proper identification and processing of only that component needs to be certified. We believe this approach would reduce dramatically the effort needed to implement new measures.

c) **Perform automated testing instead of certification for specific eCQMs**
Certification is a heavy-weight process that should be reserved for major changes. A simpler, cheaper, lighter-weight process is needed for testing measure-reporting accuracy. Unfortunately, the current CMS testing tools are not sufficiently robust and do not provide appropriately detailed feedback to meet requirements. With testing tools that fully report errors and causes, vendors could more quickly and efficiently demonstrate accuracy in calculation and reporting.

d) **Leverage clinical decision support logic and structure to enable eCQMs**
One place to look for guidance in how to develop such an eMeasure ecology is the field of Clinical Decision Support (CDS). Standard CDS structures that are already implemented in EHR systems and are in daily use should be adopted as eMeasure standards. If a CDS function is operating properly, an eMeasure that uses that function will also operate properly with little additional work needed by vendors. The best approach for CMS to take is to develop and publicize a plan to migrate to a new set of standards under development at Health Level Seven International (HL7) to address the needs of both quality measurement and CDS. This evolving set of related standards will give all stakeholders in measurement the foundation they need to develop high-quality, implementable measures.

e) **Reorient eMeasurement functionality from EHRs to secure cloud-based services**
Using modern Internet technologies, eMeasurement could operate far more efficiently as an external service. Rather than requiring every EHR vendor to develop and maintain eMeasures and measurement functionality, multiple EHR vendors, and multiple reporting institutions, should be able to share a cloud-based eMeasurement service. With appropriate changes to CMS and the Office of the National Coordinator for Health Information Technology (ONC) certification rules, a limited number of eCQM service providers could be certified to provide eMeasurement services to many EHR vendors, or directly to healthcare institutions. The Oryx measure-reporting process implemented by The Joint Commission, using third parties to collect, calculate, and report offers a model that should be adopted by CMS for all of its measurement activities. With such an approach, competing
service vendors would ensure that anyone who wants to report a particular eCQM will be able to do so. There would be no need to require that vendors support all or particular eCQMs. CMS should separate eMeasurement from the definition of a core EHR system.

f) **Leverage clinical data registries for eMeasurement and reporting**

Another option that shows great promise is the clinical data registry. Rather than base our measurement system on the implementation, calculation, and reporting of measures by clinicians, we should move to registry-based reporting as a better alternative. A registry-based system shifts the focus of quality measurement from the practice to the registry. At the end of each encounter, the EHR system collects appropriate data from the EHR and other relevant sources and submits the data set to the registry. Quality-measure developers can use the registry data to develop measures that will have known precision. Registry service providers can provide near instantaneous feedback and benchmarking to the data submitters. Measurement organizations can develop independent analyses. Finally, these data sources could be a key driver of our move to a learning health and healthcare system.

We thank you for seeking our input on these important issues, and hope that you will find value in our response. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,

Peter Basch, MD, MACP
Chair, Medical Informatics Committee
American College of Physicians