February 16, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3321–NC and CMS-3321-NC2

Submitted electronically at: www.regulations.gov

Re: Request for Information Regarding Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs

Dear Mr. Slavitt:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments regarding the Requests for Information (RFI) on Certification

Frequency and Requirements for the Reporting of Quality Measures, published December 31, 2015, in the Federal Register. The Centers for Medicare and Medicaid Services' (CMS) RFI seeks public comment regarding several items related to the certification of health information technology (IT), including electronic health records (EHR) products used for reporting to certain CMS quality reporting programs.

CHIME is an executive organization serving more than 1,800 chief information officers (CIOs) and other senior health information technology leaders at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation. CHIME strongly supports efforts to reduce the reporting burdens that hospitals and doctors face in capturing and submitting quality data.

In order to promote delivery system transformation and further advance the Triple Aim, the nation's quality measurement strategy must be more in sync with efforts to digitize the industry. CHIME members report ongoing and mounting frustrations with duplicative data capture and reporting similar measures for different programs and payers.

They also have concerns that the current set of requirements are not getting us to a shared goal of better value and better outcomes. CHIME and its members are committed to improving patient care through the use of technology, but, as our comments will detail, CMS has an opportunity to further refine and align quality programs. The RFI addresses some, but not all of our concerns with the current requirements.

Solving the challenges with quality reporting will take time. While CMS and other payers are migrating toward value-based reimbursement, it is important to recognize that many of the quality measures are largely process oriented, rather than outcomes based. The infrastructure both at payers and providers needs to evolve to more fully support alternative payment models and improved quality reporting. Last summer, CMS discovered several problems with data submitted for thousands of providers. While providers were in effect held harmless from penalties, they also lost out on incentives which for many hospitals is millions of dollars. Further, without correct quality data to serve as a baseline it makes reporting in 2016 even harder. From our perspective, it certainly raises questions around why providers are being required to meet a series of complex and burdensome requirements when CMS and vendors are experiencing so many challenges capturing and calculating quality data and how we will be able to move to an era driven by reimbursement that is based on better outcomes and value.

CHIME is pleased to offer detailed feedback below in response to the RFI. Our key recommendations, however, are summarized here:

1. **Reduce the burden on providers by better aligning the reporting requirements of different payers and government programs.**
2. **Require vendors to certify to all electronic clinical quality measures (eCQMs).**
3. **Improve the testing process to be more reflective of real-life clinical scenarios, rather than sterile testing environments.**

A. Frequency of Certification

CMS is seeking feedback on the requirement for health IT modules to undergo annual CQM testing through the CMS approved testing tools and the Office of the National Coordinator's (ONC) Certified EHR (CEHRT) Program, as well as, the benefits of a more predictable cycle from measure development to provider data submission.

The frequency of change associated with eCQMs is a significant issue for our members. They report that it is daunting trying to keep up with requirements that change every year. Many of our members report that they are constantly getting patches from their vendors; one member who uses two very large vendors noted that they received a new package once a month for the entire year. Another member reported receiving upgrades so frequently that they have a full-time equivalent employee solely devoted to validating the upgrade. This also places a big burden on the vendors. We are also hearing concerns about scenarios where a vendor decides they are no longer able to keep up with the pace of changes being required. We are also worried that such frequent changes creates havoc for clinicians in terms of what they must document.

It usually takes a minimum of 24 months for a vendor to make updates to a product and for a provider to deploy the new version. During this period, it takes roughly 18 months for the vendor to create/update the product and then at least six more months for a provider to test and deploy it. While we recognize that measures need to evolve, a balance needs to be reached such that the churn around development and deployment is not endless. It is unrealistic to expect that providers can change their systems every time a change is made to an eCQM or if the reporting standards change. We appreciate CMS recognizing that this could be a burden. **We strongly support a "predictable" cycle from measure development to provider data submission. We recommend that rather than setting specific deadlines for such a cycle a timetable is created so when certain pieces of the timeline slide that the remaining pieces can be shifted to the right rather than adhering to an unrealistic deadline.**

As we have noted before, many of our members submit over 20 reports across federal, state and private sector programs each month. In many cases, the measures are very similar, yet require duplicative reporting. Hours of work and expertise are required to comply with these reporting demands and such burdens are exacerbated by a lack of technical harmonization. In other words, even when the same CQMs are used among different reporting programs, they tend to require different technical specifications, diminishing gains inherent to alignment. We remain concerned that the complexity of generating valid, reliable and accurate eCQMs without human intervention is too often underestimated. In fact, CHIME does not believe that generation of accurate and complete CQMs is possible with current EHR technology. Ideally our members would like to see a situation where a single set of quality measures is identified by the federal government and agreed to by the states and private payers to reduce the

current climate of complexity for providers. **We urge CMS to harmonize measure reporting both among its own programs as well as with states and private payers to reduce the burden of measure reporting on providers by eliminating the duplicative and burdensome requirements.**

B. Changes to Minimum CQM Certification Requirements

As CMS notes, EHRs must be certified to more than the minimum number of CQMs as required by the ONC 2014 Edition Base EHR definition of a minimum of 9 CQMs for eligible professionals (EPs) or 16 for eligible hospitals (EHs) and Critical Access Hospitals (CAHs). Further, EPs, EHs, and CAHs may have limited CQMs available to them and may not be able to report on CQMs that are applicable to their patient population or scope of practice. CMS is seeking feedback on several policy options including whether vendors should be required to have to certify their products to meet all the quality measures.

CHIME members feel strongly that vendors should be required to seek certification for all CQMs and do not favor "partial certification." Without assurances that products can support all measures, CHIME members continue to worry that they will inadvertently purchase a product that does not meet their compliance needs. There is also concern that, after having already purchased a system, they'll decide to report on a quality measure only to find out that the EHR is not equipped to handle it. This would leave them vulnerable to financial penalties for non-compliance. **We urge CMS to take the more comprehensive approach and ONC to require vendors to be certified for all eCQMs while taking into account the impact on vendors in terms of the frequency and number of new measures.**

C. CQM Testing and Certification

As CMS notes the Agency and ONC's CEHRT Program test CQM functionality (for example, by testing a health IT system's ability to import, export, capture, calculate, and report CQM data according to certain standards) through the Cypress Testing and Certification Tool "by enabling repeatable and rigorous testing of a product's capability to accurately calculate CQMs." CMS also notes they expect that as "time progresses and technology improves, EHR systems will have to demonstrate they are able to perform to increasing levels of complexity, including requirements to identify errors, consume larger numbers of test cases, and demonstrate stricter adherence to standards."

We appreciate that CMS has identified testing and certification as areas that could be improved, however we are concerned that challenges with certified systems and the current testing process will not improve many of the issues our members are experiencing.

First, it is our understanding that the CQM testing process can be passed if enough attempts are made. Second, our members report the CQM testing environment is too sterile and that the onus to making sure their products work as intended falls on them. Products tested in a controlled environment do not reflect how well they will perform in a real-world clinical setting. In actuality, providers are grappling with scenarios where once the software is installed systems are getting suspended and tremendous time and resources are being devoted to fixing the system creating an overall cumbersome process and drain on resources. Further, some EHRs are highly customized so that when they test in a pristine environment this further renders the outcomes of testing less meaningful. For instance, one member built their own system for capturing medical history. When it came time for an upgrade from a large vendor, the system's method for capturing medical history did not match with their earlier, customized system and it made measure calculation difficult. We also have received reports from members noting that some CEHRT products could not produce the granularity needed for hospital reporting. While providers try to resolve these issues with their vendors it can take a lot of time and energy to reach a desirable outcome.

We agree with CMS that as time progresses and technology improves that EHRs will have to demonstrate they are able to perform increasing levels of complexity including requirements to identify errors, consume larger numbers of test cases, and demonstrate stricter adherence to standards. However, we do not believe that the current state of testing is prepared to validate eCQMs data in this more complex environment.

A better approach to testing eCQMs is creating a test environment that more closely mimics the workflows of a provider. That includes testing a number of EHR activities like intakes and emergency department and typical daily workflows visits (including complex events and exceptions) thus testing the system's ability to correctly calculate eCQM data using an appropriate sample size so that there is an opportunity to test whether eCQM data

can be correctly derived. Thus, we are concerned that single measure testing is insufficient and does not allow for determining how well a measure will perform in a regular clinical setting. **In order to help CMS determine how many test cases are needed for adequate testing we recommend CMS consult those with deep knowledge of EHR testing rather than those who just have eCQM experience.** Those with these types of expertise will also be able to help CMS with exception-handling and more robust testing scenarios. CMS also seeks comments on the test procedures and certification companion guides published by ONC be improved. **CHIME recommends that CMS and ONC consider developing a common testing approach including publishing robust testing tools including the ability to test continuously during development.** Collectively, these issues do not bode well for providers. If we are to prepare providers for success under new payment and delivery models of care the testing process should be improved. **We recommend CMS and ONC work together to develop a testing environment that can more accurately predict the real clinical workflow of providers.**

Conclusion

CHIME appreciates the opportunity to comment and looks forward to working with CMS and its partners on operationalizing quality reporting requirements that best leverage the use of technology and drive care improvements. Should you have any questions about our comments I encourage you to contact Mari Savickis, Vice President of Federal Affairs, at msavickis@chimecentral.org.

Sincerely,

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