November 17, 2015

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 Implementation of the
        Merit-Based Incentive Payment System, Promotion of
        Alternative Payment Models, and Incentive Payments for
        Participation in Eligible Alternative Payment Models

Dear Mr. Slavitt:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments regarding the Requests for Information (RFI) with a focus on the Meaningful Use of Certified EHR Technology (CEHRT) and Quality Performance categories. The RFIs were published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on October 1 and October 20.

CHIME is an executive organization serving more than 1,700 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. Our organization supports many initiatives under way at the Department of Health and Human Services (HHS) to advance the use of health IT.

The RFIs seek input in operationalizing Section 101 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which replaces Medicare's sustainable growth rate (SGR) formula for reimbursing physicians with a new Merit-based Incentive Payment System (MIPS). The law also sunsets and consolidates the current penalty framework under the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM), and the Meaningful Use Program (MU) into the new MIPS Program. And, the law aims to advance physician involvement in value-based reimbursement by exempting eligible professionals (EPs) participating in an alternative payment model (APM) from MIPS.

In January 2015, HHS laid out a goal of having 30 percent of traditional Medicare payments be tied to an alternative payment model, such as bundled payments or accountable care organization, by 2016. That would grow to 50 percent by 2018. Regarding Medicare fee-for-service payments, 85 percent would be tied to quality and value starting in 2016 and 90 percent in 2018. HHS is also working to advance the so-called Triple Aim of better care, smarter spending, and healthier people in many of its initiatives. A robust and interoperable health IT network is essential to achieving these goals. Two key pieces to advancing new payment models will be streamlining the MU program and quality reporting requirements. CHIME strongly supports creating a pathway for MU whereby physicians are moved to a more flexible regulatory model and away from a "pass/fail" construct. The same pathway must also be created for hospitals. Additionally, the complexities associated with quality reporting should be reduced to bring the value intended under new models of care.

As CMS operationalizes this new payment system CHIME recommends:

1. **Creating parity for both EPs and eligible hospitals (EHs) by removing the existing pass/fail approach for MU.**
2. **Aligning and streamlining quality reporting by eliminating duplicative and burdensome measures, which often take time away from direct patient care.**

CHIME appreciates the opportunity to offer comments on certain sections of the RFI. Our comments are detailed below.

A. The Merit-based Incentive Payment System

3. *Quality Performance Category*

Reporting Mechanisms Available for Quality Performance Category

CMS asked what the potential barriers are to successfully meeting the MIPS quality performance category.

CHIME appreciates CMS' intention to further harmonize measures across the various reporting programs. Providers continue to be incredibly challenged in meeting quality reporting requirements. Since the future of value-based reimbursement is contingent upon the ability to measure performance and outcomes, we believe a unified strategy for capturing and communicating quality in healthcare is needed. Currently, providers are required to report clinical quality measures (CQMs) to several public and private entities. Many CHIME members submit more than 20 reports across federal, state and private sector programs for various CQMs each month. 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 programs, they tend to require different technical specifications. The goal should be to eliminate duplicative quality measures and reporting requirements. Doing so would help to reduce healthcare costs and allow clinicians to focus more attention on patient care.

CHIME members have found that while EHRs are able to automatically produce CQM reports, data is sometimes inaccurate and largely incomparable across different providers. This is due in part to what EHRs are certified to do and what CMS submission requires. CHIME does not believe that generation of accurate and complete CQMs is possible with current EHR technology. In its *Health IT Enabled Quality Improvement* 2014 report, the Office of the National Coordinator for Health Information Technology (ONC) noted, "Standards for specifying and reporting CQMs from EHRs are in use, but these standards are complex, evolving, difficult to implement and often require extensive implementation guidance for each measure." While the 2015 Edition CEHRT works to further standardize

the way quality data is submitted electronically, significant and ongoing challenges persists and duplicative reporting remains an issue.

We also encourage CMS to assess the benefits of capturing structured and unstructured data. The provider community continues to struggle with balancing the needs of clinicians as they attempt to capture a patient's full clinical story with unstructured data versus the requirements of reporting programs to collect structured data through templates and other automations. Collecting both sets of data is important and we need to find a balance that best serves patient care.

Providers also face a challenge when merging data from multiple EHR systems. Providers who need to merge patient data have a very hard time doing so. A master patient index is needed to accomplish this, which is an extremely costly endeavor. As a result, many elect to utilize a registry instead. Additionally, CHIME members also find themselves manually abstracting data from multiple EHRs.

CHIME believes that a unique patient identifier is a foundation for helping to address this issue and ensure greater interoperability between EHRs. At a more basic level, as previously noted, many CHIME members believe that their certified products are not meeting their needs.

Providers also struggle gaining access to timely, understandable and actionable data. MU vendor dashboards have helped them with this, however, access to quality performance data is still hard to obtain with significant lags persisting. Access to real time and actionable data is an imperative for providers as they move to MIPS.

Recommendation: CMS should reduce the burden for providers by streamlining reporting redundancies and refrain from requiring data collection and submission on measures that do not advance patient care. CMS should also provide access to real-time and actionable data, both which will be critical for success under MIPS.

Data Accuracy

CMS asked what should be required in terms of testing of the qualified registry, QCDR, or direct EHR product, or EHR data submission vendor product and how can testing be enhanced to improve data integrity.

Currently under the Physician Quality Reporting System (PQRS), the reporting mechanisms that use CEHRT require that quality measures be derived from CEHRT and must be transmitted in specific file formats. For example, EHR technology that meets the CEHRT definition must be able to record, calculate, report, import, and export clinical quality measure data using the standards that ONC has specified, including use of the Quality Reporting Data Architecture (QRDA) Category I and III standards.

The 2015 Edition of CERHT requires all health IT modules presented for certification for quality to be certified to the QRDA standard. Both the QCDR XML and the QRDA formats (Category I and III) are currently permitted for use, which increases variability. Moving to the QRDA only could improve interoperability, however, the key will be reducing the variability that is likely to occur with varying interpretations of the CMS Implementation Guides (IG). Many providers who are using QRDA are using or moving to QRDA Version III. However, there are different "flavors" of QRDA III which will continue to result in variability. While some vendors will choose to adopt the CMS IG others may not. Providers will be required to make sure their vendor is meeting CMS' IG rules. Also, some vendors offer this for free to their providers while others charge several hundred dollars per clinician. CHIME urges CMS to work with ONC to require vendors adopt the CMS IG and to require vendors adopt robust, interoperability testing.

There is also persisting confusion among vendors around the four testing tools made available by HHS. More education and clarification from CMS would be welcomed. For instance the Cypress tool allows EHR vendors to send QRDA files and if they can send a file this passes for certification purposes. However, CMS has different QRDA validation tools used to support test files and production files. The confusion among vendors can hurt providers' ability to comply with quality reporting requirements.

Recommendation: CMS should require submission of eCQMs only after rigorous testing and validation of those measures has been completed. CMS encountered problems this summer when provider data had to be discarded due to "data inaccuracies." CHIME does not support moving forward with submission of eCQM data until federal regulators can certify the process.

CMS asked whether registries and qualified clinical data registries should be required to submit data to CMS using certain standards, such as the Quality Reporting Document Architecture (QRDA) standard, which certified EHRs are required to support?

Recommendation: CHIME strongly supports uniformity of standards used to drive interoperability. However, we realize that quality measures are being reported in a variety of formats today. CHIME asks CMS to recognize the complexity associated with data submission. While we support the need for flexibility to enable providers to utilize a wide array of tools for data submission, we strongly encourage the agency to work towards reducing variability where it can. This includes, as noted above, requiring vendors to adopt the CMS IGs and to explore new, more agile quality reporting formats for the future.

CMS asked if it determines that the MIPS EP (participating as an individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet data integrity standards, how the agency should calculate their quality performance category score and should there be any consequences.

Recommendation: To the degree that issues arise around data submission and validation, providers should be held harmless while these barriers are overcome.

6. Meaningful Use of Certified EHR Technology Performance Category

CHIME appreciates CMS' willingness to explore removing the pass/fail approach to MU as discussed in more detail below. We are concerned, however, with CMS taking one approach for EPs and a separate one for EHs. Based on our understanding of CMS' interpretation of the laws governing MU, the agency does not believe it has the ability under the Health Information Technology for Economic and Clinical Health Act (HITECH) to completely remove the pass/fail methodology, though, MACRA provides some relief for physicians. CHIME believes that CMS should continue to pursue policy decisions that bring EPs and EHs under a single set of MU requirements. For instance, the agency moved all providers to a calendar year reporting. We strongly support the agency's consideration of removing the pass/fail construct for EPs, however, leaving it in place for hospitals will introduce a level of complexity that will be very difficult for providers and CMS to manage. This is especially important as payment models evolve to support greater coordination between hospitals and physician offices. Having a different set of standards for different providers could jeopardize attempts to connect organizations under ACO or bundled payment models.

Recommendation: We strongly urge CMS to create parity for hospitals and to remove the pass/fail construct for all providers.

CMS asked if the performance score for this category should be based solely on full achievement of meaningful use.

Recommendation: CHIME does not support a scoring methodology that requires 100 percent achievement of all MU requirements. Many of the MU objectives providers must meet contain numerous embedded requirements in the form of multiple measures. Failure to meet all of these measures – with limited exceptions – including meeting specific measure thresholds, spells failure for providers placing them in jeopardy of receipt of financial penalties. We have previously advocated for the removal of the pass/fail methodology of the MU program. While we appreciate CMS is considering how MIPS could address the pass/fail methodology beginning in 2019 for physicians, we believe CMS should address the "all-or-nothing" construct immediately for physicians and hospitals alike.

The existing construct is detrimental not only to providers, but is also holding the field back from devoting time and resources to pursuing interoperability and adoption of other solutions – technical or otherwise – that they deem appropriate for advancing care for their patient populations. CHIME recommends that CMS award all points from this performance category if providers meet 75 percent or more of the Meaningful Use objectives in a program year.

CMS asks whether it should use a tiered methodology for determining levels of achievement in this performance category, allowing EPs to receive a higher or lower score based on their performance relative to the thresholds established in the Medicare EHR Incentive program's meaningful use objectives and measures.

CHIME is concerned that a tiered methodology could be unfair to some providers who continue to struggle to meet measures which require actions outside of their control. Our members continue to report to us that many of their patients are not willing to sign up for their portals, a necessary step to gaining access to their health information, citing data security concerns. In other cases, it is simply unreasonable to expect patients being treated by multiple providers to access the portals of all of these providers. We are deeply concerned about objectives and measures that make providers accountable for patient unwillingness or inability to complete certain actions, given the all-or-nothing construct of the patient engagement measure. Further, to the extent that policy makers wish patients to take specific actions, policy should focus on incenting the desired behavior in patients, not holding providers accountable for behavior over which they have no control.

CHIME supports CMS' change to under the "view, download and transmit" measure from a threshold that required 5% of patients to take action to one under Modified Stage 2. Several of our members, despite significant investments and efforts to engage their patients, found meeting the previous threshold of 5% to be unattainable or nearly unattainable without significant resources which in some cases were diverted away from clinical care. Providers remains concerned that the under Stage 3 the proposed 10% threshold will be unattainable for several providers.

Recommendation: CHIME recommends against the use of a tiered structure and urges CMS not to adopt this methodology. It would add more complexity into the program at a time when we are trying to simplify it. Also, we are concerned that this policy could unfairly disadvantage certain providers who are unable to meet some measures for reasons outside their control.

CMS asked how hardship exemptions should be treated.

Recommendation: CHIME believes that if a provider is granted a hardship exemption for their participation in the Meaningful Use program that this in no way should penalize them under their MIPS score; they should be awarded full credit under the Meaningful Use performance category.

B. Alternative Payment Models

1. Information Regarding APMs

Regarding Eligible APM Entity Requirements

Use of Certified EHR Technology

CMS asked what components of certified EHR technology as defined in section 1848(o)(4) of the act should APM participants be required to use. Should APM participants be required to use the same certified EHR technology currently required for the Medicare and Medicaid EHR Incentive Programs or should CMS other consider requirements around certified health IT capabilities?

Recommendation: Certified products alone will not solve the interoperability challenges that the industry faces. Instead, critical issues like establishing a unique patient identifier are pivotal for advancing patient safety and interoperability. A national approach to patient identification is a prerequisite for interoperability and the lack of a standard patient identifier only serves to aggravate our industry's technical challenges. Without a standard patient identifier, the creation of a longitudinal care record, composed of data created through disparate systems, geographies and chronology is simply not feasible.

Of note, on a recent ONC Advanced Health Models and Meaningful Use Workgroup call held on November 5th, the results of interviews with a technical expert panel (TEP) comprised of several providers asked about health IT needs for APMs were discussed. Among the issues they named as important, were usability and patient identification. Both usability and patient identification are high priorities for CHIME and we agree these two issues will be critical in determining how successful providers are in APMs.

CMS also wanted to know what core health IT functions providers need to manage patient populations, coordinate care, engage patients and monitor and report quality.

Recommendation: Population health tools will be critical for advancing provider success in APMs and we must note that significant innovation is underway. We would like to see that innovation continue to flourish and believe it is premature to try and certify this. Also addressing key barriers around quality reporting, as noted earlier, will be critical to success. Unless root issues like patient identification are addressed, interoperability challenges will persist.

CHIME appreciates the opportunity to comment and looks forward to continuing to be a constructive voice in the dialogue shaping the use of health IT to advance payment and delivery reform. If there are any questions or comments about our letter or more information is needed please contact Mari Savickis, Vice President of Federal Affairs at msavickis@chimecentral.org.

Sincerely,

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