December 16, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted electronically at: www.regulations.gov

Dear Administrator Slavitt:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment, published November 14, 2016 in the *Federal Register.*

As an organization representing more than 2,000 chief information officers (CIOs) and other senior information technology executives at hospitals and clinics across the nation, CHIME members are responsible for the selection and implementation of clinical and business information technology (IT) systems that are facilitating healthcare transformation. As such, our members are deeply engaged with the implementation of this new payment system.

CHIME recognizes that in order for payment and delivery reform to succeed, we need a high-performing, interoperable and secure technical infrastructure. As a general matter, CHIME members strongly support steps that CMS has taken to improve the flexibility by which clinicians use health IT to drive better outcomes. This includes CMS' proposal to adopt a 90-day reporting period at the outset and reduce the number of measures that must be met under the Advancing Care Information (ACI) performance category. We also endorse CMS' decision to make 2017 a transition year and allowing

clinicians to proceed at a pace that best suits their practice and patient needs. In meeting the new rules, we nonetheless see three significant challenges, namely: 1) the persisting lack of interoperability among and across our disparate health system; 2) the need for better synchronization across all Meaningful Use programs; and 3) more attention on cybersecurity. CHIME's high-level recommendations are below and are outlined in greater detail in the body of our letter:

1. **Make 2018, in addition to 2017, a year of transition;**
2. **Adopt a single set of standards to facilitate more seamless data exchange;**
3. **Align health IT reporting requirements across all provider settings to include:**
    a. **Establish a 90-day reporting period for all reporting requirements in perpetuity;**
    b. **Postpone any Stage 3-like measures and use of electronic health records (EHRs) certified to Version 2015 until no earlier than 2019;**
    c. **Remove pass / fail policies – particularly as they remain intact for hospitals - and replace them with policies that allow providers to meet at least 75% of the mandates and still meet the requirements;**
    d. **Allow facility-based clinicians to elect to use their institution's performance rates as a proxy for the MIPS' clinician's quality score;**
4. **Include improvement activities that incent clinicians to take steps to better defend against cybersecurity threats and engage in good cyber hygiene as soon as possible; and**
5. **On data blocking provisions:**
    a. **Limit the data blocking attestation to statement one at this time;**
    b. **Do not require providers to attest to the exchange of structured data; and**
    c. **Adopt an appeals process.**

"Pick Your Pace"

CHIME strongly supports CMS' intention to treat 2017 as a transition year. We believe this is a well-founded and common sense policy to onboard clinicians to an entirely new payment program. We are particularly supportive of CMS' decision to heed our - and other stakeholders' - calls for a 90-day reporting period for both 2017 and 2018. CHIME continues to assert that clinicians would be best served if they had a 90-day reporting period in perpetuity. We support CMS' policy to help more clinicians avoid a penalty by allowing them to report at least 90 days on at least one quality measure, one improvement activity, or the required measures under ACI. **We urge CMS to also consider making 2018 a transition year as well. For reasons further discussed below, we do not believe that clinicians should be required to move to Stage 3 measures any sooner than the 2019 reporting year.**

While we support the new onboarding policies, we believe additional clarity is needed. For instance, there appears to be some confusion about how the new reporting policies will work. Further education from CMS would be helpful. We have received some questions from members on whether a clinician would need to report for the entire year or just 90 days in order to receive a score of 100 under MIPS. It is our understanding that it is indeed possible for a clinician to achieve the highest score by only reporting for 90 days, though the likelihood of hitting a score of 100 is increased if reporting occurs for more than 90 days. It is therefore our understanding that a clinician can achieve the same score whether they report for a full year or as little as 90 days. We recommend CMS conduct further outreach around this topic.

Advancing Care Information

Support for Flexibility

As noted above, CHIME supports the additional flexibility CMS has offered under the ACI performance category including:

- Reducing the number of measures clinicians have to meet under the ACI performance category.
- Creating a fairer point structure that accommodates those meeting the Modified Stage 2 measures with the same number of points available to those meeting Stage 3 measures, which will be critical since most clinicians will not be able to meet Stage 3 measures in 2017 for reasons which include vendor readiness.
- Increasing the maximum number of points available under ACI from 131 to 155.
- A reporting period of 90 days for 2017 and 2018.
- Bonus points for using certified electronic health records (CEHRT) to meet a clinical practice improvement activity.
- Bonus points for reporting to more than one public health or clinical registry (beyond immunization).

Need for Synchronicity

CHIME members have expressed concerns that managing the complexity associated with having to meet three sets of Meaningful Use requirements – one for MIPS, another for Medicare hospitals, and yet another for Medicaid providers – will become untenable. CMS said in the Modified Stage 2 / Stage 3 final rule published in October 2015 that, "we do not anticipate significant challenges or delays in the adoption and implementation of the 2015 Edition CEHRT." However, with less than a month until January 1, the date by which providers have been given the option to begin voluntarily meeting Stage 3 and for which Version 2015 would be required for use should they elect to do so, it is clear most vendors are not yet ready. In fact, some of our members have already alerted us to the fact that they will not receive their upgraded products until well into 2018. If you couple this with the concerns we have outlined around interoperability, it becomes clear that the road ahead, while paved with good intentions, is fraught with signals and warning signs.

CHIME recommends CMS better align the three sets of reporting requirements, at a minimum to include: 1) **Establishing a 90-day reporting period for all reporting requirements in perpetuity; 2) Postponing any Stage 3-like measures and use of EHRs certified to Version 2015 until no earlier than 2019; 3) Removing pass / fail policies – particularly as they remain intact for hospitals - and replacing them with one that allows providers to meet at least 75% of the requirements and still pass; and 4) Giving facility-based clinicians the option to use their institution's performance rates as a proxy for the MIPS' clinician's quality score.**

State of Interoperability Will Continue to Create Challenges

The success of MIPS and APMs hinges on clinicians' access to timely and relevant information to best inform decision-making that facilitates better care. Yet, when we look at the majority of measures upon which clinicians will be judged, they are highly dependent on an interoperable healthcare system. We do not believe interoperability will become widespread without more uniformity in the use of healthcare data standards.

Many of the measures in ACI are carried over from the Meaningful Use program and the concerns we have with them under this program are no different from the concerns we have articulated throughout the history of the

Meaningful Use program. In fact, success in the ACI performance category will require clinicians to perform well beyond the thresholds set under Meaningful Use in so much as the better a clinician performs on a measure the more likely they are to score higher on MIPS.

In the rule, CMS notes that it intends "to develop the requirements for the advancing care information performance category to continue supporting the foundational objectives of the HITECH Act, and to encourage continued progress on key uses such as health information exchange and patient engagement. These more challenging objectives are essential to leveraging CEHRT to improve care coordination and they represent the greatest potential for improvement and for significant impact on delivery system reform in the context of MIPS quality reporting." Our members would strongly agree with this statement if there was indeed a state of semantic interoperability. Unfortunately, ubiquitous interoperability is still a stretch goal. Requiring clinicians to meet more aggressive measures that hinge upon interoperability sets them up for failure. The root causes for the lack of interoperability cannot be solved by CEHRT alone. In fact, we believe quite the opposite; a stronger state of interoperability facilitated by a uniform set of standards, including a national solution ensuring accurate patient identification, is our best hope for driving better care.

Recent data also points to an immature marketplace. A recent KLAS report, *Interoperability 2016 From a Clinical View: Frustrating Reality or Hopeful Future?* concluded, "Perhaps the single largest cause of the delay in interoperability progress rests at the feet of market maturation. Other barriers certainly exist …. including a lacking national infrastructure (which includes the need for a nationwide patient ID), resource challenges, and even lack of desire or need to share in some markets." KLAS also concluded that only 6% of providers actually are receiving information from outside sources electronically which is significantly benefitting patient care. While this data is limited to EHR-to-EHR data exchange, the fact remains that most providers are not benefiting from the ability to obtain information that positively impacts their ability to treat patients due to the persisting lack of semantic interoperability across the health system.

Without a more mature marketplace, a uniform set of widely adopted standards, and a way to uniquely and uniformly identify patients across the care continuum, we fear interoperability challenges will persist and the measures clinicians and other providers must meet for CMS reporting programs must reflect this reality. CHIME continues to lead the charge with our $1 million dollar challenge aimed at locating a solution for uniquely and securely identifying patients with 100% success. We expect to announce a winner to our competition in 2017. We also continue to work to remove the legislative ban that prohibits HHS from using any resources to implement a unique patient identifier. **CHIME recommends CMS work with ONC to ensure that a single set of standards are adopted to facilitate more seamless data exchange and offer support to private sector initiatives focused on improving patient identification at a national level.**

Vendor Readiness Impacts Provider Readiness

Since the inception of the Meaningful Use program, and now with MACRA, CHIME has consistently advocated that vendor readiness and product availability is paramount to provider success. We are deeply concerned with CMS' decision to push forward with timelines that call for Stage 3 and Stage 3-like measures beginning in 2018. Both vendors and providers need time to prepare for the requirements. For vendors that means development time and for providers that means testing and deployment. As noted earlier, providers are now facing three sets of Meaningful Use requirements creating the need for even more time to prepare. A quick review of the Office of the National Coordinator for Health IT's (ONC) Certified Health IT Product List (CHPL) reveals that as of November 30,

only 23 products have been certified for Version 2015 and almost half are those are from one particular vendor. Compared with the 4,069 certified products for Version 2014, this represents 0.6% of all products. Even if some vendors choose not to seek certification for Version 2015, the low number calls into question vendors' ability to deliver products in time for providers to meet Stage 3 / Stage 3-like measures in 2018 let alone do so voluntarily in 2017 as envisioned by CMS**. CHIME again urges CMS postpone requiring the use of Stage 3 / Stage 3-like measures until no earlier than 2019.**

We have also received feedback from some members questioning how vendors plan on supporting products in the ambulatory space given that the ACI performance category gives some discretion to clinicians in terms of what measures they choose to meet. It is not clear to us that vendors will support all of the measures equally. Usability issues also continue to persist as a challenge that our members must help clinicians navigate daily.

Improvement Activities

CHIME appreciates that CMS has reduced the number of points and activities that must be met under the final rule in order to achieve maximum success under this performance category. CHIME is also pleased to see that CMS will be offering bonus points to clinicians who use their CEHRT to meet certain improvement activities under ACI, as noted above. We are also very pleased to see that CMS has listed a number of Improvement Activities which can be met using CEHRT functionality.

CHIME is disappointed that CMS did not accept our suggestion for new activities, including participation in OpenNotes, use of a health information exchange (HIE), or giving credit to clinicians for taking steps to fortify their practices against cybersecurity threats. We are particularly concerned given with the growth of cyber threats facing the provider community. The transformation of our healthcare system is predicated on robust data exchange and the ability for clinicians to access data where and when they need it. Meanwhile, patients are increasingly demanding ubiquitous access to their records. As healthcare grows more digital, more data is susceptible to compromise and we are seeing this play out with more breaches and highly-publicized headlines around ransomware.

American healthcare providers are under a state of attack from criminal enterprises and nation states intent on doing harm. Providers of all sizes are struggling to keep up. To put this in context consider the following two examples. One our members who works for a 130-bed community hospital turned away 3,000+ attempted attacks on their network on Mother's Day 2016 alone. On the flip side, a member from a large, multi-billion east coast health system blocked one million ransomware-ridden emails during the month of March. Since most clinicians are small practitioners, they are at a significant disadvantage from a resource standpoint to ward off these types of threats making the need to help shore up their ability to ward off threats vitally important.

According to data from the Office for Civil Rights (OCR), the number of healthcare breaches has spiked from an incidence of 10 in 2010 to 57 in 2015 and the number of lives affected by this has increased from 568,358 to 111,812,172 during that same time period. Also, according to a recent Ponemon Institute report on health data security, roughly 90 percent of healthcare organizations had a data breach in the last two years and 45 percent had more than five breaches. Poneman also found that criminal attacks were the leading cause of breaches, accounting for nearly half, a five percent increase from last year's study and that ransomware and malware are the top new threat. In short, they conclude, "the cyber threat landscape has never been more dangerous."

Finally, we would add that the proliferation of networked medical devices will substantially increase the role of the Internet of Things (IoT) in healthcare, opening up providers and patients to increased threats, some of which can pose substantial risks to patient safety. Intel has forecasted that the IoT will increase from 15 billion "things" in 2015 to 200 billion "things" by 2020. As Intel also notes, most devices are not in people's homes. One of the highest areas of concentration they cite is healthcare (30%), second only to factories (40%). **With the growing amount of healthcare information being accessible and moved electronically CHIME recommends CMS include as soon as possible clinical improvement activities that incent clinicians to take steps to better ward off cybersecurity threats and engage in good cyber hygiene.**

Data Blocking

We recognize that CMS is bound by the MACRA statutory requirements that call for providers to attest they are not engaging in "data blocking." Specifically, CMS is calling on providers to attest to the following three statements, which remain largely unchanged from CMS' proposed rule:

Statement 1: *A health care provider must attest that it did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.*

Statement 2: *A health care provider must attest that it implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) implemented in a manner that allowed for timely access by patients to their electronic health information (including the ability to view, download, and transmit this information); and (4) implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated health care providers, and with disparate certified EHR technology and vendors.*

Statement 3: *A health care provider must attest that it responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.*

We appreciate that CMS has acknowledged in the preamble of the final rule that it is not their intent to hold providers responsible for issues outside their control and that "a variety of factors may prevent the exchange or use of electronic health information." We also agree with CMS that, "the compatibility or interoperability of certified EHR technology may be limited or restricted in ways that are too numerous and varied to catalog." We appreciate that CMS has provided more insight into possible business, technical and organization practices that could constitute situations outside the control of a provider and "that are inherently likely to interfere with the exchange or use of electronic health information," include: contract terms; charging cost prohibitive prices; implementing EHRs in "non-standard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information"; and locking users into using EHRs in a certain manner (i.e. steering referrals).

MACRA only calls on providers to "demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the professional has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology." Statement one largely mirrors what is in the statute and CHIME supports this. While CHIME proposed alternate language for the second and third

attestation statements, CMS elected not to adopt our suggested changes. In thinking through how best to accomplish the objectives set forth in statute, and balance that with statements that could be unduly burdensome for providers in so much whether a provider successfully or unsuccessfully met the requirements, is fairly subjective.

First, our members found the phrase under the second statement, "to the greatest extent practical and by law," and the word "timely" under statement three to be subjective and they questioned who would be the arbiter of these decisions? We would like to point out that providers are already required to meet "timely" requirements to furnish data electronically to patients under the "Patient Electronic Access to Health Information" objective which is a mandated under all three sets of Meaningful Use requirements.

Second, we are concerned with the use of the term "structured" in the second statement under the fourth item which reads, "(4) implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated health care providers, and with disparate certified EHR technology and vendors." Not all information that is stored and exchanged via CERHT is necessarily structured and we worry inclusion of this word will create significant challenges for providers (and even vendors) to meet. For instance, dictated reports like progress notes, radiology, and operative notes are often not structured and even when they are converted (i.e. office notes) into structured data some of the value is often lost. Take the example of a heart ejection fraction test which measures the heart's ability to eject blood and which is used to determine the health of a heart. The results are included in an echocardiogram which can indicate when there is heart failure, however, these are not depicted as structured data in all cases.

Lastly, we are concerned providers will be called upon under the second statement to attest to bi-directional exchange of structured data. CMS notes that, according to 2014 data, one-fifth of all non-federal acute care hospitals had bi-directional data capabilities and were able to easily integrate summaries of care into their systems, but we would argue that this data is not a ringing endorsement for providers' capabilities. The earlier referenced KLAS report is also peppered with examples of challenges providers are facing around achieving bi-directional data exchange. While this may be less of a challenge for some and more for others, we believe it warrants a second look by CMS. It also seems patently unfair to hold providers accountable to statements 2 and 3 when there is no comparable set of requirements for the vendors. Finally, we are concerned that there is no appeals process or informal review in place should a provider dispute the data blocking provisions which we think need to be instituted in order to afford due process.

Given the concerns we have outlined above we recommend CMS only move forward with requiring attestation statement #1 at this time and hold off on requiring providers to attest to statements 2 and 3 no earlier than 2019. In no case should providers be required to attest to the exchange of structured data at this time. Additionally, CMS should institute an appeals process for providers.

Conclusion

CHIME appreciates the opportunity to lend our perspective to this new program and stands ready to aid the Administration navigate the technical landscape such that policies put into place best support patients and the providers who serve them. Should you have any questions on our comments please contact my staff, Mari Savickis, Vice President, Federal Affairs at msavickis@chimecentral.org.

Sincerely,

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CEO & President, CHIME

Marc Probst, CHCIO
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