

May 29, 2015

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

Karen B. DeSalvo, MD, MPH
National Coordinator for Health Information
Technology
U.S. Department of Health and Human Services
Office of the National Coordinator for Health
Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Slavitt and Dr. DeSalvo:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide our comments on the proposed Stage 3 of the Meaningful Use (MU) program for electronic health records (EHRs). As you are aware, the AMA has been actively engaged with the Administration to improve the MU program and ensure its success for both physicians and patients. These incentives along with physician engagement have resulted in the vast majority of physicians, over 80 percent, are now using EHRs. Our goal now is to move from adoption to improving patient care and enhancing innovation. To do this, we cannot ignore the problems and barriers that are preventing us from moving towards a learning health system—including focusing on patient safety, privacy and security, interoperability, and how we can promote rather than hinder innovation. The following provides our detailed comments on the proposed Stage 3 rule with these thoughts in mind. Overall, we continue to see a program that will create significant challenges for physicians, patients, and vendors and urge you to strongly consider our recommendations. **In particular, we caution against finalizing Stage 3 at this time given the overarching concerns listed below:**

1. **Patient Safety:** There remains no thorough evaluation of how implementing EHRs and meeting complex MU requirements impact patient safety;
2. **Modifications Rule Impact:** Sufficient time is needed to ascertain the industry's response and ability to meet the modified versions of Stages 1-2;
3. **Privacy and Security:** There remains huge gaps in how to protect patient data, which must be addressed before expanding the program to include additional technology and other requirements;
4. **Focus on Interoperability:** More time is needed to prioritize interoperability, reduce barriers to data exchange, and promote the use of innovative technologies through pilot projects;
5. **Quality Measures:** The technology and infrastructure are still lacking to handle the next generation of quality measures and electronic reporting; and
6. **Merit-Based Incentive Payment System (MIPS):** The structure and requirements of MIPS have yet to be outlined to ensure physicians have the appropriate tools to improve health care.

Moving to a high-performing health system necessitates high performing and interoperable systems as well as ensuring that all of the gaps above are addressed. **As such, our primary recommendation is that the Centers for Medicare & Medicaid Services (CMS) should hold off on finalizing Stage 3 to allow sufficient time to thoughtfully address these issues, focus on ensuring physicians have access to high-performing EHRs, and that the “cornerstones” for interoperability (as discussed in greater detail in our comments to the proposed certification rule and [Interoperability Roadmap](#)) are systematically resolved.**

I. **Overarching Issues**

A. **Patient Safety**

The AMA strongly supports the widespread adoption of health information technology (health IT) and believes that efforts should be made to encourage the use of new tools that can improve patient care. EHRs and health IT, however, introduce new kinds of risks and challenges into an already complex health care environment. While we are becoming aware of these concerns, a full understanding of these issues and their solutions is not yet known by stakeholders. Recently, the Joint Commission provided a comprehensive review of its sentinel events related to health IT, finding that between January 1, 2010, and June 30, 2013, over 120 events occurred.¹ The report found that the vast majority of these problems were caused by usability, workflow, and design or decision support issues and concluded that health IT-related harm will likely increase unless risk-reducing measures are put in place.²

The AMA echoes these concerns—if we do not focus on improving usability and the design of EHRs, harm to patients will result. Part of the problem is that the necessary solutions to mitigate against patient safety events are still unknown. Moreover, contract clauses continue to preclude physicians from speaking freely about patient safety issues, further concealing these problems. We are equally concerned that the vast number of MU requirements has rushed products into the marketplace without the proper considerations for patient safety and that the certification program continues to solely follow the MU requirements without evaluating the safety and security of these systems. The proposed rule, nonetheless, continues to expand the amount of data collected and stored in EHRs, heightens decision support requirements, and creates new workflow challenges without addressing these growing safety problems. **Additional study and evaluation of patient safety is greatly needed before further expanding the program.**

B. **Impact of the Modifications Rule**

CMS proposes several modifications for MU program years 2015 – 2017 to improve participation and allow flexibility. Yet, the Stage 3 rule reverts back to adding new measures and increasing measure thresholds that have proved challenging beyond physician control. For

¹ The Joint Commission *Sentinel Event Alert 54: Safe use of health information technology*. March 31, 2015. Available at http://www.jointcommission.org/sea_issue_54/

² *Id.*

example, most physicians have been unable to meet the requirement under Stage 2 that calls for five percent of patients to “view, download or transmit” their information. CMS recognized this barrier in its Modifications proposed rule by proposing that only one patient must view, download or transmit their data. However, under the proposed Stage 3 rule, CMS proposes a significantly greater threshold for this measure—25 percent—along with new requirements, making it very likely that most physicians will continue to be unable to meet this specific part of the program. As noted in our comments on the [Modifications rule](#), the AMA is committed to working with CMS, patient groups, and other interested stakeholders to help physicians better engage their patients in the use of online tools. The sentiment on the front lines, however, is that CMS is headed in one direction for the Modifications rule and an entirely different one for Stage 3 without addressing fundamental problems in the program. **We therefore urge CMS to study the impact of the Modifications rule on physician participation before finalizing Stage 3.**

C. **Privacy and Security**

Another area where attention is lacking is how to address the growing privacy and security risks related to EHRs and other technology. Between 2010-2013 there were almost a 1,000 significant data breaches affecting 29 million patients, two-thirds of which involved electronic data.³ Moving to an electronic environment has greatly increased the probability of cyber-security threats and breaches of patient data. Already, we have seen major institutions experience large data breaches that affect thousands of patients, as well as new cyber-attacks that cause EHRs to go dark literally for days. The FBI has reported that the rate of health care data breaches is rapidly increasing partly because medical data is more valuable on the black market than financial or other information. We therefore can expect an increase in the frequency and number of patient files that may be inappropriately accessed. Data also continue to show that patients have serious doubts about sharing their health information electronically given these problems.

The federal government is still ascertaining how best to respond to cyber threats and attacks to appropriately protect patient data. Physicians remain ill-equipped to address these highly technical and emerging threats that depend on technology to protect and secure patient data. Furthermore, most practices have not established contingency plans for when their EHR system is inaccessible and what to do if physicians cannot access, enter, or view patient data that is stored in their system. This problem is likely to get worse as the addition of other technology and more data will increase the probability of system failures.

Rather than address these concerns, the proposed rule tries to highlight the numerous technology advancements that can be used and added to EHRs. It, however, fails to address how this may increase the risk for privacy and security problems. Indeed, the Food and Drug Administration (FDA) jointly with the Federal Communications Commission (FCC) has

³ Blumenthal, David, M.D., McGraw, Devon, J.D. (2015) Keeping Personal Health Information Safe The Importance of Good Data Hygiene. *Journal of the American Medical Association (JAMA)*, 313(14):1424. Retrieved from <http://jama.jamanetwork.com/article.aspx?articleid=2247128>.

highlighted this problem by pointing out that the addition of technology will require sufficient wireless connectivity and broadband availability to support more software or allow older technology to work with newer technology on the same network.⁴ **Before expanding the program to include additional technology and other requirements, we believe that the immediate need for greater protection of patient information must first be addressed.**

D. Focus on Interoperability

The AMA is grateful for the Office of the National Coordinator for Health IT's (ONC) proposal to increase transparency of certified products and implement post-market surveillance. Nonetheless, we remain very concerned that CMS continues to require physicians to meet objectives that require interoperability when, by and large, this still does not widely exist. We continue to believe that the ONC certification process is driving EHR development at the expense of innovation and patient and physician needs. Requiring health care providers to move more data electronically, and to do so using systems that do not interoperate, is not only unfair, but is counterproductive and will not solve the barriers that currently exist.

The AMA is committed to working productively to address interoperability challenges. We are founding members of Healthway and CareQuality, efforts aimed at addressing key pieces of interoperability, such as patient matching and standards. Instead of finding solutions, we are very concerned the Administration is looking to fix interoperability by simply expanding the use of certified products, including going beyond the MU program. Moving more data does not equal greater interoperability and adopting more products that have the same barriers to data exchange will also not improve the current state of this technology. **We strongly recommend a certification program that remains focused on cornerstone issues integral to interoperability, such as standardized vocabularies, patient matching, privacy, security, and high value use cases.**

While we understand that the rule is trying to design a program that will drive the use of new technology, we strongly believe that it will be impossible to predict how health IT will develop over time and the new opportunities to improve patient care. To do this, we believe that the MU program should allow physicians to pilot test new technology while not penalizing physicians. We understand the goal of streamlining and simplifying the program, but believe that there should be opportunities for physicians to seek out alternative pathways that may drive innovation in the future, including promoting telemedicine, digital health beyond EHRs, and other novel approaches to delivering care. **CMS and ONC should work together to foster pilot programs that offer the opportunity to test new technology and new ways of engaging patients and coordinating care as part of the final stage of MU.**

⁴ FCC – FDA Joint Workshop: Promoting Medical Technology Innovation – The Role of Wireless Test Beds. March 2015. Available at <https://www.fcc.gov/events/fcc-and-fda-joint-workshop-promoting-medical-technology-innovation-role-wireless-test-beds>.

E. Quality Measures

A complete discussion of our comments and concerns on quality reporting can be found below under the headings “Public Health and Clinical Data Registry Reporting” and “Quality.” In general, we continue to see problems with timelines, requirements, and new objectives that fail to align with existing quality improvement efforts.

F. The Merit-Based Incentive Payment System

The Medicare Access and CHIP Reauthorization Act of 2015 requires significant changes to the physician quality reporting programs by combining MU and other programs into a single Merit-Based Incentive Payment System or MIPS. This change will require alignment, resources, and new regulations, transforming MU from a stand-alone program to one component of a larger reporting system. Rather than create all of the new requirements and program changes for Stage 3 now, CMS should consider these changes as it develops and implements the MIPS program. This will save physicians from the heavy lift of a new program that is subsequently altered again in future rulemaking. It will also allow vendors to implement measures for the new reporting program without having to re-tool products. Finally, it will save resources for CMS by reducing the number of new educational and guidance tools, which will quickly become out of date if Stage 3 is finalized without reference to MIPS.

Given this changing landscape and the broad concerns identified above, we are hesitant at this point in time to try and pin down the requirements and parameters for Stage 3, especially since this will be the permanent structure of the program moving forward. We also continue to harbor concerns that the MU program remains one that is overly prescriptive and could impede the transition to outcomes-based care. Changes in technology and our understanding of privacy and patient safety will likely be very different in only a few years’ time. We are concerned that trying to predict these changes will result in a program that is less than optimal, limits innovation, and may go down the wrong path for improving patient care. **Consequently, we urge CMS to not finalize its proposal for Stage 3 at this time but reevaluate this proposal in the next year to incorporate feedback from physicians, patients, and vendors as they gain more experience with EHRs and other health IT.** We do not believe that this is stopping the momentum of the program, but simply allows for evaluation and a more careful analysis of what physicians and patients will need in 2018 and beyond. We, however, offer our following comments below on proposed Stage 3 based on our current understanding of the program, recognizing that such views are limited and may be very different in the course of a year.

II. Proposals for Stage 3

A. Single Stage for All Participants

CMS proposes to adopt a single set of requirements, known as Stage 3, which would apply across the Medicare and Medicaid programs to all providers, regardless if they participated previously. To the degree that CMS elects to move forward with finalizing Stage 3, we agree

that it should be the last Stage of the MU program and that, at minimum, 2017 should be a transitional year. Doing so will greatly alleviate many of the concerns for both vendors and providers who have had to constantly monitor for program updates, system changes, and reengineer workflows to accommodate new rules and requirements.

We are, however, concerned that new participants will be unable to jump straight into Stage 3. By immediately moving all participants, regardless of their previous experience, to Stage 3, CMS provides no glide path but assumes that those new to the program will be able to meet advanced levels of reporting, including high percentage thresholds. This approach ignores the realities of implementing EHRs, which requires significant workflow adjustments, training, implementation, and a general learning curve. In particular, those just starting the program in 2018 are likely to be the least advanced and most challenged practices because they will not receive any incentive payments to assist in this transition.

In its 2015-2017 Modification rule, CMS took a more measured approach by providing accommodations to Stage 1 providers in 2015 through alternate exclusions and specifications. **We believe a similar approach should be used for any new participants so that they are not immediately placed on the same level as providers who have had several years of experience with the program requirements.** While we recognize that CMS wants to simplify the program, we believe that basic accommodations for new participants will not be overly complex and can help encourage participation for those who may have previously struggled to join the program.

B. Full-Year Reporting Requirement

The proposed rule seeks to move all participants to a full calendar year reporting period but fails to consider the complexities of this mandate for vendors and providers. Pushing vendors to develop products too quickly and without time to test products risks introducing patient safety issues and could stifle technical innovation. The AMA also worries that updated versions of certified software will be unavailable until the last quarter of 2017, and that it could be later for some vendors.

The yearly reporting period also introduces problems for quality reporting. We are concerned that vendors have insufficient time to update and test their products, especially for new quality measures that will not be finalized under the Physician Fee Schedule (PFS) until November 1 of the previous year. Vendors are unlikely to be able to implement the changes made in final PFS rule in time to deliver updated products prior to the January 1, 2018, Stage 3 deadline, and these conflicting deadlines will continue to be a problem that will impact future program years.

The full year reporting period also fails to afford time for physicians to change vendors and perform system changes. Problems with the usability of EHRs have left some physicians in situations that require multiple EHR upgrades or even entire system changes. We have heard from physicians that, since the start of the MU program, their practices have changed vendors up to three times. These switches were further complicated by a lack of access to data in old

systems, timely implementation, and staff retraining, as well as significant expense to the practice.

Switching vendors is not the only challenge. There are numerous technical reasons for why an EHR system can go down, limiting the ability to report for a full year. Indeed, there have been numerous well-documented cases of technology glitches that require the entire EHR to stop working for several days, not only hurting successful participation in the program but jeopardizing patient care when physicians have no access to records. For example, a recent internet “brown out” last summer left numerous physicians who use a particular cloud-based vendor without access to their system for several days. There have been several other documented cases of system failures, requiring physicians to revert back to paper for several days and then go back and try to manually enter data into the EHRs. By requiring a full calendar year of reporting, the program structure penalizes physicians for actions outside of their control and makes meeting the higher thresholds proposed in Stage 3 an even greater challenge. **We therefore strongly urge CMS to implement a reporting period that is less than a full year to account for technology updates, downtime, and changes as well as provide a period that can be devoted to innovation and improvements.**

C. 90-day Reporting Period for New Entrants

As noted above, we are very concerned that CMS proposes to eliminate the 90-day reporting period for participants new to the program, requiring that these individuals start the program at full speed and report for a full calendar year. The program has always afforded new entrants a shorter reporting period to allow them to adjust to the new requirements. This is in part because of the pass-fail program design, which leaves no room for error and requires physicians to devote significant time and resources to ensuring they meet every measure and requirement. **Removing this initial 90-day reporting period will create an enormous barrier for new entrants and likely deter participation in the program.**

Moreover, we are very concerned that CMS has misconstrued messaging on quality to justify the removal of the 90-day reporting period for new EPs. We see no reason to allow an initial 90-day reporting period for Medicaid EPs and hospitals while excluding Medicare EPs. Rather, CMS should level the playing field for all new entrants without exception and provide all new participants with an initial 90-day reporting period.

We once again remind CMS that Congress authorized the Secretary to define the “quality reporting period” for Physician Quality Reporting System (PQRS) penalties in 2015 and beyond. Section 1848(a)(8)(A)(i) of the Social Security Act requires a PQRS adjustment “if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under subsection (m)(3)(A)...” Section 1848(a)(8)(C)(iii) also states that “The term ‘quality reporting period’ means, with respect to a year, a period specified by the Secretary.” There is no explicit requirement that the “period specified by the Secretary” must be an entire year. In addition, the phrase “with respect to a year” logically refers to the year in which penalties would apply; otherwise, Congress could have stated that the “quality reporting period” means a

“prior year” specified by the Secretary, instead of a “period specified by the Secretary.” The referenced subsection 1848(m)(3)(A) says “an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or for purposes of subsection (a)(8), for the quality reporting period for the year)...” Again, the term “for the year” refers to the year that penalties will apply, as differentiated from the quality reporting period. We believe this authority permits CMS to shorten and align quality reporting periods.

D. Topped-out Objectives and Measures

The AMA understands that over time reporting on certain measures may become unnecessary because they become the standard of care and are widely adopted. We caution, however, that CMS should not remove measures that may be fundamental to the necessary infrastructure for health IT. Standardizing certain data elements may be necessary to ensure data can be exchanged across EHR systems and other technology. The two criteria outlined in the proposed rule to evaluate whether a measure is “topped out” solely focus on performance of the measures and do not consider the role the measure plays in promoting and enabling a viable health IT infrastructure. We do not believe that performance rates alone provide a valid reason to consider a measure “topped out.” High performance rates on some measures among reporting EPs may be partly attributable to intensified improvement efforts motivated by the reporting opportunities. Furthermore, classifying any given measure as having a high performance rate when the Stage 2 reporting rate is less than 10 percent of all EPs is premature. **Accordingly, we urge CMS to consult stakeholders, including physicians and vendors, before removing measures. Any proposal to deem a measure “topped out” should be addressed through notice and comment rulemaking to ensure appropriate stakeholder feedback.**

E. Clarity on MU Denominators and Numerators

We are encouraged that CMS recognizes telehealth visits when considering how physicians should calculate their MU performance. This proposal is forward-thinking and will help provide guidance as more care is moved beyond the typical office visit. We also support the ability for the EP to choose whether to include the patient in the denominator in cases where the EP and patient do not have a real time physical or telehealth encounter.

We are also pleased that CMS proposed to include the patient-authorized representative in the MU numerators as equivalent to the patient. We believe this will encourage physicians to treat the authorized representative in the same fashion as the patient and may help clarify existing confusion with certain privacy rules.

CMS has also proposed to maintain the policy that at least 50 percent of an EP’s patient encounters must occur at a practice/location or practices/locations equipped with CEHRT. CMS also proposed to retain the policy of using for the denominator the number of unique patients seen. In the case of the Computerized Provider Order Entry (CPOE) objective, the proposed denominator is the total number of medication, laboratory, or diagnostic imaging

orders created by the EP. For the eRx objective and related EP measure, it is the total number of permissible prescriptions. These policies disadvantage physicians when their patient encounters take place in post-acute and long-term care settings, which CMS has considered to be “outpatient” encounters for purposes of EHR meaningful use. These physicians also lack control over the availability of CEHRT in such settings. The AMA recommends for these physicians that, given the limited adoption of CEHRT by nursing facilities, the EP measures should not include in their denominators unique patients seen or orders created for patients in POS 31 and POS 32. Similarly, for purposes of satisfying the definition of meaningful EHR user, we believe that such patients should not be counted.

III. Specific MU Objectives

Overall, the AMA strongly supports streamlining the MU program to focus on a key set of objectives that will encourage the expansion of EHRs, facilitate interoperability, and improve care quality, as was the initial intent of the MU statute. We have extensively outlined in previous letters how the complex nature of the MU program has stymied innovation, diverted resources, and slowed progress. While in this proposed rule CMS highlights how it has simplified the program into eight objectives, in reality, the program maintains almost all of the same measures and simply repackages them.

We recognize that some flexibility is provided by grouping these measures and offering the ability to meet thresholds for two out of the three requirements. In addition, we welcome the removal of the core vs. menu design, which was confusing to many physicians. Yet, we are concerned that the program as proposed is still overly burdensome and goes well beyond what the statute outlined for MU. The following provides our specific asks with respect to each proposed objective, however, we continue to believe that greater evaluation of the current program is necessary before moving to Stage 3.

A. Protect Patient Health Information

Protecting patient health data is one of the most important components of ensuring the wide-adoption and use of EHRs and other health IT. The move to EHRs has rapidly increased the possibility for theft and security breaches as noted in a recent article published by the *Journal of the American Medical Association*. The article documented that close to a thousand data breaches affected 29 million medical records between 2010 and 2013 and that the number of breaches reported per year increased over the same period, from 214 in 2010 to 265 in 2013.⁵ If patients are concerned that their health information will be compromised, they are likely to resist sharing key information, reducing the value of these tools. Some surveys suggest that this reluctance to share data is already occurring.⁶

⁵ Vincent Liu et. al *Data Breaches of Protected Health Information in the United States*. JAMA April 14, 2015. Available at <http://jama.jamanetwork.com/article.aspx?articleid=2247135>.

⁶ Agaku IT, Adisa AO, Ayo-Yusuf OA, Connolly GN. *Concern about security and privacy, and perceived control over collection and use of health information are related to withholding of health information from healthcare providers*. Journal of American Medical Informatics Assoc. 2014; 21(2):374-378.

We strongly support the need to secure patient information. Nonetheless, to fully protect patient data, physicians need greater technical assistance and support. While most physicians understood how to properly secure paper files, the complex requirements to protect electronic data are beyond a physician's expertise. We believe a national educational campaign sponsored by the federal government is needed to help physicians ensure that they are adequately equipped to protect electronic patient information. **Vendors, developers, and other health IT stakeholders need to play a more pivotal role in providing appropriate data protection and safeguards.** The risks of a data breach should be fully conveyed to physicians and patients in an easily understandable manner when they are implementing a product so that they can take the appropriate steps to protect data. CMS should further recognize that attaching additional hardware, importing data from mobile applications, and other actions will further increase the risk for data breaches, especially since these other uses may fall outside of the HIPAA privacy and security protections. Both physicians and patients need more information about how to balance the interests of adopting new tools while ensuring privacy and security are maintained.

We do, however, agree that CMS has struck the right balance with respect to audit logs. We believe that their use is an important feature of EHRs, but recognize that there may be situations and technological problems that warrant disabling this function, especially to prevent patient safety problems. We support the proposal to enable this function when possible but appreciate that CMS has not taken an overly heavy-handed approach in this rule.

B. Electronic Prescribing (eRx)

Many prescriptions still cannot be electronically transmitted due to technical barriers and specific patient considerations. CMS' proposal to increase the threshold to 80 percent simply fails to account for these reasonable exceptions that are common in most physician practices and are largely used to accommodate patients. A few examples of why this threshold could be challenging to meet are outlined below:

- Mail order drugs: Mail orders often result in an exceptionally high rate of follow-up phone calls and faxes to confirm prescriptions, which will not count for the eRx measure.
 - Government pharmacies: Military and government pharmacies, including Tricare, only accept printed prescriptions.
 - Nursing home patients: Physicians who treat a significant number of patients that reside in nursing homes may be unable to e-prescribe because the nursing home is responsible for the issuance of the prescriptions.
 - Controlled substances: Technology barriers, state laws, and workflow challenges can prevent e-prescribing of controlled substances.
 - Patient preference: Many patients prefer paper prescriptions for financial reasons (e.g., they are undecided as to whether to fill the prescription locally or through mail-order) or because the prescription may not be necessary (e.g., a physician may prescribe pain medication that may not be needed but is used as a precaution). Using paper prescriptions
-

in these cases can save money and time by avoiding filling expensive medications that go unused.

- Patient Choice of Pharmacy: Many times the patients will have a default pharmacy but due to the time of day or the patient's daily activities, the patient prefers to go to a different or closer pharmacy. Since a physician cannot cancel a prescription electronically, many patients prefer to have a written script that allows them to fill the prescription at the pharmacy of their choice.
- International patients: It is our understanding that physicians who serve a large contingency of international patients are unable to send scripts electronically.

We also think it is unreasonable for CMS to include this higher threshold for Stage 3 when several critical eRx standards, such as prior authorization, have not been finalized. In 2003, the Medicare Modernization Act (MMA) specifically mandated the development and promulgation of uniform standards, recognizing the cost savings that would result from streamlining this process. Physicians should be able to obtain real-time information about their patients' benefits and medications authorization status, however, this functionality remains elusive. **Based on these concerns, we urge CMS to:**

- 1. Limit the threshold for this measure to no higher than 60 percent;**
- 2. Establish standards before moving on to higher thresholds and requirements for eRx;**
- 3. Expand the exclusion category to cover physicians who cannot meet the eRx threshold due to individual circumstances or patient populations; and**
- 4. Adopt the proposal to allow the provider to include or exclude prescriptions for controlled substances when calculating their performance for this measure.**

C. Clinical Decision Support (CDS)

We support CMS' explanation that CDS can include tools beyond pop-up alerts. In particular, we are encouraged that the agency highlights other methods that may be less disruptive and can be incorporated more seamlessly into physician workflows. We strongly encourage vendors to consider usability concerns when implementing CDS tools.

We continue to hear that certain specialists and sub-specialists are struggling to find CDS tools relevant to their practice to meet the requirements of this measure. Both the clinical quality measures and high-priority health conditions are more focused on primary care practices and may have limited applicability across different patient populations. While these practices may be able to identify two or more CDS tools, we believe setting the threshold arbitrarily at five interventions, without any exclusion, will continue to be challenging and require practices to implement tools that may have little value to patient care. **We therefore recommend CMS allow an exclusion for physicians who face challenges implementing five CDS interventions relevant to clinical quality measures or high-priority health conditions.**

D. Computerized Provider Order Entry (CPOE)

The CPOE objective contains three measures: 1) that at least 80 percent of medications are ordered electronically; 2) at least 60 percent of lab orders are entered using CPOE; and 3) at least 60 percent of imaging orders are entered using CPOE. The AMA appreciates that CMS expanded the category for imaging to include diagnostic imaging, such as ultrasound, magnetic resonance, and computed tomography, as it may allow more specialists to meet this measure.

CMS has proposed to retain the policy from Stage 2 that requires orders meeting the CPOE measures be “directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.” We appreciate that CMS has clarified that:

- A credentialed medical assistant may enter orders if they are appropriately credentialed;
- A physician’s staff member may enter orders if they are appropriately credentialed and performs assistive services similar to a medical assistant, but carry a more specific title due to either specialization of their duties or to the specialty of the medical professional they assist;
- Medical staff whose organizational or job title, or the title of their credential, is other than medical assistant can also enter orders if appropriately credentialed to perform equivalent duties of a credentialed medical assistant; and
- Providers may use their discretion to determine the appropriateness of the credentialing of staff to enter orders.

The AMA, nonetheless, maintains the same concerns we have registered on several occasions in the past with respect to this requirement. While we understand the intention behind these restrictions is to ensure that the physician or other provider sees and responds to alerts, we believe the better approach, given the well-documented and rising physician frustrations with workflow concerns, is to allow the individual physician or their institution to decide how to facilitate CPOE. We continue to hear that physicians can no longer delegate basic administrative tasks to other workers because of this MU measure, wasting time and resources for physicians and their practice. **We strongly recommend physicians, medically licensed professionals, credentialed medical assistants, and other trained individuals as deemed appropriate by the individual provider or institution, be able to enter orders for patients for the purposes of meeting these measures.**

E. Patient Electronic Access to Health Information

Measure 1 (Access to Patient Information Provided):

As a preliminary matter, the AMA strongly supports ensuring patients have access to their health information. Unobstructed access is necessary to fully engage patients in their health and promote better health care decision-making. We believe that any barriers to patient access

should be removed and are willing to work with CMS, ONC, vendors, and patients to find innovative and easy-to-use solutions that fully inform patients.

We also welcome the proposal to allow patients to use application-program interfaces (APIs) rather than solely patient portals to supports data access and exchange, as this new technology may provide more usable and accessible tools for patients and be more financially feasible for providers. We believe that the use of APIs should be optional (Alternate B) given that this new technology is still developing and that many physicians have already invested and implemented portals, which may be working well for their practices.

CMS' proposal requiring information be made available in 24 hours, however, sets a high bar that we believe will penalize physicians who may not be capable of moving at lightning speed. The 24 hour requirement for more than 80 percent of patients simply ignores the reality that technology is not yet seamlessly incorporated into physician workflows and that these tools take significant time and resources away from patient care. We worry that setting the threshold this high will not account for technology failures, system upgrades, switching products, or other actions outside of the physicians' control that may prevent them from providing access in such a short time. We continue to hear more and more stories of cyber-attacks and systems being completely down for weeks a time; yet, this measure has no release valve for these problems.⁷

In addition, this quick turnaround fails to recognize that physicians often need time, longer than 24 hours, to review, analyze, and evaluate patient results. Chronic care patients often have complex disorders that can be interpreted in many different ways, requiring physicians to consider journal articles and other resources before drawing conclusions about treatment. Similarly, many physicians need to consider the results of several different tests before reaching decisions on the most appropriate way to provide care. We worry that the tight timeframe mandated by CMS will force physicians to answer patient questions and provide advice based on insufficient information.

We would also add that physicians need timely access to information, especially as we transition into MIPS and alternative payment and delivery models. Physician access to patient data, however, is significantly hampered by the lag time in obtaining quality measure feedback reports from CMS. Often it is over two years before a physician has an opportunity to actually act upon the information contained in the feedback reports. In addition, extracting data from the EHR has become an extremely costly endeavor. Timely access to this information is needed at the point of care to help physicians improve population health and better treat patients. In an ideal world, access for physicians and patients would be immediate. However, we need to acknowledge existing barriers and continue to work to remove them. **Based on these realities, we recommend CMS:**

⁷ See e.g., Politico *MedStar EHR goes offline* April 9, 2015. Available at http://www.politico.com/morninghealth/0415/morninghealth17818.html?ml=ae_1 Health IT New *Boston Children's EHR down for days* March 27, 2015. Available at <http://www.healthcareitnews.com/news/boston-childrens-ehr-down-days>

- 1. Limit the threshold for this measure to no higher than 60 percent of all patients;**
- 2. Retain the four business day timeframe;**
- 3. Provide an exclusion for physicians who face technological difficulties that prevent them from providing such access; and**
- 4. Make use of APIs optional.**

Measure 2 (Use CEHRT to identify patient education materials):

With respect to the second measure on specific educational resources, we continue to believe that physicians should have the flexibility to provide these resources in whatever is the most useful format for their patients (e.g., electronic copy, printed copy, electronic link to source materials, through a patient portal or personal health record). The following outlines specific challenges associated with this measure:

- Availability: EHRs may not include the full spectrum of educational materials, leaving out tools that may be the best sources for patients.
- Foreign Languages: The EHR may contain insufficient resources in foreign languages for patients who do not speak English or English is their second language.
- Usability of EHRs: Physicians report that they have to hunt and peck for the information in the EHR, which takes longer than providing the patients a handout. What was once a one minute task has now expanded into a process that requires querying, searching, filtering, and printing. Because the EHR search query is not always accurate, we have heard that physicians must read through over 40 potential handouts before finding an exact match to the patient's actual condition. As one physician aptly noted, "Since when did documenting become more important than actually talking to a patient?"

We therefore recommend CMS:

- 1. Not limit educational resources to those identified by Certified EHR Technology; and**
- 2. Consider other methods that may be more efficient and reasonable at providing this information.**

F. Coordination of Care through Patient Engagement

Measure 1 (Active Engagement by Patients):

We appreciate CMS' effort to allow options beyond the patient portal to satisfy the requirement for patient engagement. Recent surveys have found that additional tools and mobile devices may be better equipped at engaging patients. For instance, a recent survey by the Healthcare Information and Management Systems Society (HIMSS) found that nearly 75 percent of respondents said they used patient portals, but just 36 percent considered the app-enabled portals a "highly effective means of engaging patients."⁸ Similarly, a recent study published in the *Journal of the American Medical Informatics Association* found that patient portals could

⁸ 2015 HIMSS Mobile Technology Survey. Available at <http://www.himss.org/2015-mobile-survey>

widen the gap in health disparities—patients with low health literacy, less education, and who are African American were much less likely to use portals compared with white patients and those who were more health literate.⁹ CMS’ proposal may ameliorate these concerns to some degree by allowing alternatives to the patient portal, including APIs and other technology that may be more accessible to different patient groups.

We are very concerned, however, that the proposal requiring 25 percent of patients to view, download and transmit their information is an exceedingly high bar. We believe this measure is poorly crafted for several reasons. First, it limits how patients can engage with technology and their physicians. Patients have repeatedly prioritized other functions, such as scheduling appointments, paying for services, refill reminders, and discussing treatment options with their doctor over viewing, downloading, and transmitting data. Yet, none of these other activities “count” for purposes of this MU measure. Our members also report that patients often want to review their health care data at the point of care, alongside their physician. Instead of incentivizing this behavior, the measure requires patients to access the portal themselves at a later time and date. Physicians are placed in a difficult position of encouraging patients to access the portal despite the information being redundant, if already provided at the point of care, and confusing if provided without the interpretation of a care provider.

Unfortunately, the Stage 3 rule does nothing to improve these problems or recognize the broader set of activities desired by patients. Instead, the proposal simply establishes a five-fold threshold increase, moving from five percent to 25 percent of a physician’s patients. This increase directly counters CMS’ own data on the program that suggest that physicians are struggling to meet even a five percent requirement. We do not believe this significant jump will be achieved or will improve the exchange of data. Rather, we believe the measure must be changed to include other functions and new uses of technology. Such a revision would allow patients to become more accustomed to using these tools so that they are then more inclined to use them in the future for clinical purposes.

We recommend CMS modify this measure to:

- 1. Include a broader set of actions, such as convenience tools (billing/appointment scheduling) to better meet patients’ needs and increase the likelihood that physicians will meet this measure;**
- 2. Recognize age and cultural gaps that could result in a digital divide if physicians do not have explicit exceptions to ensure these patients can be included in the MU measure; and**
- 3. Take into account the changes proposed in the Modifications rule that establish a lower threshold before setting a higher one for Stage 3.**

⁹ S. G. Smith, et al. **Disparities in registration and use of an online patient portal among older adults: findings from the LitCog cohort.** *Journal of the American Medical Informatics Association*, April 2015. Available at <http://jamia.oxfordjournals.org/content/early/2015/04/21/jamia.ocv025>

Measure 2 (Secure Messaging)

Again, while we appreciate and support the intent of this measure, we worry physicians will struggle to meet the proposed threshold, which would require physicians to send or receive a secure message for 35 percent of all of their patients. The current program's data simply do not support such an increase nor does the rule explain how this jump in the measure threshold can be accomplished. We nonetheless strongly support the proposal to include in the measure situations where providers communicate with other team care members. The AMA, however, is unclear as to how the measure will calculate when patients are "included in the conversation" and believe this requirement could unnecessarily limit the utility of this measure. For example, do patients need to be mentioned by name, identifier, date of birth, or some other option to be tracked for measurement purposes? Given the lack of patient identification tools, we do not believe this proposal will be easily monitored, creating significant barriers for physicians. **We recommend that CMS:**

- 1. Drop the threshold from 35 percent to 10 percent; and**
- 2. Broadly count situations where secure messaging is occurring between a physician and another health care provider.**

Measure 3 (Patient-Generated Data)

CMS has also called for a new measure that requires physicians to accept patient-generated data from at least 15 percent of their patients. First, we continue to point out that physicians are quick to adopt new technology when it will allow them to improve patient care. While the prospect of patient-generated data is evolving, the evidence base for these data remains unclear. For example, a recent article in the *British Journal of Medicine* published opposing viewpoints on the utility of mobile apps.¹⁰ Other data suggest that there remain serious questions as to whether patient information is relevant, accurate, and meaningful. Accordingly, the AMA worries that CMS' proposal, if adopted, mandates the use of an electronic tool that is still developing and requires the incorporation of data that have not yet been sufficiently studied.

Moreover, before mandating sharing of data, patients have expressed the desire to understand what information is being collected, how it is being stored, and the goals for its use. None of this is clearly established with respect to patient-generated data, placing the cart before the horse. Some patients may not be aware that the Health Insurance Portability and Accountability Act (HIPAA) Rules are inapplicable to networks and service providers that are neither covered entities nor business associates, thereby affording a significantly lower degree of regulatory protection to information generated or transmitted in this fashion. Moreover, the information yielded through health-related smartphone applications can be of uncertain reliability, as indicated by a recent study showing a 30 percent error rate in assessing melanoma

¹⁰ Husain, Iltifat, M.D. & Spence, Des, M.D. "Can healthy people benefit from health apps?" *British Journal of Medicine*, April 2015.

risk that could result in delayed diagnosis and associated patient harm.¹¹ Instead, the AMA would like to first engage patients to discuss data collection and identify the best ways to improve care. The real question should be not what data do we want to collect, but what problem do we want to solve?¹² Identifying answers first will help guide decisions and the tools needed to improve care.

Second, we worry that the technology landscape is still evolving. Not every EHR vendor is capable of handling patient-generated data, and while this would be a mandated functionality under Version 2015 of CEHRT, there are no fully-developed standards for incorporating this information. Furthermore, we do not believe the timelines proposed in these regulations will accommodate a smooth transition. As highlighted in a Jason report published for the Agency for Healthcare Research & Quality (AHRQ) in November 2014:

There is insufficient openness of data formats and algorithms for these devices, preventing interoperability and innovation in synthesis of individual health data. Although many of today's activity monitors include some open protocols, the data are usually locked in data structures that make it difficult for individuals to directly use the data. For example, service agreements have significant restrictions on how individuals may use what is in fact their own health data....

While standards such as the IEEE Personal Health Data Standards (ISO/IEEE 11073) do exist, the accuracy of the devices appears to be based on mostly proprietary algorithms and calibration processes. As a result, devices from different vendors measuring the same health or fitness activity will provide significantly different and thus incomparable data, e.g., numbers for steps, distance, and calorie counts. In fact, even the same device used in a slightly different way (e.g., attached to one's hip as opposed to one's wrist) will produce different results....

To truly enable patients to improve their health and wellness with better knowledge from such devices, the industry should establish meaningful statements of uncertainty for both fitness measurement and fitness calculations so that data are comparable and interpretable. Metrics and standards should be independently reproducible from raw sensor data.¹³

We are also very concerned that this new measure will lead to mounds of information without proper context or data segregation. It is not clear how data will be tagged so that it is obvious to the physician where external data originated. Tagging is also an important feature to ensure information is not inadvertently mixed in with clinically generated data. Without data

¹¹ Joel A. Wolf *et al.*, *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, *JAMA Dermatology*, 149 no. 4 (2013): 422-426.

¹² Robert Wood Johnson Foundation. *Data For Health: Learning What Works*. April 2, 2015.

¹³ "Data for Individual Health," Prepared for: Agency for Healthcare Research and Quality, AHRQ Publication No. 15-0006-EF, November 2014.

integration standards, vendors are likely to vary in the form patient-generated data are presented to the physician. While this variation could be seen as flexibility in system design, the simple fact is physicians will be challenged to ensure usability. We are concerned patient information could be entered simply as a “data dump” that is not actionable for physicians. Instead, we believe that patient-generated data should be encouraged but more appropriately belongs in the certification regulation, promoting vendors to first get this capability correct and secure before requiring physicians to act on it. Systems should be capable of receiving such information to anticipate future uses of the data that could improve patient care.

Lastly, we worry about security issues associated with patient-generated data and seek clarification on how CMS intends to mitigate these issues. For instance, patient-generated data could be incorporated into an EHR in a variety of ways. It could be hand keyed into a portal by a patient, sent through secure email, or uploaded into the EHR as a file attachment. Each method could open an EHR up to external threats or cyber-attacks. In one of many scenarios, a physician’s EHR allows patients to upload patient-generated data into the EHR through a portal. In this instance, if a patient felt it was necessary to share their data collected through a wearable or remote monitoring device, more than likely the data would be encapsulated into a file for ease of transfer. By selecting and uploading the file from their local computer, the patient may inadvertently introduce a virus or other malicious software into the physician’s EHR. We are very aware of the well-documented threats large medical centers and payers are facing when it comes to cyber-attacks. Even in one small practice, one infected file uploaded from a patient’s computer could devastate their own medical information. Worse still, a compromised EHR could expose the personal medical history of tens of thousands individuals to the outside world. This level of data breach is drastically different from someone’s credit card number being stolen given the sensitive nature of health care information. As with other industries, it will take time for best practices to develop and evolve to protect EHRs. **Based on these numerous concerns we recommend that CMS include this requirement as part of the certification regulation and not mandate it as a separate measure in Stage 3 until these issues are thoroughly thought through and addressed.**

G. Health Information Exchange (HIE)

The AMA is very concerned that this measure does not take into account the current realities around data exchange. According to a Blackbook survey in 2015:

- 81 percent of medical specialty and primary care physicians indicate that getting their patients’ data into the EHR system is too difficult;
- 95 percent of all physicians are very certain that the lack of interoperability/access to historical patient results from reference and outpatient freestanding labs are directly causing excessive over-testing;
- 98 percent of physicians believe that missing diagnostic imaging results cause over-testing;
- 82 percent of small physician practices admit to routine meaningful use workarounds as standard operating procedure; and
- 71 percent of providers confirm public HIE connection and use fees are prohibitive for regular use.

Physicians strongly support interoperable EHRs that would be capable of supporting the proposed measures; however, today's technology still does not adequately support this functionality. Even Version 2014 CEHRT is woefully inadequate to meet both physicians' workflow and patients' needs and CMS/ONC has still not resolved key interoperability barriers, including patient matching. Rather, the Administration's approach appears intent on driving interoperability through increased data exchange. The AMA remains very concerned that CMS has not only increased the thresholds for measures that are unattainable but continues to add requirements and expand MU to other delivery and payment proposals.

Aside from the persisting lack of interoperability, several specialists noted to us challenges with the medication reconciliation requirement that could preclude successful participation. First, medication reconciliation is a time consuming activity that often occurs outside of the office visit, particularly for medically complex patients. Second, there are a number of EHR workflow issues not addressed by CMS. Third, for physicians such as radiologists who do not treat patients face to face, it is unlikely that they will be able to meet these requirements. Since incorporation and reconciliation of the minimum data sets required for these two measures may not be pertinent to the interpretation of imaging studies (or other referral-based care), **if CMS decides to move forward with this objective, we recommend that they explicitly exclude referrals for ancillary services, such as imaging studies and laboratory tests from the denominators of the second and third measures. Alternatively, CMS could add a "no office visits" exclusion.**

While we appreciate that CMS has proposed a number of exceptions and that that physicians would only have to meet the thresholds for two of the three measures, we nonetheless are deeply concerned that this objective will be too hard for most physicians to meet for reasons outside of their control. As you are aware, only approximately nine percent of EPs graduated successfully to Stage 2. Given the ongoing and well-documented lack of interoperability among disparate EHR systems, the AMA does not believe it is prudent to move forward with an objective that requires physicians to continuously move data in non-interoperable manner. **Rather than focusing efforts on moving more data, we strongly recommend, as discussed above, that the focus remain on furthering functional interoperability, that is, the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.**

H. Public Health and Clinical Data Registry Reporting

CMS proposes to consolidate all optional public health agency (PHA) and clinical data registry (CDR) objectives into one new mandatory objective, similar to the 2015-2017 MU rule. Physicians must select to report on any combination of three out of five available options. Essentially, this mandates a new requirement without addressing how a physician, who is reporting through a CDR, may receive credit for MU quality requirements and PQRS. We believe submitting data to CDRs should not be just another MU objective, but reporting through CDRs should directly count toward a physician's quality measurement reporting objective in MU.

While we support population and public health activities, we believe the expanded mandate is premature and the exclusions are insufficient. There is now a burden on states and physicians to register and engage in PHA reporting when there is no guarantee that state and local PHA will neither comply with the standards, nor be able to meet the standards in time. We are also concerned that many vendors will charge to connect with each physician's desired PHA or CDR due to our awareness of vendors erecting technical and financial barriers to connect to a physician's desired PHA or CDR or otherwise limit choice of connections. Several widely used EHR vendors charge into the thousands of dollars to connect and some outright refuse to connect. Ultimately this may limit options, especially for certain specialties.

We acknowledge that CMS proposes exclusions within each PHA and CDR objective and broadly defines "active engagement," but we do not feel that these exceptions are sufficient. CMS provides three options for defining "active engagement." The most flexible option, Option 1, states that "registration was completed within 60 days after the start of the EHR reporting period; and eligible professional, eligible hospital or critical access hospital is awaiting an invitation from the PHA or CDR to begin testing and validation." This 60-day timeframe is overly restrictive when physicians, vendors and jurisdictions may not be ready to comply with this new requirement. We are seriously concerned with the ability of third parties/external entities to handle the onslaught of requests, whether it is an EHR vendor, registry or state or local agency to complete registration. Connecting to a third party, such as a registry, requires a physician practice to enter into a legally binding contractual relationship that may take more than 60 days. There are also various factors a physician may have to consider outside of routine practice, such as complying with human research subject protections, researching the availability of PHA and CDR in their jurisdiction and specialty area, EHR vendor's willingness to connect to their desired third parties, the cost charged by the EHR vendor, and cost to participate in one of these PHA and CDR activities. Consequently registration may not be completed within 60 days after the start of the reporting period, despite good faith effort of the physician.

Measure 1 (Immunization Registry Reporting)

The proposed exclusion pathways associated with the measure and the requirement for bi-directional exchange for immunization registries go beyond what current Stage 2 requires. There are opportunities to make submission of this measure more efficient if public health agencies would standardize their collection methods around a common transport mechanism. We urge HHS to work on standardization of immunization registries to further the overall goal of national interoperability.

We also request that CMS expand what it considers successful reporting under this measure to allow for variation in standards at the local level. A physician who submits to an immunization registry in the method expected by their state or local agency, but not using the standards of certification should be considered as meeting this measure for the purpose of MU. For example, if a state immunization registry still expects HL7 2.3.1. or is not ready in 2018 for bidirectional exchange, providers should still be able to have met this objective.

Measure 5 (Clinical Data Registry (CDR) Reporting)

We are also concerned with physician's ability to meet this requirement because the 2015 CEHRT proposed rule does not include certification standards for connecting EHRs with CDR. The rule only addresses standards with EHRs and PHA. Essentially, vendors do not have to be accountable to meet the CDR measure option. In addition, the proposed exclusion for this measure is jurisdiction based, but the vast majority of CDRs, specifically qualified clinical data registries (QCDR) within the PQRS program are national. **Accordingly, we believe the exclusion should be expanded to include the fact that a vendor may not connect or make it cost prohibitive to connect to a physician's preferred CDR.**

The AMA recommends CMS:

- 1. Alter the definition of "Active Engagement" in Option 1 to "contact was initiated by the physician to the CDR or PHA via email or written notice within the EHR reporting period;"**
- 2. Expand the exclusions to account for specialty variation. A more appropriate exclusion is "does not treat or diagnose or directly treat any disease or condition associated with Measure 1, 2, 3, 4 or 5;"**
- 3. Allow a physician to receive credit when submitting to an immunization registry in the method expected by their state or local agency;**
- 4. Deem a physician who is participating in CDR/QCDR activity as satisfying MU quality requirements. Actively engaging with a CDR/QCDR is a form of quality improvement that should be sufficient to satisfy quality reporting without duplicating efforts; and**
- 5. Expand the CDR Measure to include the fact that a vendor may not connect or make it cost prohibitive to connect to a physician's preferred CDR.**

IV. Quality

We appreciate CMS' effort to attempt to align MU clinical quality requirements with PQRS by addressing future quality reporting requirements in the Medicare Physician Fee Schedule. However, we are concerned with vendors' ability to meet the growing complexity of quality measures, especially as MIPS is implemented. As we move away from strictly process measures to outcomes, resource use, patient reported and appropriate use measures, there needs to be a process in place to ensure vendors update their systems to incorporate the new data elements, as well as ensure CQMs can be exchanged, captured and transmitted within the EHR. **Therefore, we are concerned with CMS' proposal to move away from attestation of clinical quality measures (CQMs) to electronic reporting by 2018. We urge CMS not to move forward with its proposal until the below health IT infrastructure challenges are resolved:**

- Lack of standardized clinical data terminologies to allow information in the EHRs/registries to be exchanged and captured seamlessly;
- Lack of developed standards to appropriately capture electronic quality measures within the EHR;

- Deficient CMS infrastructure to accept electronic transmission of measures (the only way for CMS to accept eCQMs is through electronic generation of files);
- Reliance on demographic data that are often not needed for clinical diagnosis and are often housed in the practice management system (PMS), which makes data collection difficult and costly;
- Obstacles for Clinical Decision Support (CDS) since it is tied to MU quality requirements;
- Module certification for registries to report CQMs; and
- Ensure CQMs are part of the MU program and included by vendors.

Certification Requirements for Reporting of CQMs

We are supportive of CMS' proposal to require vendors to certify to all eCQMs that are in the EP selection list. Without an assurance through CEHRT that vendors will have to certify against the entire eCQM list, physicians will be on the hook to report on measures that are not the most clinically relevant or claim an exclusion, and have to report separately to satisfy other CMS physician quality programs. For many specialty areas, there might not be a business case for vendors to update their systems with the relevant specialty specific measures due to low volume and/or a small share of a vendor's market. Physicians and patients should be assured they have the tools to assist with care, especially if CMS moves forward with its proposal to require electronic reporting by 2018.

V. Maintaining the Pass-Fail Program Design

CMS declines to move away from its all-or-nothing program construct stating that it is constrained by statutory language, which requires more stringent objectives over time and the inclusion of certain core measures. In reading the statute, however, it is hard to understand how CMS interprets this language as tying its hands from offering needed flexibility. Unlike the MU program, the statute calls for a limited and discrete set of requirements to become a meaningful user— using certified technology, electronic prescribing, exchanging information, and reporting on clinical quality measures. Had CMS focused on these discrete principles, there may not be a need to offer flexibility. Yet, the program design, even in Stage 3, goes vastly beyond the statutory language, creating measures, within objectives, within stages, never contemplated by the law. If CMS has the authority to significantly expand upon the statutory requirements, it certainly has the authority to establish these requirements in a fashion that offers flexibility.

The challenge with the current program is that it offers no incentive to try. Physicians are penalized when they miss or cannot substantiate just one of the numerous requirements that were never contemplated or included in the MU statute. A technological failure, that is no fault of the physician, can limit the ability to hit thresholds. Delays in software and hardware technology are placed on the backs of physicians with no consequences on other actors. Flexibility, therefore, solves the growing apathy by allowing the program to account for these circumstances.

We continue to have concerns that the program is not adequately suited for all specialists, though even primary care physicians are struggling to comply. The hardship exemption in place for anesthesiologists, pathologists, and radiologists recognizes the challenges that many in these

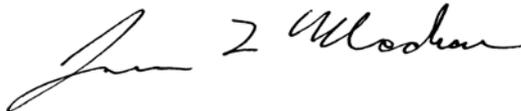
specialties encounter to meaningfully participating in the EHR Incentive Program. For these physicians, greater flexibility is needed to accommodate their practice needs. For instance, while there are a small number of pathologists who have successfully attested to MU, it is largely because they were adequately enabled to participate because they work primarily in large integrated, academic medical centers. This enables them to “ride” the data of other physicians. If a specialist relies on faulty data provided by another eligible physician in the integrated hospital setting, that specialist will be liable even though they have no control over the other physician's data. Therefore, data “riding” while allowed by CMS, is not without risk. There is also some uncertainty as to whether CMS intends to continue the blanket hardship exception beyond 2016 for anesthesiologists, pathologists, and radiologists. We seek clarification as to whether this will continue or whether these specialists will be required to apply for one in 2017 and 2018.

CMS has also declined for Stage 3 to expand hardships, establish lower thresholds for penalties, or mitigate measures that have proved to be poorly written and implemented (despite never being included in the MU statute). Instead, we continue to hear that CMS may incorporate further mandates by using conditions of participation and other levers to mandate the use of EHRs and the requirements of MU. We are very concerned that this is moving far beyond what the statute intended and authorized CMS and ONC to do in creating the MU program. Congress is already weighing in on several aspects of the program, such as interoperability, where it believes there are significant failures in what it hoped to achieve. We encourage CMS to focus on fixing these problems before it expands the program beyond what was outlined in the statute.

Conclusion

The AMA appreciates the opportunity to comment on Stage 3 of the MU program and is eager to help advance our nation towards an interoperable, safe and secure learning health system. We stand ready to discuss our ideas and work collaboratively to achieve these goals. If we can be of any further assistance, please contact Mari Savickis, Assistant Director, Federal Affairs, at 202-789-7414 or mari.savickis@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD