

May 20, 2015

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

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments on the proposed rule, *Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017*, published April 15 by the Centers for Medicare & Medicaid Services (CMS). The AMA strongly applauds the Administration for proposing a number of changes that make meeting the program's requirements for reporting years 2015-2017 more flexible. Many of these changes respond to several ongoing concerns expressed by physicians, hospitals, vendors, and other stakeholders over the complexities of the Meaningful Use (MU) program.

The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) has successfully spurred adoption of electronic health records (EHRs) among physicians—today, approximately 80 percent are using some form of EHR. Physicians are also adopting other forms of technology at a rapid pace, which is indicative of their appetite for solutions that engage patients, improve health outcomes, and deliver efficiencies to the health care system.

Despite this rapid uptake, physicians have faced a number of barriers to meeting the MU program requirements, many of which are outside of their control. Ongoing challenges include, but are not limited to, the lack of usability and interoperability among EHRs, significant data exchange fees, and numerous quality reporting programs with their own requirements. Some of these challenges are due to an immature technology infrastructure, which is still growing and evolving to meet the needs of 21<sup>st</sup> Century digitalized health care. Other challenges are associated with the complexities inherent in large programs, and still other issues are rooted in program requirements that do not align with existing high-value clinical and business use cases. The AMA believes many of the proposals in this rule offer common sense solutions to real life predicaments physicians have faced in the past several years that have hampered participation and success in the MU program.

Below are the AMA's specific comments that strongly support a number of the proposals offered by CMS for reporting years 2015-2017 for Stages 1-2. We believe these changes, along with a number of suggestions, especially streamlining quality reporting requirements, will help facilitate stronger physician participation in the program while also better engaging patients in their care.

Overall, the sooner this rule can be finalized, the sooner physicians, other providers, and vendors are given a level of certainty that will allow them to successfully participate in MU and move forward in future years. There are a number of pieces to this rule that will require significant education to ensure the requirements and changes are well-understood. **The AMA therefore strongly urges CMS to publish this final rule as soon as possible.**

#### **I. Proposals Strongly Supported by Physicians**

There are numerous improvements proposed by CMS in this regulation that engender strong support by physicians, as discussed in more detail below.

1. **90-day reporting period for 2015:** We strongly endorse the 90-day reporting period for 2015 for all providers as it represents a sensible glide path for keeping physicians and other health care providers participating in the MU program. Given the rule will not be finalized until late in 2015, we believe this is a necessary step to keep the program moving forward.
2. **Streamlining MU requirements:** We strongly support CMS' thoughtful proposal that provides reasonable steps to consolidate program requirements. We believe this change will help physicians, many of whom have struggled with measures for reasons outside of their control, to successfully participate in the program. For example, we strongly support the proposal to establish an exclusion for meeting Stage 2 measures that do not have an equivalent Stage 1 measure, are not associated with any Stage 1 objective, or where the provider did not plan to attest to the menu objective, which would now be otherwise required. We also support moving towards more streamlined objectives and removing the core vs. menu structure, which created confusion for both physicians and vendors.
3. **Maintaining patient access while removing participation barriers for physicians:** The AMA is thankful for CMS' proposal to modify the measure that has colloquially become known as "View, Download, and Transmit" or VDT. We recognize that there has been significant misunderstanding regarding the proposed change. The VDT measure in Stage 2 has two components. The first ensures patients have electronic access to their information. The second requires patients to interact with a patient portal in a very specific and constrained manner, mandating them to view, download, or transmit their information. Under the current rules, at least five percent of patients need to take this action or the physician will incur a financial penalty.

CMS reviewed the progress on this measure to date and found that the vast majority of patients were not taking this action. Data on this measure from 2014 showed that, while two million patients had accessed portals, significantly less than half performed these specific actions.<sup>1</sup> Furthermore, CMS cited in its purposed MU modification rule that, "there is a wide variance at the high and low ends, which indicates that

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<sup>1</sup> Health IT Policy Committee Meeting Data on Eligible Professional Performance on Stage 2 Meaningful Use Measures.

there may be external factors impacting performance.”<sup>2</sup> This variance in actively engaging a patient portal is a clear indication that patients differ greatly in when, where, and in what format they desire to view their medical information. In light of this performance, CMS has proposed to reduce this measure to simply ensure that those patients who want this capability can use it, while not mandating that a certain percentage of patients be compelled to take this action. **We are very pleased that the Administration has chosen not to limit patient access to their records, but instead allow physicians with varying patient populations to meet this measure.** In addition, we provide the below points to encourage patient access and engagement in the future:

- **Education** - The AMA recognizes that patients want to go beyond accessing their records, and we are committed to working with physicians and patients to promote clinical uses of this information. Technology should allow patients to access their information, use it when and where they need it, and become more involved with their health care. The AMA has [free information](#) on our website educating physicians about this measure and tips for successfully engaging patients on the use of the portal. We plan to continue to offer tools, further engage with patient groups, and provide support to physicians to improve engagement.
- **Usability** - We also hear from many physicians that patients are not signing up for portals despite outreach. Some physicians report patients are finding the portals hard to navigate, requiring multiple steps to access their information, or feel they are of limited value. In addition, due to the lack of interoperability across EHRs, many patients who see multiple physicians must interact with multiple portals, requiring numerous user names and passwords. The AMA is committed to working collaboratively with stakeholders to tackle these usability issues as well as improving information for patients on security and privacy.
- **Broadening engagement** – The previous measure limited the types of actions that counted for patient engagement, solely focusing on patient portals and viewing, downloading and transmitting information. Yet, there are more robust tools available to engage patients that are being employed and adopted in numerous settings. For example, a number of larger institutions are using the [Open Notes](#) project, supported by the Robert Wood Johnson Foundation, which gives patients access to the visit notes written by their doctors, nurses, or other clinicians. Evidence from this study suggests that having physicians view visit notes with their patients in person may make care more efficient, improve communication, and, most importantly, may help patients become more actively involved with their health care. Patients have also expressed a desire to have access to online scheduling and billing information. In December of 2014, the National Partnership for Women and Families conducted a nationwide survey

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<sup>2</sup> Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Modifications to Meaningful Use in 2015 through 2017. 80 Fed. Reg. 20,346, 20,357 (April 15, 2015).

that showed that a “strong majority”—64 percent—wanted the ability to schedule appointments or submit medication refill requests online.”<sup>3</sup> Presently, accessing this type of information online does not count for meeting this MU measure. Broadening the measure to include these types of activities and innovative patient engagement tools could be an initial first step in engaging patients who otherwise have not sought online access. We suspect that, once they become acclimated with these tools, they will begin to also access clinical information. **We strongly suggest that CMS allow multiple patient engagement functions as future options for this MU objective.**

- **Privacy & Security** - We recognize that all too often privacy and security laws can inhibit patient access. Physicians and other caregivers harbor significant concerns and questions about what will be seen as a violation of these complex rules and often err on the side of caution. Distilling the rules into easily understandable and actionable information continues to be a challenge. There is also a dearth of solutions for smaller practices, which aim to address electronic data protection needs. Helping physicians of all practice sizes have access to scalable and affordable solutions for protecting data electronically are needed and should be a national priority. The AMA has [free](#) tools for physicians to help them provide electronic access to patients’ medical information and meet privacy and security requirements. We applaud ONC for recently publishing a privacy toolkit and look forward to working to generate understanding and awareness on this issue. We will continue to work with the Administration and others to meet this growing challenge.

**Again, the AMA strongly supports CMS’ proposal for modifying the VDT measure because it retains the ability for patients to access their information.** This means patient access to their data is preserved while also supporting successful physician participation in MU and accommodating the challenges discussed above. **We recommend CMS consider ways to expand tools and the types of information that are supported under this MU measure, including but not limited to, participation in other innovative programs and accessing billing and online scheduling.**

4. **Enabling secure messaging:** Current Stage 2 rules require patients to securely communicate with physicians on relevant health information. Under CMS’ proposal, this would be changed from a measure that requires physicians to be responsible for the actions of five percent of their patients to one that ensures this option is available. Similar to the VDT measure, the functionality for performing secure messaging would still be enabled, thereby removing barriers to meeting the five percent threshold, yet ensuring secure messaging for patients. **The AMA strongly supports CMS’ proposal to remove the percentage-based threshold for meeting the secure messaging requirement.**

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<sup>3</sup> The National Partnership for Women and Families. *Engaging Patients and Families: How Consumers Value and Use Health IT*. December 2014. From: <http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf>.

5. **Improving the summary of care:** Current Stage 2 rules require physicians that transition their patient's care to another setting to: 1) use certified EHRs to create a summary of care document for more than 50 percent of transitions of care and referrals; 2) electronically transmit that record to a receiving provider for more than ten percent of the transitions and referrals; and 3) transmit the summary of care in a specified manner. Under CMS' proposal, the summary of care document must still be created by a certified EHR, however, it may simply now be exchanged electronically. From our understanding, we take this to mean physicians may choose any electronic method to transmit these documents to other physicians or care settings. While there are various methods to securely transfer documents through electronic means, we agree with CMS' assessment that this may help reduce interface costs charged by vendors to transfer data. Because this may warrant a change in the current workflow of physicians or their staff, we ask that CMS provide detailed examples and further clarify its thinking on this proposal.

## **II. Additional Program Enhancements that will Further Strengthen MU**

The AMA offers the following additional enhancements to the program that, if adopted by CMS in this final rule, will help ensure program success.

1. **Program structure:** CMS has proposed a modified version of Stage 2 with accommodations for new participants for 2015. The AMA appreciates the intent of the proposals, however, we worry that physicians have already been working within the existing program's construct, and that there is insufficient time to reeducate physicians on all of the proposed changes. Making too many alterations this late in the year could have unintended consequences and jeopardize successful participation. Moreover, the proposed jump between the 2015 requirements compared to those in 2016-2017 represents a sharp increase and a steep learning curve that may not be feasible. We therefore offer the following recommendations that largely leave the program intact for 2015.

### **Recommendation:**

- ***For 2015: Keep current Stage 1 and Stage 2 measures with the following modifications:***
  - ***Retain the 90-day reporting period;***
  - ***Retain the proposal for patient electronic access, secure messaging, and summary of care objectives; and***
  - ***Make the public health objective optional.***
- ***For 2016 and 2017: Adopt modified Stage 2 and***
  - ***Maintain a reporting period that is less than a full calendar year;***
  - ***Allow accommodations for new participants (as proposed for 2015);***
  - ***Make the public health objective optional; and***
  - ***Include other recommendations made elsewhere in this letter, like a shorter reporting period.***

2. **Reporting period:** We are concerned that a full-year reporting period for all participants does not adequately account for a number of real life scenarios that could easily hinder both small and large providers alike. As a preliminary matter, CMS has the authority to define and institute a shorter reporting period. Second, we believe it is prudent to maintain the policy of a 90-day reporting period to anyone entering the program and for anyone beginning a new stage, as it requires significant changes for practices. We also strongly urge CMS to consider the following scenarios that justify a shorter reporting period:
- **Switching EHRs** - Physician dissatisfaction with their EHRs is growing and thousands of physicians want to switch their systems for new ones; however, changing products can take several months to years and would cause physicians to incur an MU penalty if not allowed a shorter reporting period.
  - **System Downtime & Cyber-Attacks** - The AMA has a number of examples of well-known institutions that have experienced crippling downtimes that hamstrung physicians' and other clinicians' ability to meet a full-year reporting period despite having no ability to control these events. There are also a growing number of digital threats that have required immediate attention, unscheduled downtime, and loss of patient data. Organizations facing these challenges need to divert resources and attention to addressing any possible data breach and patient safety concerns without the fear of failing MU.
  - **Office Relocations** - While physicians generally tend to move office locations during non-patient hours, the reality is that the move involves installing hardware, ensuring network connectivity, and juggling overall logistics. A simple example includes problems connecting to a new service provider that may make it impossible to meet a full year-reporting period.

**Recommendation:**

- *Institute a reporting period that is less than 365 days for the program moving forward to address the concerns listed above; and*
  - *At the very least, maintain the policy that allows those new to MU to report for only 90 days, and establish a similar 90-day reporting period for those starting a new stage.*
3. **Hardships:** We remain concerned that there are insufficient hardship categories available to physicians to account for real world scenarios that prevent successful participation. We also believe that the changes to the program this late in the year will require changes to the hardship deadlines. Furthermore, we are concerned that the planned move to ICD-10 will further complicate the reporting requirements, especially for quality reporting.

**Recommendation:**

- *Expand the hardship exemptions available to physicians in the absence of a reporting period of less than a full year (i.e., switching EHRs, system downtime and cyber-attacks, and office moves);*

- *Offer a new hardship for any physician who fails quality reporting as a result of Medicare's inability to correctly tabulate the new ICD-10 codes; and*
- *Expand the hardship reporting deadline for physicians to November 15th in order to give physicians adequate time to file.*

4. **Delayed Attestation:** Based upon comments made by CMS officials we understand the agency's intent is to delay attestation until after January 2016 for the 2015 reporting period. While we understand the need to make modifications to the attestation system, we are concerned about the substantial bottleneck that will result when all providers attempt to attest at the same time, which could result in system-wide failure. We are also concerned how this action will affect physician reimbursement due to the current mandate to levy penalties for physicians who do not attest by the deadline. We believe physicians should not be subjected to penalties—even if CMS intends to reprocess claims—if, by no fault of their own, the attestation system is not prepared to accept their reports.

**Recommendation:**

- *Prepare plans to mitigate the likelihood of a system crash and ensure that there are sufficient customer service representatives on hand to handle any related inquiries; and*
- *Open the attestation system now to make it available immediately to any physician who is ready to attest.*

5. **Proportionality:** While we appreciate a number of the changes proposed in the rule, we continue to be concerned that missing even a single measure jeopardizes successful participation. The all-or-nothing approach fails to recognize differences across specialties and patient populations, and is contrary to other quality reporting programs (such as e-prescribing) that set different thresholds for success and failure. For example, a provider who misses one measure threshold by a single percent should not incur the same penalty as a provider who chose not to participate in the program.

**Recommendation:**

- *Incentivize participation by creating a fairer system—incentives and penalties should be proportional to the measurers successfully completed.*

### **III. Quality Measure Program Enhancements**

We appreciate CMS' effort to attempt to align MU clinical quality requirements and the Physician Quality Reporting System (PQRS) by addressing future quality reporting requirements in the Medicare Physician Fee Schedule. For years 2015-2017, however, we remain concerned that if a physician would like their MU electronic clinical quality measure requirements to count towards PQRS, the physician must report for a full calendar year, as opposed to taking advantage of the flexible 90-day reporting period.

We once again remind CMS that Congress authorized the Secretary to define the “quality reporting period” for 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. Moreover, 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. Below are our recommendations for improving this piece of the MU program.

1. **Reporting:** We are unaware of any plans by CMS to address or update the MU quality measure list until 2017, at the earliest, leaving many physicians to continue to report on process measures, as opposed to more meaningful and relevant clinical quality measures pertinent to their specialty. These more meaningful outcomes oriented measures are often reported through a Qualified Clinical Data Registry (QCDR) within PQRS and cannot be captured within the EHR due to the lack of EHR functionality and interoperability. Therefore, physicians who are actively engaging in true quality improvement through a QCDR will have to continue to report twice to satisfy MU quality requirements. We note, however, that the solution is not to require QCDRs to employ or use CEHRT. Connecting a registry with CEHRT is cost prohibitive, and many EHR vendors have not yet achieved interoperability with these systems or included all of the relevant measures given their focus on implementing MU requirements.

**Recommendation:**

- *Allow the 2015 MU 90-day reporting period and any shortened MU reporting period to count toward successful quality reporting for PQRS and the Value-Based Modifier; and*
  - *Permit QCDR reporting to count towards satisfying MU quality requirements, but do not require QCDR measures to be within the MU program.*
2. **Registry Requirement:** CMS proposes to consolidate all optional public health agency (PHA) and clinical data registry (CDR) objectives into one new mandatory objective, which is the same public health and CDR objective as proposed in the Stage 3 rule. Physicians must select to report on any combination of two of the five available options under the objective. Essentially, this mandates an increased number of requirements without addressing how a physician, who is reporting through a CDR, may receive credit for MU quality requirements and PQRS. While we appreciate and are supportive of



CMS allowing physicians to meet some of their MU requirements through these population and public health activities, we believe the mandate is premature. There is now a burden on states and physicians to register and engage in PHA or CDR reporting without any advance warning to physicians, EHR vendors, registries, and state and local jurisdictions. Additionally, certification requirements do not address standards for connecting CDRs with EHRs.

We appreciate 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 for this new requirement. The proposed exclusion pathways associated with the measure and the requirement for bi-directional exchange for immunizations registries go beyond what current Stage 2 requires. In terms of 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 the [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 were given no advance warning of this requirement for 2015-2017. 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 within CMS’ timeframe. 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 the vendor may charge the physician, 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 the good faith effort of the physician.

**Recommendation:**

- *Make the requirement for PHA or CDR reporting optional in 2015-2017 given the lack of notice for this new requirement;*
- *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*
- *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.”*

**IV. Certification and EHR Usability**

The AMA recognizes that this rule does not make changes to the EHR version required for use in MU in 2015-2017. We did, however, want to note that we are very pleased with a number of the changes proposed by Office of the National Coordinator (ONC) to the Version 2015 certification program. If adopted, these changes could address several of the concerns we have raised on the utility and safety of EHRs. We are particularly

pleased with the increased emphasis on transparency of vendor product certification, “in-the-field” surveillance, user-centered design, and interoperability and testing. These proposals also dovetail nicely with the proposal to allow for the use of Application Programming Interfaces in Stage 3 for patient engagement, and we generally support federal actions that ensure data are more freely accessible and portable.

While we see all of these changes as promising, we are concerned with:

- The volume and complexity of the certification requirements vendors will need to meet to deliver Version 2015 products in time for a successful, safe deployment prior to the end of 2017.
- The extent to which certification requirements will be considerably altered. Although the number of criteria a vendor must certify against has not increased, fully 55 percent of the criteria has either changed or are new. Additionally, many of the criteria incorporate draft standards that either are not fully tested or are not widely used within the health information technology industry. We believe a more focused approach is warranted to facilitate high-performing, interoperable, innovative, safe, and secure technology.
- The Administration’s growing desire to tie all forms of reimbursement (both public and private) to the use of certified technologies. While this may drive more data exchange it does not address the root issue of the lack of interoperability, which is governed by factors outside the average practicing physicians’ control.

CMS sought feedback on whether providers should be allowed to move to Stage 3 as early as 2017 or whether the new Stage would only be available starting 2018. To the degree that products are available and providers want to move to Stage 3, we support this option. Yet, we are very concerned that vendors will not be ready to offer products in time for 2018, let alone 2017. The focus of the certification program has always been to provide assurances that the product purchased by a physician will allow them to participate in the MU program. In contrast, we believe the certification program should be refocused to testing the interoperability, safety, privacy/security, and usability of EHRs as well as the associated modules needed to meet MU. Without this change, we believe these products will continue to fail to meet the needs of patients and physicians. The timeframe, as proposed, will simply not allow for these interests to be a priority.

We are also concerned with ONC’s proposal to expand their certification program by providing an “a la carte” selection of criteria for other federal and non-federal payers. CMS’ and ONC’s intent may be to expand certified technology to other programs; however, we are concerned that this may perpetuate existing problems with EHRs, spreading them to other programs and technology. Expanding the ONC certification program beyond MU could negatively affect innovation and cause further dissatisfaction among participants. The AMA recognizes that physicians need tools that comply with the law. Nonetheless, we remain concerned with the utility of these products and the ability of vendors to deliver high-performing systems in sufficient time for physicians to incorporate their use safely.

**Recommendation:**

- ***Further streamline the certification program to focus exclusively on helping providers successfully participate before expanding the program to additional areas beyond MU.***

**Conclusion**

The AMA appreciates the numerous efforts by CMS to make improvements to the MU program. We urge CMS to consider these comments and swiftly publish a final rule as quickly as possible to instill confidence in the program and ensure that as many providers are able to take advantage of these flexibilities. We look forward to discussing these policies and suggested areas for improvement. 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](mailto:mari.savickis@ama-assn.org).

Sincerely,

James L. Madara, MD