AMA
AMERICAN MEDICAL ASSOCIATION

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Dear Administrator Tavenner and Dr. DeSalvo:

Thank you for seeking the American Medical Association's (AMA) input on ways to improve the Electronic Health Records Meaningful Use (MU) program. The AMA is committed to ensuring physician access to and use of well-developed electronic health records (EHRs) and other health information technology (health IT). Adoption of these technologies has the potential to help improve patient quality of care and drive practice efficiencies.

Unfortunately, the existing MU program and many of the EHRs certified for use in meeting the program's requirements stand in the way of these goals. The AMA is concerned that the rigid program requirements and financial penalties will discourage physicians who are making good faith efforts to incorporate health IT into their practices. **Unless significant changes are made to both the current program and future stages, we believe that**:

- More physicians will drop-out of the MU Program;
- Patients will face disruptions and inefficiency in their care, as existing EHRs are unable to migrate data or facilitate more coordinated care;
- Thousands of physicians will incur financial penalties that hinder future technology purchases and limit resources dedicated to advancing care; and
- Outcomes-based delivery models, which require data driven approaches, will be jeopardized.

The AMA, therefore, recommends that the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) make the following changes to the MU program, including to the certification process for EHRs.

I. Stages 1-2

We recognize that both CMS and ONC are focusing on moving to Stage 3 of the MU program; however, physicians are still struggling with the first MU stages. Without assistance, we believe many physicians will not be capable of moving on to Stage 3. Accordingly, we continue to urge CMS and ONC to consider the following changes to Stage 1 and Stage 2:

1. **Remove the existing program's all-or-nothing approach and replace it with a 75 percent pass rate (as described in more detail below).**

2. **Allow physicians who meet at least 50 percent of the MU requirements to avoid a financial penalty.**

II. Stage 3

1. **Remove the all-or-nothing approach and replace it with a 75 percent pass rate.**

   Adding flexibility, both to the threshold required to earn the MU incentives and to avoid the penalties (described below), is the single most pressing change needed to ensure physicians can successfully participate in the MU program. Expecting every physician to meet the same set of requirements despite varying specialties and patient populations is an ill-defined approach that is not working. The existing requirements are too primary care-centric, yet even some primary care physicians are still struggling with the program. An analysis of CMS' own data, which does not include the entire year of 2013, shows a 20 percent drop-out rate in the MU program. We expect this to grow substantially unless the all-or-nothing approach is removed. **Instead, physicians should only be required to have to meet 75 percent of the requirements to obtain an incentive. At a very minimum, this threshold should be used for at least the first year of each new stage.**

2. **The bar to avoiding a financial penalty should be lowered to 50 percent.**

   Physicians who are making strides towards adopting and using a certified EHR should not be penalized financially, especially if they have met at least 50 percent of the program requirements. We want to encourage participation and not create a program that leaves no room for error; however, the MU payment adjustment fails to recognize any good faith attempts by physicians. Further, it is only one of several penalties physicians are facing under the Medicare program. Combined, these penalties will limit funds to invest in new technologies and will constrain resources that could be used to drive care innovations. **There is precedent for creating a lower penalty threshold—a similar approach was used in the Medicare e-Prescribing program. Physicians who meet at least 50 percent of the MU program requirements, while not receiving an incentive, should not incur a financial penalty.**

3. **Remove the concept of menu vs. core.**

   The current framework of a set of "menu" and a set of "core" requirements is contributing to physician problems in achieving the MU requirements. Physicians need the maximum flexibility possible to implement and meet the MU measures they feel are relevant to their practice and patient

needs. Rather than taking an overly prescriptive approach, we recommend that physicians select the measures that best apply to their practices and patients. To this extent, we strongly urge CMS to also include broad exception criteria for measures. Without this flexibility, physicians are taken out of the driver's seat in deciding how to best practice medicine, mandating that physicians report on measures that they do not believe are relevant to their patients or to improving care.

4. Streamline and refocus the number of requirements.

Section 4101(a) of the Health Information Technology for Economic and Clinical Health (HITECH) Act outlines only three key requirements for achieving MU. The statute states that the eligible professional shall be treated as a meaningful user if the following items are met: 1) "the professional **is using certified EHR technology** in a meaningful manner, which shall include the use of **electronic prescribing** as determined to be appropriate by the Secretary;" 2) "that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, **for the electronic exchange of health information** to improve the quality of health care, such as promoting care coordination;" and 3) the "eligible professional submits information for such period, in a form and manner specified by the Secretary, on such **clinical quality measures** and such other measures as selected by the Secretary" (emphasis added). Requirements in Stages 1 and 2 greatly exceed those provided in the statute both in terms of volume and complexity. These numerous requirements impede EHR usability and advancements in technology, especially in achieving interoperability. **The AMA strongly urges CMS to revisit the law and focus on requirements that adhere to the statute's original intent.**

In addition, Stage 3 measures should focus less on specifying the data and more on coordinating and encouraging the methods of exchange. We applaud the work by the Health Information Technology Policy Committee (HITPC), however most of their recommendations continue to specify thresholds or specific data fields that must be met and collected. Yet, the focus on achieving data migration and interoperability are lacking. Continuing this rigid approach will only frustrate physicians who feel locked into a program that is overly complex. **CMS and ONC should recognize the current technology limitations involving data exchange and consider that the physician and patient are best suited to determine what data points need to be collected.**

5. Remove any mandates that are outside the control of physicians.

The AMA is strongly supportive of engaging patients and their families so that they are more informed in treatment plans and care decisions. In particular, many physicians are embracing new tools that improve communication and interaction with their patients. However, many of these new technologies are still developing, and their impact on patient care and the security of practices has not yet been clearly tested. We are aware of instances where patient portals and other patient engagement tools may pose a threat to the security of a practice's EHR system. Further, while we appreciate the intent behind these MU requirements, such as measures that track when patients log onto portals or receive electronic communications, successfully meeting these measures lies squarely with the patient, not the physician. Many physicians continue to report to us challenges in convincing patients to use these tools because of the patient's own preference to speak directly with the physician. It should be sufficient for physicians to exchange information they deem important and to encourage their patients to participate in their own care through innovative technologies without requiring an

individual to view, download, or transmit information. According to a recent *Health Affairs* article, "[s]everal respondents cited patients' resistance to change and inexperience with computers and e-mail as barriers to the use of electronic communication. For some patients, electronic communication is a ['whole new way of communication – it's a different world.'] "[1] The AMA agrees that electronic communications is one of many ways physicians can interact with their patients; however, we do not believe this should be a mandated part of the MU program.

6. Quality reporting programs must be aligned.

The quality reporting pieces of the MU and the Physician Quality Reporting System (PQRS) programs need to be better aligned to avoid conflicting deadlines and reporting requirements. In order for MU quality reporting to count towards PQRS, a physician must take into consideration the following detailed rules and requirements:

- PQRS quality measures must be reported for a full year, as opposed to 90 days.
    - In 2014, MU only requires reporting quality measures for 90 days.
    - Regardless of calendar year, the first year of participation in MU only requires 90 days of reporting.
- MU quality measures must be reported through Version 2014 Certified Software.
- The MU program requires reporting on at least nine electronic quality measures (eCQMs), which must be available through Version 2014 Certified Software and cover three of the National Quality Strategy Domains in the MU program.
- Some of the MU eCQMs include "look back" or "look forward" periods requiring data outside of the PQRS and Value Based Modifier (VBM) reporting periods. If CMS cannot calculate a performance rate for that measure, a physician would be subject to both PQRS and VBM penalties.
- Measures reported through the PQRS Qualified Clinical Data Registry (QCDR) option must be in the MU program.
- The QCDR must be certified by ONC.
- For MU, it is acceptable to report zeroes on measures (including not having any denominator-eligible patients for any of the measures for which their EHR is certified).
    - This is not permissible for the PQRS EHR reporting option or any other option under PQRS. If a physician does not have any data on Medicare patients (i.e., none of their Medicare patients fall into the denominator of any of the quality measures for which their EHR is certified), then the physician needs to report separately for PQRS.

To streamline reporting, physicians who successfully participate in PQRS, regardless of the reporting mechanism, should be deemed as successfully meeting the MU quality measure requirements.

ONC and CMS should develop a reduced quality measure reporting requirement for physicians who only want to avoid the MU penalty, as there are a limited number of quality measures in the MU program compared to PQRS. We also recommend that the list of quality measures be

[1] Tara Bishop, et al. "Electronic Communication Improves Access, But Barriers to its Widespread Adoption Remains," August 6, 2013," *Health Affairs*, August 6, 2013.

updated annually to allow for a more robust set of quality measures and for homegrown registry-based measures to be incorporated into the MU program. We feel these changes are needed in order to comply with the American Taxpayer Relief Act (ATRA) that authorizes physicians to receive incentive payments for reporting on quality measures by participating in a QCDR. Yet, currently only measures that are in the MU program can be reported to meet the MU quality measure requirement.

7. **MU mandates should be evidence-based.**

   The AMA believes that mandates should be evidence-based before they are deemed eligible for inclusion in the MU program. Requiring physicians to meet criteria for which there is no or little documented and well-established evidence for a wide, cross-cutting sample of physicians—not just a particular specialty or subset—is wasteful and can detract from other well-documented methods of treating patients. In fact, there is evidence that many of the MU requirements may not lead to better care. According to a recent article in the *Journal of the American Medical Association (JAMA),* a study at Brigham and Women's Hospital concluded that, "[d]espite hope that achieving meaningful use improves quality, we found that meaningful users did not consistently provide higher quality care."[2]

8. **Mandates must be tied to tested and high-performing standards as well as implementation guides (IGs).**

   The AMA remains concerned that requiring physicians to meet requirements that are not supported by tested or agreed upon standards, or where there are no IGs, is the wrong approach and one that will further hurt efforts in achieving interoperability. As an example, the version 2015 certification proposed rule (2015 Edition EHR Certification Criterion § 170.315(f)(3)) cites the lack of an ambulatory IG for syndromic surveillance as a reason to backtrack on a 2014 certification criterion. Because this requirement was accepted into regulation before a corresponding IG was available, vendors who wished to provide this functionality and be certified lacked the appropriate guidance from a balloted IG. **We strongly recommend that any requirements that are included in Stage 3 be tied to high-performing testing standards and IGs.**

9. **Consider costs.**

   While achieving many of the requirements under MU is a laudable goal, the cost to implement these measures, including establishing multiple interfaces, can run into tens of thousands of dollars. We believe it is unwise and unfair to ignore the cost of multiple, expensive technology requirements, especially since most disparate EHRs still cannot interoperate. Furthermore, physicians want to invest in other technologies that they feel would better serve their patient populations, but may be hindered from doing so due to costly MU mandates. **The AMA recommends that cost should be among the factors taken into consideration when requiring physicians to have to meet a particular MU mandate.**

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[2] Lipika Samal, MD, MPH, et al. Letter to the *JAMA Internal Medicine*, April 14, 2014, http://archinte.jamanetwork.com/article.aspx?articleid=1860495.

III. Certification of EHRs

Many of the problems we are seeing with EHRs today are rooted in certification requirements that include rigid and overly complex MU mandates. We are deeply concerned with the volume and prescriptiveness of these requirements and believe they are hindering many vendors from being able to deliver high-performing systems. We believe that the certification process should be redesigned to focus on the product's ability to incorporate data to provide value to physicians and patients. EHRs and other health technologies can promote a future health care system that ensures data migration, interoperability, and a more coordinated care system. To achieve this, we believe several certification changes are necessary to bring about higher-performing EHRs.

1. Interoperability.

The AMA believes that the future state of EHRs and other health IT is ripe with potential, but that interoperability must be a key focus to improve data sharing and care coordination. The recent JASON report funded by the Agency for Healthcare Research and Quality concisely described the current state of interoperability, finding "[a]t present, large-scale interoperability amounts to little more than replacing fax machines with the electronic delivery of page-formatted medical records."[3] If we are to move away from this approach, the certification process must be keenly focused on achieving true interoperability that is deployed in a fashion that requires minimal user intervention. We believe ONC should focus less on what specific data points are exchanged, and more on identifying and coordinating the standards needed to exchange information.

2. Data Synthesis.

The AMA encourages a certification model that is driven by data synthesis rather than one that is focused on data collection. Physicians believe and expect that EHRs will be more than a mere reporting tool and will facilitate gathering, organizing, and transferring health information. An EHR focused on data synthesis would provide tools to facilitate a physician's workflow, such as technology that recalls the physician's preferences and provides choices in how data are presented. Sophisticated data analytics and decision support tools that can be customized to meet the needs of unique patient populations are needed. While some EHR vendors are capable of developing these tools, it is more likely that EHRs will require integration with third party applications to achieve this goal.

3. Emerging Technologies.

We believe more focus is needed on emerging technologies that can facilitate interoperability and support modularity in EHR technology, like Application Program Interfaces (APIs) and Fast Healthcare Interoperability Resources. Use of APIs has the potential to unlock data and facilitate exchange by allowing disparate systems to speak with one another, a concept that is well-supported in

[3] JASON, A Robust Health Data Infrastructure, November 2013 http://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf

the aforementioned JASON report. We urge ONC to consider how best to highlight these other technologies and their potential uses.

4. Testing.

Currently, EHR certification is seen as a high-water mark since vendors are not required to continually test and update their software once approved. The AMA believes that poor EHR usability is partially an outcropping of this certification process, which allows products to be developed, tested, and certified in computer labs that do not reflect true use environments. We believe that testing is a key component of ensuring properly performing technology, usability, and patient safety. Testing early and often in the development of EHRs and utilizing impartial practicing physicians should be strongly encouraged by ONC.

Furthermore, ONC should ensure that testing reports posted on the Certified Health IT Product List are clear of technical jargon and are easily understood by the consumer. ONC should also require vendors to perform scenario-based testing prior to certification to ensure the exception handling capabilities of their products. A method for post-certification testing should also be established, allowing for ONC certification to be used as a base-line benchmark. Although not required, EHR vendors should have the opportunity to continually test their products—post-certification—and receive de-identified testing reports comparing their products to other high scoring EHR technologies.

Conclusion

The AMA stands ready to continue to offer advice and suggestions on ways to improve the MU program and the certification process. The course that is charted now for EHRs will have a significant impact on the future state of technology and the adoption of new care delivery and payment models. We therefore, encourage ONC and CMS to consider these changes and work with physicians to improve EHRs and other technologies. 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,

/s/

James L. Madara, MD