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AMERICAN MEDICAL ASSOCIATION

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The Honorable John Thune
United States Senate
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Washington, DC 20510

The Honorable Lamar Alexander
United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Pat Roberts
United States Senate
109 Hart Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
United States Senate
217 Russell Senate Office Building
Washington, DC 20510

The Honorable Tom Coburn, MD
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Michael Enzi
United States Senate
379A Russell Senate Office Building
Washington, DC 20510

Dear Senators Thune, Alexander, Roberts, Burr, Coburn, and Enzi:

The American Medical Association (AMA) welcomes the opportunity to provide feedback on "REBOOT: Re-Examining the Strategies Needed to Successfully Adopt Health IT." The Meaningful Use (MU) of Electronic Health Records (EHRs) Program has provided unprecedented financial incentives to help physicians purchase EHRs. The AMA continues to support the need for these incentives as the steep financial costs of EHRs represent one of the biggest barriers to widespread adoption among physicians and other health care providers. We strongly agree that the MU program should not simply focus on the number of providers adopting EHRs. Rather, MU of EHRs should provide value in the context of improved patient care and improved physician workflow and efficiency.

It is important to recognize that physicians, in general, are prolific users of technology. They use technology when they know it will help them deliver better patient care and when it will help them become more efficient. They quickly incorporate and make use of new patient monitoring devices, diagnostic imaging equipment, advanced surgical tools, and mobile devices, to name a few. For example, according to a 2012 Manhattan Research study, physician use of tablets in their practices reached 62 percent in 2012, almost doubling since 2011 and far surpassing estimated adoption rates.

The use of EHRs has been on the rise for the past several years and the incentive program has helped to significantly drive uptake, but adoption still lags behind many other technologies. We believe there are several reasons for this, including the lack of interoperability across different EHRs, which in many cases do not meet the workflow needs of physicians. ***The AMA strongly supports the need***

for incentives to help drive EHR adoption forward. However, we have serious concerns with the way the MU program has been structured, and we share your concerns about the direction the program is headed.

I. Lack of Clear Path Towards Interoperability

The AMA agrees that interoperability of disparate health care providers' systems is a critical component for driving efficiencies in the health care system. Physicians need to have timely information at the point of care to make well-informed decisions to treat their patients. Physician use of interoperable EHRs will also be critical to advancing payment and delivery reform by helping them deliver care in a more coordinated manner.

Unfortunately, as noted in the report, interoperability has proven very difficult to establish. Today, there are some areas where health information exchange (HIE) is occurring. However, nationally, physician and other health care providers remain largely unable to exchange data with one another on a wide scale basis. While Section 3001 of the American Recovery and Reinvestment Act (ARRA) tasked the Office of the National Coordinator for Health Information Technology (ONC) with developing a nationwide health information technology infrastructure that allows for the electronic use and exchange of information, HIE remains elusive.

We do not believe there is one single barrier behind the lack of interoperability. Rather, we believe it is a complex set of intertwined variables, most of which are largely outside the control of the average practicing physician. These include: 1) the systems (EHRs) available to physicians still remain in many cases cumbersome and challenging to use and are not well adapted to physician workflows, despite being certified by ONC; 2) the technology, standards, and policies needed to achieve interoperability still remain under construction; and 3) the business case to motivate private and public organizations to deploy this infrastructure remains unstable. Physicians are reluctant to make costly HIT investments when it is uncertain whether their local HIE will be able to sustain itself. Until these issues are more adequately addressed, information that was once contained in paper silos will simply be retained in digitalized silos. The AMA agrees that simply requiring physicians to race through progressively difficult stages of MU does not address the pressing issue of interoperability, nor does it promote use that is truly "meaningful" in terms of having a positive impact on patient care delivery and improving health system efficiency.

The AMA is pleased that the Centers for Medicare & Medicaid Services (CMS) and ONC elected to extend Stage 1 an additional year, through 2013. However, we remain very concerned that unless changes are also made to Stage 2 criteria to make them more flexible, many physicians will be unable to meet these requirements, including ones who successfully attested and received an incentive under Stage 1. Specifically, the Department of Health and Human Services (HHS) is requiring physicians to meet 100 percent of the measures in order to collect incentive payments and avoid penalties. Based upon feedback we continue to receive from physicians concerning Stage 1, some of the requirements are virtually impossible to meet, are not relevant to a physician's practice or patient population, or are simply considered "check box" activities. In some cases, the lack of EHR interoperability and lack of an information exchange infrastructure have resulted in physicians having to manually enter data (e.g., lab test results) into their systems in order to meet some of the MU program requirements. The mandate to meet 100 percent of the regulatory requirements is unnecessarily burdensome and not necessary to demonstrate that a physician is, in fact, using EHRs in

a meaningful way. ***Therefore, we recommend that CMS: 1) modify rulemaking for Stage 2 and change the rigid requirements to provide physicians with more flexibility; 2) allow physicians to be deemed Meaningful Users if they meet 75 percent of the current requirements; and 3) allow physicians to be excluded from meeting requirements that are inappropriate for their workflow or patient populations.***

Additionally, we are in full agreement that the lack of an evaluation of Stage 1 before moving to Stage 2 was a missed opportunity to improve the program. ***The AMA firmly believes that the most prudent course of action is to comprehensively evaluate what worked well in Stage 1 and assess where implementation challenges remain. Furthermore, the progression to Stage 3 should not take place until this evaluation occurs, and in no event should the move to Stage 3 happen before 2017.***

II. Misuse of EHRs May Actually Increase Health Care Costs

The AMA recognizes the concerns with reports that use of EHRs has increased health care spending. However, the data does not support the assertion that EHRs are the primary driver for increased level of intensity in Evaluation and Management (E/M) reporting by office-based physicians. At the May 3 listening session co-hosted by CMS and ONC, a CMS official stated that they have not yet found evidence to indicate that EHRs are driving upcoding. The Office of the Inspector General (OIG) also concluded in a study (OEI-04-10-00182) conducted in 2012 that, of the physicians they studied, "Although EHR systems can automatically assign codes for E/M services, 88 percent of Medicare physicians assigned codes manually in 2011. The remaining 12 percent had codes assigned manually by staff (e.g., professional coders)."

The AMA is concerned, however, that as more physicians begin using EHRs—particularly those systems that are certified for use in the MU Program by the federal government—they could be penalized in the form of denied claims or audits for problems associated with documentation, coding, and billing. The AMA recently addressed these issues in depth at the May 3 listening session.[1] To overcome the inefficiencies of existing EHRs, various shortcuts and tools are used in the EHR. The most common of these are templates, macros, and cut & paste. The testimony, which is summarized below, demonstrates that none of these shortcuts is inherently bad, but each of them can be misapplied, accidentally or intentionally.

"Templates" are pre-formatted portions of a chart. For a physical exam, for instance, there may be a list of 12 organ systems, each with specific terminology presented within each organ to describe normal or abnormal findings. All the words are already on the page, but nothing has yet been documented. The physician then checks boxes, circles words, or slashes through words to indicate the presence or absence of each discrete item. As long as the physician documents only those things he actually did and documents them accurately, this results in an accurate, very homogenous-looking, physical exam record. Additionally, templates can prompt or remind physicians to check or do things they might otherwise have forgotten to do and, in this manner, can provide some degree of clinical decision support. Unfortunately, selecting every single item individually takes a fairly long time, so a second documentation tool is often used to streamline this process.

[1] The AMA's testimony can be found at http://www.ama-assn.org/resources/doc/washington/ehr-meaningful-use-testimony-03may2013.pdf.

A "macro" is essentially a completed template with answers previously determined and automatically entered. For example, rather than recreating an entire exam from scratch, the physician can select and import the normal macro for the relevant examination and the EHR will automatically populate the exam based on previously entered selections. Again, as long as the physician has actually performed the work documented, the use of this macro is an efficient and effective means to streamline the data entry process. Additionally, if there are minor variations, the physician can import the macro and then only alter those data points that differ for a specific patient. Macros can be a problem, however, when a physician, either through innocent human oversight or active intent, imports a macro containing information that the physician did not actually verify. In this instance, extra care and attention is required because the technology tool can make it alarmingly easy to accidentally introduce inaccurate information into the medical record.

"Cut & paste," "carry forward," and "importing" are differing ways to describe a third concept that arises uniquely with EHR documentation. In this instance, the clinician reuses information previously documented. For static information, this is a logical and beneficial use of the EHR. For example, if a patient had his or her appendix removed, that data will not change for the rest of the patient's life. Additionally, if it was learned that the patient was allergic to penicillin while having the appendectomy, that information will also follow the patient for the rest of his or her life. As long as these items are accurate, it makes good sense to carry them forward through the electronic record so every clinician has this information. There is no value added by a clinician re-asking all these questions and, in fact, there is risk that the patient or physician will overlook some important historical data and an otherwise avoidable error could occur.

"Cut & paste" becomes bad and is appropriately criticized as "cloning" when clinicians reproduce information created by themselves or others either without attribution or without attention to its accuracy. It is not appropriate for a clinician to copy another professional's history, verbatim, and present it as if the physician had obtained it from the patient. It is often appropriate, however, for a clinician to document that he or she has reviewed the note of another professional and to summarize the key elements in a new note with attribution to its source. Errors in charting remain errors in charting whether done in an EHR or on paper. Regardless of the frustrations associated with the EHRs, physicians and other clinicians still have the obligation to review their own documentation to ensure that the information is accurate. EHRs can make this process infuriatingly difficult at times. Even so, though it may not be fraud, glaring inaccuracies created by carrying forward prior notes with obvious errors are not acceptable.

All three of the above concepts (i.e., templates, macros, and cut & paste) create another peril for physicians. In large measure, every clinician using the same EHR will create charts that look remarkably similar to every other clinician using that same EHR system. Many in payer and compliance communities have long bemoaned the inconsistencies and variation in physician documentation. Now, EHRs have shifted the criticism to one of overwhelming homogeny. Even if the clinician accurately selects the individual data points on a template, every single chart containing that documentation template will look essentially the same and make use of the exact same words. In this case, it looks as though every clinician has plagiarized the words of every other clinician.

In fact, many large EHRs enable users to access the templates and macros created by any user in the system. If one physician has a particularly pithy, erudite, or precise way of describing a certain finding or condition and saves it as a "favorite," the physician may later find that his or her own

words begin to appear in the notes created by other clinicians who liked the description so much they adopted it themselves. Again, as long as the description accurately describes the work done by the physician and the condition of the patient they are treating, this is not fraud but it certainly is "cloning."

Alarmingly, some Medicare carriers have already disseminated rules that if charts look too much alike they will deny payment. In this instance, even when clinicians are appropriately using the EHR, a tool with which they are frustrated and the use of which the federal government has mandated under threat of financial penalty, they are now being accused of inappropriate behavior, being economically penalized, and being effectively instructed to re-engineer non-value-added variation into their clinical notes. This is an appalling Catch-22 for physicians.

Additionally, it is important to note that government and private payers are requiring more and more specific data, quality reporting elements, and specialized reporting be collected in the EHR. Capturing and entering all this data takes time and can elevate the intensity of service. Because so many people and so many devices collect so much information, the medical record is becoming so large and unwieldy as to be indecipherable. Simple patient encounters now routinely generate scores of pages of documentation and can be nearly impossible to identify the truly important data amidst all the clutter.

To address these concerns, the AMA recommends that: 1) CMS should provide clear and direct guidance to physicians concerning the permissible use of EHR clinical documentation for the purposes of coding and billing; and 2) Stage 2 of the Meaningful Use program should be reconsidered to allow more flexibility to providers to meet these requirements while the EHRs are better adapted to accommodate the diversity of clinical settings and appropriate variation in workflows.

III. Insufficient Oversight Has Put Taxpayer Money at Risk

The AMA is in full agreement with the assertion that taxpayer dollars spent represents an insufficient metric of success. To date, CMS and the OIG continue to assert that the vast majority of health care providers are honest.[2] The AMA also is unaware of any widespread fraud and abuse associated with receipt of MU incentives by physicians. While some individuals may have inappropriately sought these funds, the vast majority of physicians are trying their best to implement EHRs while adhering to the MU requirements at considerable cost and time to themselves.

In order to obtain an incentive under the MU program, physicians must first purchase and begin using a certified EHR. According to CMS, the average adopt/implement/upgrade cost is $54,000 per physician, while annual maintenance costs average $10,000 per physician. These costs do not account for all the functionalities associated with meeting the MU requirements such as purchasing lab interfaces, which taken together can represent thousands of dollars. Furthermore, it may take five years or more to reach pre-EHR levels of productivity, particularly for smaller practices, according to

[2] http://oig.hhs.gov/testimony/docs/2011/perez_testimony_03022011.pdf , http://www.aging.senate.gov/minority/public/index.cfm/files/serve?File_id=41a195e0-c269-3fd2-3af3-7066282a2972, http://www.hhs.gov/asl/testify/2011/02/t20110215b.html,

the American EHR Survey. This results in lost revenue to physician practices for a period of time, compounding the financial impact of EHR implementation.

The AMA is very concerned that physicians who have invested considerable resources are being subjected to pre-payment reviews. The AMA has received numerous reports from physicians who have been audited by CMS that they have been asked to supply documentation that is not obtainable to substantiate their incentive payment. In several instances, it is clear that CMS never instructed physicians nor the certified vendors to retain or have the functionality to produce certain types of documents such as screen shots of their products from a past date. The AMA has communicated these concerns to CMS, and we are working with them to try and make the audit process less burdensome.

In order to balance the need for ensuring taxpayer dollars are being appropriately dispensed, we recommend a balanced approach in which: 1) audits are limited to post-payment review and that pre-payment review be used only in instances where true fraud is suspected; 2) CMS provides direct guidance to physicians concerning audit documentation requirements prior to attestation; 3) physicians and vendors are well-informed about what is needed to ensure they can demonstrate to the federal government that they have met the MU requirement; and 4) ONC requires certified products to be capable of producing required documentation.

IV. Long-Term Questions on Data Security and Patient Safety Remain

Physicians place a high priority on patient safety and the privacy of patient information. The AMA shares the authors' concerns surrounding these two issues. Physicians have also expressed serious concerns with the impact some EHRs have on patient safety and the AMA has commented numerous times on the matter of patient safety as it relates to the use of EHRs.[3] While it is widely accepted that EHRs can support better clinical decisions, facilitate information exchange, and reduce duplicative efforts and costs, studies have found they can also result in unintended patient safety issues. In some cases, EHR design and software flaws have been found to contribute directly to errors, including some that have caused patient harm. Clinical usability issues that can contribute to unsafe conditions include: use of certain colors on screens (e.g., persons with red-green color blindness might not see important distinctions); information overload due to packing too much information onto a single screen; difficult or non-intuitive navigation steps to obtain key data; use of small fonts; facilitation of "cut & paste" issues; alert overload leading to alert fatigue; and selecting the wrong patient when multiple patient records are open. The Healthcare Information and Management Systems Society (HIMSS) EHR Usability Task Force has acknowledged these problems and has found that "clinical systems are complex as well as information dense–it is essential for efficiency as well as patient safety that displays are easy to read, that important information stands out, and that function options are straightforward."[4] The Agency for Health Care Quality and Research (AHRQ) similarly concluded that health IT can negatively impact patient safety if there is "a lack of integration of health IT into clinical workflow in a way that supports the cognitive work of the clinician and the workflows

[3] AMA has addressed patient safety concerns in the following places: http://www.ama-assn.org/resources/doc/washington/health-information-technology-patient-safety-letter-01march2012.pdf; http://www.ama-assn.org/resources/doc/washington/onc-health-it-patient-safety-plan-letter-01feb2013.pdf ; http://www.ama-assn.org/resources/doc/washington/ehr-meaningful-use-testimony-03may2013.pdf.

[4] HIMSS EHR Usability Task Force, "Defining and Testing EMR Usability: Principles and Proposed Methods of EMR usability Evaluation and Rating," June 2009.

among organizations (e.g., between a clinic and community pharmacy), within a clinic and within a visit."[5]

The use of EHRs is a relatively new area for office-based physicians and most doctors are not technology or encryption experts. The AMA believes more needs to be done to ensure that physicians are well educated on the best approaches for securing and ensuring patient information remains private within an EHR when it is exchanged electronically, and that access is only granted to those who should have access. The AMA has numerous resources online to aid physicians in meeting the Health Insurance Portability and Accountability (HIPAA) privacy, security, and breach notification requirements. Many of these resources are being updated to help physicians meet the new requirements that will go into place in September 2013.

We also agree that concerns about the security of patient information needs to be balanced against the burdens placed on entities that are responsible for safekeeping and disclosing data. The AMA is concerned with the Office for Civil Rights (OCR) proposed rule regarding the accounting for disclosures of patient's protected health information (PHI). Unless significant changes are made, the proposed rule will have the unintended effect of deterring physicians and other health care providers from using EHRs.[6] The AMA recommends that OCR, in the final rule, withdraw the proposed access report requirement and that it make the following modifications to the proposed accounting of disclosure reports:

- Physicians and other HIPAA covered entities should only be required to produce accounting of disclosure reports based off of information maintained in an EHR that has the functionality to readily produce reports that are not burdensome to create and are meaningful to the patient. Physicians should not be required to produce information from other non-EHR systems that contain PHI, including but not limited to practice management and billing systems.

- Physicians should have the option to furnish an accounting of disclosure reports on behalf of their business associates or the option to furnish an accounting of disclosure reports limited to information from the physician's EHR and provide the patient with a list of the physician's business associates (with contact information for each business associate), so that the patient can directly contact the business associates for a report.

- The 30-day time limit to provide an accounting of disclosure reports to a patient, with an additional 30 days upon notice to the patient, should be expanded to 60 days, with an additional 30 days upon notice to the patient.

- Physicians should be allowed to provide their patients with a copy of the accounting of disclosure reports in an electronic format determined by the practice or on paper.

- The compliance enforcement deadline for the new HIPAA accounting of disclosure requirement should be adequate to provide the time needed for the development of

[5] HRQ Incorporating Health Information Technology Into Workflow Redesign, AHRQ Publication No. 10-0098-EF, October 2010.
[6] http://www.ama-assn.org/resources/doc/washington/hipaa-accounting-of-disclosure-sign-on-letter-01aug2011.pdf

appropriate EHR software, the pursuit of educational outreach, and preparation by physicians and others to ensure compliance with the new HIPAA requirements.

- Physicians should only be required to produce information necessary to satisfy the new accounting of disclosure reports that is dated on or after the compliance effective date.

We have learned that protecting patient data in an electronic environment will require ongoing education, especially with the proliferation of mobile devices and as physicians begin to participate in HIEs. We believe helping educate physicians on these issues is a shared responsibility. The AMA believes that the Regional Extension Centers (RECs) originally established to help primary care physicians select, purchase and use a certified EHR, could be helpful partners in helping all physicians ensure they have the information and resources they need to best protect their systems and patient's information and that consideration should be given to expanding their mission to include this.

V. Questions Remain About Long-Term Sustainability of the EHR Program

The AMA agrees with the authors that multiple, overlapping reporting requirements and regulatory burdens pose serious challenges for physicians that compete for precious patient care time. We, furthermore, share the authors' concerns that the pressure to meet these requirements will only grow as they face penalties for non-adoption of EHRs. In fact, we have already seen this with the Medicare e-Prescribing program. In 2012 approximately 135,000 physicians received a penalty for not meeting the requirements of the Medicare e-prescribing program. In many cases, some of these physicians were, in fact, prescribing electronically but were penalized for technical and administrative reasons (i.e., their certified system was unable to communicate the G code that indicated they were e-Prescribing to Medicare).

We also agree that long-term risks for meeting multiple, competing deadlines and requirements combined with the confluence of the penalty programs (including the MU program, the Medicare e-Prescribing Program, and the Physician Quality Reporting System) will be especially pronounced for small and medium size practitioners who do not have the same resources as larger providers. This is another reason the AMA strongly believes that Stage 2 requirements must be made more flexible.

We are also deeply concerned with the long-term sustainability of the program due to other financial pressures on physicians. Due to the operation of the flawed sustainable growth rate (SGR) formula and repeated temporary patches, physician payments are only two percent higher than they were in 2001 while practice costs have increased by 25 percent. The current payment system does not provide the stability to allow many physician practices to make new technological investments of the size described above. It is imperative that the SGR be repealed and replaced with a new delivery system that will provide the resources necessary for implementing and sustaining EHRs.

Additional Concerns

The AMA firmly believes that the MU certification process must immediately be retooled in order to address a variety of problems many physicians are experiencing with their use of certified EHRs. Physicians are complaining that the certified EHRs available in the market are not matching their clinical needs.

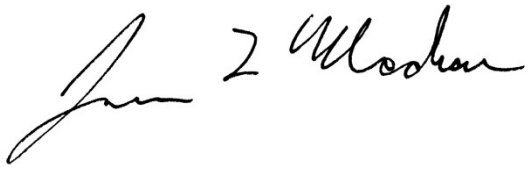
Specifically, physicians' overall dissatisfaction centers on how well the products work both from a workflow and usability standpoint, including concerns about ensuring they are meeting Medicare's documentation and coding requirements. Data from the American EHR Survey found that between 2010 to 2012, the percentage of doctors who would not recommend their EHR to a colleague increased from 24 percent to 39 percent, and approximately one-third of all surveyed said they were "very dissatisfied" with their EHR and that it is becoming more difficult to return to pre-EHR productivity levels.

To address these issues, we recommend that: 1) HHS should hold off on adding additional measures to the meaningful use program to allow vendors to address physician EHR usability concern; 2) ONC should add physician usability criteria to the EHR certification program; and 3) ONC's rulemaking for Stage 2 certification must be re-opened to address these concerns prior to the start of Stage 2 on January 1, 2014.

Conclusion

The AMA is committed to facilitating the widespread adoption of EHRs. In addition to the promise that EHRs have for helping to improve the quality and efficiency of care, they are also critical to the success of efforts to reform the health care delivery system. We appreciate your efforts to identify and address issues with the MU program and the implementation of EHRs, and we look forward to working with you, your colleagues, and the Administration on this important endeavor.

Sincerely,



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