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June 5, 2014

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Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
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Washington, DC 20201

Dear Administrator Tavenner, Inspector General Levinson, and National Coordinator DeSalvo:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to you in regard to the work by the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General (OIG), and the Office of the National Coordinator for Health Information Technology (ONC) (herein-after "the agencies") to determine and address program integrity vulnerabilities presented by electronic health records (EHRs). It is our understanding that this work follows recent reports by the OIG concerning the program integrity of EHRs and potential safeguards.¹

The AMA is firmly committed to eradicating health care fraud; misappropriation of health care dollars robs funds that could otherwise be devoted to patient care. At the same time, the vast majorities of physicians are honest, and should not be subjected to overly restrictive or broad brush regulations that detract from patient care. Any program integrity safeguards should therefore be targeted and streamlined to identify and expel true fraudsters, and, at the same time, allow honest physicians to easily navigate patient interactions and clinical workflow. Our specific recommendations with respect to program integrity efforts related to EHRs follow and are elucidated throughout this document with additional discussion:

- (1) Prior to the publication of any EHR program integrity guidance for providers or audit contractors, we request that the agencies work closely with the AMA and other stakeholders to ensure that such guidance is well-informed of stakeholder perspectives on these issues. EHR program integrity guidance should not be finalized until stakeholders have had an ample opportunity to provide constructive feedback;

- (2) Rather than constraining or prohibiting documentation technology features, the agencies should provide meaningful education and best practices for documentation to physicians and other stakeholders;
- (3) The AMA is actively working on efforts to improve the usability of EHRs with federal regulators and vendors. We ask that the agencies review the AMA's forthcoming recommendations to improve EHR Usability—anticipated to be released in the late Summer 2014—prior to publication of EHR program integrity recommendations or guidelines so that you fully understand and consider the challenges and potential solutions of EHR usability from the physician perspective; and
- (4) Physicians' ability to successfully adopt certified EHR, which is required under the Meaningful Use (MU) program, has been significantly challenged because of software limitations and the numerous MU requirements. Any recommendations or guidelines on proper documentation must be flexible to take into account that CMS is making major changes to the MU program and that EHRs technology is still evolving.

AMA Focus on EHRs

Last year, the AMA commissioned the RAND Corporation to study factors affecting physician professional satisfaction and implications for patient care, health systems, and health policy.ⁱⁱ RAND found that EHRs are a major source of dissatisfaction for physicians because they lack usability and interoperability, are costly, and are not designed to accommodate physicians' workflow and patient interactions. As you are aware, physicians are required to use EHRs that are certified by ONC in order to obtain an incentive payment and to avoid financial penalties under the MU program.

Following the RAND results, the AMA has identified improving the usability of EHRs as a key priority of its Professional Satisfaction and Practice Sustainability strategic focus area, and is devoting considerable resources to this subject. As part of this strategic focus, the AMA has convened an advisory group of health information technology (HIT) experts, including noted health informaticists, human factor researchers, chief information officers of large integrated health care systems, and physicians in small practices, to develop a set of characteristics that are aimed at improving EHR usability. These characteristics will be used to inform the next generation of EHR products and physician decision-making in the purchase and use of EHRs, and will be a valuable resource for your agencies to understand EHRs usability from the physician perspective.

Because we believe that this work will add value and perspective to your review of EHR program integrity vulnerabilities, we strongly urge you to postpone publication of EHR program integrity guidance until it may be informed by the AMA's efforts.

Documentation Tools

As a threshold matter, we urge the agencies to take into account that physicians are extremely frustrated with a multitude of issues concerning EHR usability, and many of these frustrations dovetail with the program integrity vulnerabilities highlighted by the OIG.

For example, physicians report using templates (or “macros”) and copy & paste to ease the writing of clinical notes (i.e., to overcome data entry problems), to efficiently document routine entries, and to ensure that carefully drafted information or lists can be carried forward to inform future decision-making. These valid reasons for using documentation tools are highlighted in the AMA’s testimony before ONC in 2013, which we have included along with this letter.

Yet, the RAND report also documented template-based notes as a potential threat to both clinical quality and professional satisfaction. Such notes were described as complicating the task of retrieving useful clinical information, a phenomenon often referred to by stakeholders as “note bloat.”

This problem was reported by physicians in all specialties and practice models included in the RAND study. The following report is typical:

We’ve been in the [EHR] system for what must be almost three years now. It’s hard to believe it’s been that long. And how do we like it? As with all electronic medical records, I greatly dislike the document that’s produced. We live in a world now where almost every provider, or at least I would say the majority of the providers around here, seem to have electronic systems, none of which are particularly easy to interpret. And it is a source of general, I think, dissatisfaction among the physicians that we have been forced to abandon [a way of documentation] that was always very effective and very succinct. And the days of being able to dictate in a meaningful fashion, in the form of a letter or a concise document to send to a primary care doctor, are gone, and that’s lamentable, because that has been a step down in quality. These new documents are unreadable because you’ve got to skim through them really quickly and say, “Where’s the meat here?”

—Cardiologist

While note bloat is a source of consternation for physicians, use of templates, macros, copy & paste, and other functionalities are in part due to the failure of EHRs to provide efficient documentation and viewing tools. To be clear, we are not advocating for removing the availability or use of templates, macros, or copy & paste. Rather, we believe that more usable products will obviate some of the challenges we are describing.

In addition, the lack of education on the appropriate use of these documentation methods has left physicians without practical guidance on when and how to employ these techniques. Previously common documentation practices may no longer be appropriate or may need to be modified given the new environment. We believe that education is the key to ensuring physicians best learn how to use the EHRs currently available to them while we work with vendors to have more usable systems delivered to the marketplace.

To overcome current usability challenges, we urge the agencies to work proactively with physician organizations to identify problems and risks in using these tools while also recognizing their potential benefits as EHRs continue to evolve.

Impact of the MU Program and EHRs Certification Requirements

We believe that much of the deficit in EHRs usability stems from an onerous and restrictive MU program. EHRs vendors have been saddled with burdensome and complicated requirements they must meet, in order to deliver a certified product to the market. To date, EHR vendors have largely focused on meeting these requirements to obtain certification rather than the usability of their products. The AMA strongly supports a streamlined certification process for vendors because we believe it will provide the requisite flexibility to deliver more innovative and useful products.

The AMA has closely monitored and provided agency feedback regarding EHRs since the inception of the MU program. Over the past three years, we have seen progress in adoption of EHRs but also significant frustrations. Our most recent analysis of CMS' own data suggest that almost 22 percent of physicians are dropping out of the MU program due to the lack of program flexibility.

We strongly recommend that any guidelines published concerning EHR documentation be informed by the challenges physicians and vendors face in meeting a plethora of MU and other reporting program mandates, and take into consideration the fact that physicians are required to use certified EHRs.

Audit Logs

The OIG and ONC, in its 2015 certification rule, have proposed requiring that EHR technology prevent users from being able to disable the audit log. While we acknowledge that audit logs may have some utility in fraud *prosecutions*, we do not think that audit logs are a useful tool for fraud *detection* and, most importantly, we have serious concerns about significant office workflow problems stemming from operational audit logs.

Audit logs can contain millions of entries, are very complex, and require specialized knowledge and significant time to read. Importantly, audit logs by themselves are not demonstrative of fraud. While audit logs may be appropriate evidentiary tools in a legal proceeding, they present only superficial information that by itself is not a reliable or full picture of what has transpired. For this reason, audit logs should not be relied upon as a vehicle to proactively identify fraudulent or improper documentation.

We also caution that audit logs may have similar obstacles and complexities as the HIPAA Accounting for Disclosure regulation. This requirement, while a seemingly valid tool for patients to track who has viewed their medical records, has led to an unworkable and overly complex mandate that HHS has not been able to implement.

Providers have had to shut off the EHR audit log function, not due to fraudulent intentions, but because the logs take up a significant amount of memory and action for the EHR system. In particular, audit logs

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can lead to significant delays in processing patient records. This is akin to when you run virus software on your computer, which slows down all other functions. Given the lack of usability of these systems, we caution against preventing this practice in its entirety.

In addition, the agencies should consider that physicians will have to store this information in their EHRs, which will further impede their software and require additional costs. The potential benefits of requiring audit logs to be turned on are outweighed by the significant lag in response time for EHR systems and resulting office workflow issues.

Combined with the aforementioned EHR usability challenges, requiring audit logs be turned on could significantly hamper physicians' ability to use these systems and could contribute to productivity losses. For these reasons, we do not support certification requirements that require a vendor or provider to keep the EHR's audit log on at all times or prohibit disabling this feature when necessary.

We appreciate the opportunity to provide these comments and look forward to a continued dialogue on appropriate documentation techniques for EHRs. If we can be of any further assistance, please contact Cybil Roehrenbeck, Assistant Director, Federal Affairs, at cybil.roehrenbeck@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD

Attachment

ⁱ OIG. Not All Recommended Fraud Safeguards Have Been Implemented In Hospital EHR Technology. December 2013. OEI-01-11-00570. See also: OIG. CMS and Its Contractors Have Adopted Few Program Integrity Practices to Address Vulnerabilities in EHRs. January 2014. OEI-01-11-00571.

ⁱⁱ AMA-RAND. Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. October 2013.