TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

December 26, 2019

Joanne M Chiedi
Acting Inspector General
Office of the Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P, Room 5521
Cohen Building
330 Independence Avenue, SW
Washington, DC

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RE: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Acting Inspector General Chiedi:

The Texas Medical Association (TMA) is the largest state medical society in the nation and is the voice of more than 53,000 physician and medical student members. TMA is committed to improving the health of all Texas. It is the mission of TMA to stand up for Texas physicians by providing distinctive solutions to the challenges they encounter in the care of patients. TMA thanks you for the opportunity to comment on the above-referenced proposed rules specific to the section on electronic health records.

As a general comment, just as medicine is becoming more "evidence-based," these and other regulations should be evidence-based rather than reflect the belief of those writing the regulations. The phrase "we believe" appears 64 times in the proposed rule. Basing these regulations on beliefs rather than data risks unintended and adverse consequences that can be avoided if regulations are based upon facts rooted in data and analysis.

I.1. Interoperability. [Federal regulations] require that donated items and services are interoperable and prohibit the donor (or someone acting on the donor's behalf) from taking action to limit the interoperability of the donated item or service.

Comment: TMA strongly supports the requirement that donated items and services be interoperable. Demonstrated failure on the part of the donor to meet this requirement should not result in a financial impact to the recipient physician, unless the physician was found to be in collusion with the donor to violate this requirement.

I.3. Information Blocking. We propose modifications to 1001.952(y)(3) to recognize these significant updates since the 2013 Final EHR Safe Harbor Rule. Specifically we propose aligning the condition at 1001.952(y)(3) with the proposed information blocking definition and related exceptions in 45 CFR part 171.

Comment: TMA supports the alignment of all federal laws and regulations. However, we are very concerned that the final regulations regarding "information blocking" may contain restrictions that would limit the effectiveness of these exemption regulations. We therefore propose that the comment period of these regulations be held open until 60 days after the finalization of the "information blocking" regulations. That will allow stakeholders an opportunity to compare and contrast these proposed regulations with the final rule on information blocking.

I.3. Information Blocking. [OIG notes that health plans, which are protected donors under the EHR safe harbor, may not be subject to the information blocking provisions of the 21st Century Cures Act or the ONC NPRM.] Rather than have different conditions for healthcare providers and health plans, we believe it is reasonable to have one condition that applies the same information blocking knowledge standard to all parties who voluntarily use the safe harbor to protect donations of EHR items and services. For purposes of donations under this safe harbor, we propose to apply the knowledge standard articulated in the PHSA at section 3022(a)(1)(B)(ii) as applicable to both providers and health plans, and we seek comments on this approach."

Comment: TMA supports the use of the standard in the Public Health Services Act (PHSA). "Information blocking" requirements for purposes of these donations should apply equally to all those involved, including health plans. Failure to apply requirements evenly across all donors and recipients sets up an uneven playing field.

I.4. Cybersecurity. We are proposing to expand the EHR exception to expressly include cybersecurity software and services so that it is clear that an entity donating EHR software, and providing training and other related services, may also donate related cybersecurity software and services to protect the EHR. [1. definitions] While we recognize that effective cybersecurity may require hardware that meets certain standards (e.g., encrypted endpoints, updated servers), we remain concerned that donations of valuable, multifunctional hardware pose a higher risk of constituting a disguised payment for referrals.

Comment. While TMA supports OIG's attempts to expand of the exception for cybersecurity and finds the proposal well written, we disagree with the approach being taken. Cybersecurity is too important to our public health and patient safety – and our national security – to limit its support through these types of regulations. It is insanity to think that all physician offices across the country can be kept at the highest state of cybersecurity protection – a level constantly needed – without significant external support. The form of that support may not be easily definable as a "cybersecurity product" as cybersecurity will, like other aspects of electronic health care, come in too many forms to allow regulatory definition.

Therefore, TMA supports expansion of the exception for cybersecurity hardware, software, infrastructure and services, without exception. This is consistent with our recommendation above that OIG and others need to think about these electronic health systems as an integrated network of multiple products rather than a monolithic electronic health record (EHR) in a physician office.

While we recognize that the possibility of fraud exists by opening this exception, the risk to public health, patient safety, and national security from cyber attacks is so great that TMA feels strongly alternative measures to control abuse are needed rather than using product and service definitions that are too complex and potentially too vague to be effective. We also support the elimination of any barriers to cybersecurity donations, such as a copayment.

As remarked in the proposed regulations, "We note that, if a system is only as strong as its weakest link, then even a very low-referring physician's practice poses a cybersecurity risk." In brief, a radically different approach is needed for effective cybersecurity.

I.5. The Sunset Provision. We are proposing to eliminate the sunset provision at 42CFR 1001.952(y)(13). As an alternative to this proposed elimination of the sunset provision, we are considering an extension of the sunset date for the final rule. We seek comment on whether we should select a later sunset date instead of making the safe harbor permanent, and if so, what that date should be.

Comment: TMA supports elimination of the sunset date. If data suggest the electronic health items and services exemption should be eliminated, that can be revisited at the appropriate time. There will always be new physicians, or physicians leaving their existing health care systems, who desire to set up independent practices. Those serving rural and/or indigent populations particularly will need this exception. An inability to obtain subsidized EHRs and cybersecurity support through this exception will be a significant economic deterrent to setting up these practices, and fewer physicians will pursue this path, leaving vulnerable populations with limited access to care.

I.6. Definitions. We are proposing to modify the definitions of ''interoperable'' and ''electronic health record."

Comment: TMA supports updating definitions but recommends adding the words "used for clinical diagnosis and treatment" into the new definition. This would better distinguish the EHR from the multitude of other tools used to provide clinical care. Importantly, TMA recommends that the definition of an EHR should be standardized across all federal regulations, to the limits permitted by legislation.

TMA doubts that changing the wording to what is proposed will keep up with what we see as a dynamic redefinition of how electronic health care is provided.

Clinical care is increasingly not provided by using a monolithic software product that can be identified easily. We are moving to a more distributed electronic care environment where health care is provided by using a collection of web-based tools from multiple different vendors, including personal health tools. By using "EHR" as the focus for these regulations, we risk the possibility that we are supporting the use of yesterday's technology. Therefore, TMA encourages OIG and others to investigate how to expand the use of donations for web-based artificial intelligence, clinical decision support, and other non-EHR tools. Failure to provide donation capabilities for their use may bias their implementation towards large health care organizations, which provide only a fraction of the patient care given in the U.S.

I.7.a. Additional Proposals and Considerations; 15-Percent Recipient Contribution. We are considering eliminating or reducing the percentage contribution required for small or rural practices. We solicit comments on how "small or rural practices" should be defined. In the alternative, we are considering reducing or eliminating the 15-percent contribution requirement in this safe harbor for all recipients. We solicit comments regarding the impact this might have on the use and adoption of EHR technology, and any attendant risks of fraud and abuse.

Comment: TMA doubts the only reason fewer rural doctors than others have not incorporated an EHR into their practice is that only 85% of the cost could be covered by a donor entity. TMA suspects other factors are more important, such as the cost and the lack of reliable internet connections. There likely are many other reasons requiring data and analysis to reveal what steps should be taken.

TMA supports removal of the 15% for all physicians as it would be unwieldy to set up conditions where some must pay and some must not. Additionally, TMA is not aware of any evidence that 15% prevents fraud and abuse any more than 0% does. There is little question that 15% represents a financial barrier in some cases of small, new, or rural physician practices.

I.7.a. Additional Proposals and Considerations; 15 Percent Recipient Contribution. We are considering modifying or eliminating the contribution requirement for updates to previously donated EHR software or technology. We solicit comments on this approach as well as what such a modification should entail. For example, we are considering requiring a contribution for the initial investment only, as well as any "new" modules, but not requiring a contribution for any update of the software already purchased.

Comment. TMA supports the removal of the 15% contribution for updates. The 15% requirement on updates can be impractical from both a physician recipient and a donor standpoint when their EHRs are linked, as is sometimes the case. Once these two are linked, it often becomes impossible for them to be out of sync with each other if they share an "instance" of an EHR. Because supporting EHRs in varying versions becomes cost-prohibitive, having to pay 15% for an upgrade that a practice may not use, want, or need right now is essentially a tax and damages the financial stability of small practices. Even if the EHRs are not linked, in the age of interoperability, it is cost-prohibitive and does not support patient safety to have to connect multiple versions of software. Upgrades are important, and all barriers to their implementation should be removed.

I.7.b. Additional Proposals and Considerations; Replacement Technology. We noted that providing equivalent items and services confers independent value on the physician recipient and noted our expectation that "physicians would not select or continue to use a substandard system if it posed a threat to patient safety." We appreciate that advancements in EHR technology are continuous, rapid, and sometimes prohibitively expensive for the purchaser of such technology, and that in some situations, replacement technology is appropriate. We are proposing to delete the condition that prohibits the donation of equivalent items or services at current 1001.952(y)(7) to allow donations of replacement EHR technology. We specifically seek comment as to whether deleting this condition is necessary, and in what situations replacement technology would be appropriate. We further solicit comment as to how we might safeguard against situations where donors inappropriately offer, or recipients inappropriately solicit, unnecessary technology instead of upgrading their existing technology for appropriate reasons.

Comment: TMA supports the expansion of the exception to replacement technology. EHRs, as currently structured and promoted by the Centers for Medicare & Medicaid Services and the Office of the National Coordinator, have been designed to lock physicians into their use, and switching is enormously costly. There often is no choice but to stay with a substandard proprietary vendor.

TMA recommends that OIG and others investigate approaches that would encourage the donation and use of products that can be rapidly replaced if significant problems occur. The concept of being able to "pick up your database and move to a new product" is not new, but regulations support the opposite, which is vendor lock-in.

If you have questions about this recommendation, please do not hesitate to contact Shannon Vogel by calling (512) 370-1411.

Sincerely,

Joseph H. Schneider, MD, MBA
Chair, Committee on Health Information Technology
Texas Medical Association