



Michael D. Maves, MD, MBA, Executive Vice President, CEO

December 12, 2005

Daniel R. Levinson
Inspector General
Office of the Inspector General
Department of Health and Human Services
Attn: OIG-405-P
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Re: *Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute*; 70 Fed. Reg. 195, 59015 (Oct. 11, 2005); OIG-405-P

Dear Inspector General Levinson:

The American Medical Association (AMA) appreciates the opportunity to provide its views on the Office of the Inspector General's (OIG) proposed rule concerning *Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute*; 70 Fed. Reg. 195, 59015 (Oct. 11, 2005); OIG-405-P

I. General

The AMA appreciates the OIG's efforts to foster the development and utilization of health information technology (HIT) by proposing a safe harbor to the Federal anti-kickback statute for electronic prescribing technology. The AMA is optimistic that e-prescribing and other health information technology can achieve the promise of improving patient safety and increasing administrative efficiency.

The AMA supports legislation and other appropriate initiatives that provide positive incentives for physicians to acquire health information technology. We believe that the creation of safe harbors for assisting physicians with the adoption of HIT is necessary in order to facilitate wide-spread usage of such technology. While the AMA supports

assistance to physicians purchasing HIT, it strongly believes that such assistance cannot unreasonably constrain physicians' choices regarding which HIT system to purchase. In addition, the AMA believes that any assistance must promote voluntary rather than mandatory sharing of Protected Health Information (HIPAA – PHI) with the assisting facility consistent with the patient's wishes as well as applicable legal and ethical considerations.

In order to encourage voluntary electronic prescribing in the Medicare program, the Department of Health and Human Services should be fully aware of the future Medicare environment for physicians. Initial standards for e-prescribing will be in place by January 1, 2006. And, by law, full e-prescribing standards must be in place by April 1, 2009. The 2009 standards include broad HIT requirements such as, the ability to identify drug interaction, warnings, or cautions; the ability to provide information on lower cost therapeutically appropriate alternatives; and the ability to provide information that relates to the medical history of individuals. At the same time, Centers for Medicare and Medicaid Services (CMS) actuaries predict five percent annual payment reductions for physicians for six years, starting in 2006. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. This means that by 2012, physicians will be paid about 26% less than in 2005, while practice costs will have increased significantly.

Moreover, a recent study by Robert H. Miller, et al, published in *Health Affairs* September/October 2005 issue, found that initial electronic health record costs were approximately \$44,000 per full-time equivalent (FTE) provider per year, and ongoing costs were about \$8,500 per FTE provider per year. Initial costs for twelve of the 14 solo or small practices looked at, ranged from \$37,056 to \$63,600 per FTE provider. With these potential costs and this financial environment, it will be extremely difficult for physicians to allocate the resources necessary to invest in new technologies. The AMA is confident that e-prescribing has significant potential benefits to physicians and their patients, but is commensurately concerned that investments in e-prescribing technology and electronic health records will be difficult given the dramatic reimbursement reductions forecast in Medicare.

While the AMA appreciates the OIG's efforts to encourage e-prescribing by adding a safe harbor for the federal anti-kickback statute, given the limited financial and technological resources of many physician practices, we are concerned that the safe harbor is not sufficiently broad to encourage widespread and successful adoption of e-prescribing technology. To this end, the AMA believes that both the OIG and CMS should adopt final rules that reflect liberal exceptions that will better achieve the ultimate promise of e-prescribing – improved efficiency, patient safety, and health care quality.

II. Provisions of the Proposed Rule

A. Electronic Prescribing Safe Harbor Required Under Section 101 of the MMA: Paragraph (x)

1. Protected Nonmonetary Remuneration

“Necessary” Non-monetary Remuneration

Pursuant to the proposed rule, allowable non-monetary remuneration includes hardware, software, internet connectivity, training, and support services. Given the enormous costs related to implementation of HIT, the AMA strongly believes that the list of acceptable donations should be more expansive. The AMA thinks that in addition to the aforementioned allowable non-monetary remuneration, the safe harbor should include donations of maintenance, associated costs related to implementation, and upgrades, as well as any costs associated with licenses, rights of use, or intellectual property.

There will be numerous unanticipated costs associated with implementation and use of e-prescribing technology. In addition, there will be extended maintenance fees incurred as a result of the 24-hour-day, 7-day-a-week online technical support required by physicians' schedules. And, due to the ever-changing nature of the technology industry, there will undoubtedly be costs associated with upgrading any and all e-prescribing technology in the future. Any safe harbor for donations of e-prescribing technology, therefore, should address not only the costs of acquisition, but the costs of implementing, maintaining, and upgrading e-prescribing technology.

The regulations also require that physicians determine what technology they possess. Specifically, physicians must certify that any technology they receive is not technically or functionally equivalent to any existing technology. While the AMA recognizes the OIG's concern regarding divestment and replacement of technology, we believe that requiring such a certification, and effectively banning physicians from utilizing the safe harbor to obtain potentially more efficient and effective e-prescribing technology, will create an additional financial burden on physicians and will be at odds with the goal of encouraging e-prescribing by outfitting physicians with the most useful technology.

Requiring physicians to certify existing technology capabilities is an enormous financial and administrative burden on physicians. Many physicians do not know the capabilities of the technology they possess or how their technology relates to the technology being offered by donors. Assessing these capabilities takes both time and expertise. Acquiring the expertise to determine technological capabilities would require time away from patient care for, or in the alternative, money to hire an outside expert, both of which would further deter those physicians already skeptical about implementing new e-prescribing technology.

Moreover, the AMA is concerned about the administrative process associated with a certification. We believe that such a requirement would raise numerous questions and complications, including: what, exactly, the certification would attest to; who would be liable for the information in the certification when a physician relies on someone in his/her office, or relies on an outside expert for making technological determinations; what the repercussions for misinformation on a certification would be; who would be responsible for determining that the information was incorrect; how the person or group making that determination would determine whether the incorrect information was submitted intentionally or just the result of a lack of knowledge or mistake; and whether there would be a right to appeal that decision. These questions, and more, surround any proposal to force physicians to certify technological information for which they do not have the expertise, and would lead to additional apprehension and skepticism on the part of the physician.

Finally, the AMA believes that a prohibition on donating technology to physicians that already have similar technology would ultimately hinder the goals of widespread usage of e-prescribing technology. Such a prohibition could bar qualified physicians from receiving technology that could result in standardization among all physicians working at a single donating hospital. It could bar physicians that have outdated, outmoded, or unusable technology from accepting updated, user-friendly technology. And, it could bar physicians who might have the capability to support e-prescribing technology, but not the knowledge or incentive to put it into practice, from receiving realized technology that would encourage them to e-prescribe. It is at odds with the goals of these regulations to restrict physicians from receiving technology that would most strongly encourage extensive adoption of e-prescribing.

“Used Solely”

Under the proposed regulation, the technology provided to physicians must be “used solely” for the transmission or receipt of electronic prescribing information. This limits donated hardware and software to that necessary, and used solely, to transmit and receive electronic prescribing information to/from a drug program that meets CMS program standards. The AMA is concerned that such a strong limitation will constrain software interoperability and hamper the widespread implementation of electronic health records and e-prescribing.

Requiring technology to be used solely for e-prescribing where such technology may have electronic health record or other health information usages will hinder the types of quality and IT initiatives that CMS intends to encourage. Further, the proposed language would either exclude or require the dismantling of such common technologies as hardware and software suites containing email applications, office systems, internet capability, and connectivity. This prohibition would severely limit the types and brands of technology that could be donated and would likely result in the incurring of additional delays and expenses related to stripping multi-function technology. In addition, it would require physicians to

maintain two completely separate systems. The AMA does not believe that it is practical to require physicians to acquire or use software and hardware solely for electronic prescribing. Requiring a stand alone system creates all sorts of unnecessary complexities and confusion and would be another obstacle to encouraging the worthy goal of broad adoption of e-prescribing technology.

Finally, the AMA urges the OIG to broadly interpret qualified prescriptions. The AMA believes that permissible e-prescribing should not be limited to pharmaceuticals. Rather, allowable prescriptions should include non-pharmaceutical prescriptions such as physical therapy, imaging, durable medical equipment, and laboratory tests.

2. Donors and Recipients Protected by the Proposed Safe Harbor

Under the proposed regulations, donors and recipients include hospitals to members of their medical staffs, group practices to physician members, Prescription Drug Program (PDP) sponsors and Medicare Advantage (MA) organizations to physicians. The AMA believes that donors and recipients should be broadly defined in order to encourage the greatest number of physicians to implement and utilize e-prescribing technology. We are concerned that restricting the donors and recipients as proposed will exclude many physicians, including those who are not affiliated with any hospital, those who have privileges but are not members of a hospital staff, and those who are employees of a hospital that is not willing or able to donate. And will, in addition, exclude health plans, labs, and networks as donors. Furthermore, the enumerated donors and recipients do not account for those physicians who may work with several potential donors, creating a situation whereby the donors might be encouraged to compete against each other, or to the contrary, no donor feels truly responsible for supplying the technology.

In addition, the AMA believes that the restrictions will create unnecessary burdens and complications for physician networks, Independent Physician Associations (IPA), and group practices. The proposed rule does not appear to allow donations to physician networks, IPAs, and group practices. This could easily result in a situation whereby only one or a small number of physicians in a physician network, IPA, or group practice are members of a hospital medical staff, and thus the only ones permitted to utilize the e-prescribing technology. Not to mention where members of a group practice, physician network or IPA are members of different hospital medical staffs and thus offered different, potentially incompatible technology. Moreover, the AMA believes that the proposed rule unnecessarily prohibits donations by group practices to physicians who are not members of the group, physician networks, and IPAs, even where physicians in group practices share patients with such physicians or need to be clinically integrated with a physician network or IPA. The AMA believes that donations to and from physician networks, IPAs, and group practices should be included in any exception or safe harbor. Allowing all entities that bill Medicare to donate electronic health records and e-prescribing technology to any physician or group of physicians would go a long way toward implementing interoperable electronic health records on a national scale.

3. Additional Conditions on the Provision of Qualifying Electronic Prescribing Technology

Value of Protected Technology

While the AMA appreciates the OIG's efforts to reduce the threat of fraud and abuse, we do not think that a cap on the value of protected technology should be imposed. Imposition of a cap would unquestionably result in costs being passed on to physicians. Because there is no way of knowing what the costs of products will be in the future, or even what products will be available, a specific monetary cap could easily be exceeded by new, more advanced technology. Such a situation would result in physicians being forced to cover all costs that exceed the cap. This threat is compounded by the absence of any language in the proposed rules that accord physicians a choice with regard to the donated technology. Without any input as to the technology being donated, physicians could easily be faced with a product donation that exceeds the cap and be required to choose between absorbing the additional cost and rejecting the donation in whole. Such a situation is even more likely where the cap is based on the value of the technology to the physician as opposed to the cost to the donor, and the donor is able to obtain valuable technology at reduced rates. Thus, the AMA does not believe that a cap is necessary so long as any non-monetary remuneration that is donated is done so without limiting or restricting the use of the e-prescribing technology to services provided by the donating entity, and so long as it does not take into account the volume or value of referrals.

B. Proposed Electronic Health Records Safe Harbors

The AMA strongly urges the OIG to adopt an anti-kickback safe harbor for electronic health records similar to the Stark exception proposed by CMS. Full implementation of the e-prescribing standards set forth under the Medicare Prescription Drug, Improvement Modernization Act (MMA) may require e-prescribing technology to be fully integrated into electronic health records. Lack of a safe harbor for electronic health records under the anti-kickback statute, therefore, creates a challenge for physicians and hospitals, undercuts the applicability of the proposed Stark exception, and jeopardizes the adoption of e-prescribing as envisioned by the MMA. The threat of an anti-kickback violation would compound physician apprehension and resistance to adopting electronic health records technology. In addition, the Stark exception for electronic health records requires that any arrangement not violate the federal anti-kickback statute. Thus, the lack of a similar anti-kickback safe harbor for electronic health records renders the Stark exception virtually hollow.

The AMA believes that the proposed anti-kickback safe harbor should be broad and encourage rapid adoption of e-prescribing technology. The OIG should craft definitions, limitations, and conditions that address realistic concerns about program and patient abuse without being unnecessarily restrictive. Such latitude is necessary in order to overcome considerable physician trepidation and realize the promise of e-prescribing and electronic health record technology.

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We are pleased that the OIG is moving forward with adoption of a safe harbor to the anti-kickback statute for e-prescribing and we support the OIG in this effort. We appreciate the opportunity to provide our views on the implementation of the proposed rule and look forward to working further with the OIG on this important matter. Should you have any questions regarding these comments, please contact Carolyn Ratner, Washington Counsel, by phone, 202-789-8510, or by email, Carolyn.Ratner@ama-assn.org.

Sincerely,

A handwritten signature in black ink that reads "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA