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June 10, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5541
330 Independence Avenue, SW
Washington, DC 20201

Re: **Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements [CMS-1454-P]; Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute [OIG-404-P].**

Dear Administrator Tavenner and Inspector General Levinson:

On behalf of the physician and medical student members of the American Medical Association (AMA), I offer our comments on the proposals put forth by the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) to extend the anti-kickback statute safe harbor and exception to the physician self-referral law for electronic health records (EHRs). We have long advocated that the safe harbor and exception should be extended beyond the current December 31, 2013 deadline, and are pleased that CMS and OIG have undertaken an effort to do so. We offer below our detailed comments on the specific proposals put forth by CMS and OIG.

We support the proposal to modify current regulations to reflect that the Office of the National Coordinator for Health Information Technology (ONC) is responsible for recognizing certifying bodies. We also support the proposal to modify the current 12-month timeframe for certification to more closely track the current ONC certification program, which is anticipated to occur on a two-year time interval. We agree that the current policy does not provide the requisite flexibility, given ONC's timeframe, and think that these modifications would help to ensure that donated EHRs meet the needs of physicians.

We support the proposal to remove the requirement of electronic prescribing capability from the EHR safe harbor and exception. We agree with CMS' assessment that there are numerous drivers beyond the electronic prescribing requirement in the EHR safe harbor and exception that will continue to spur adoption of electronic prescribing. We also believe that removal of the electronic prescribing requirement will create more flexibility for physicians, giving physicians the option to purchase

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“complete” certified EHR solutions, or specific certified “modules,” in order to meet Meaningful Use requirements. Furthermore, we appreciate that electronic prescribing technology will remain eligible for donation under the EHR safe harbor and exception and the electronic prescribing safe harbor and exception.

We strongly urge CMS and OIG to adopt an indefinite extension of the Stark law exception and anti-kickback statute safe harbor for the donation of EHR products and services. While we support CMS’ and OIG’s effort to extend the current December 31, 2013 sunset date, the proposed sunset date of December 31, 2016 is too near in the future to be effective. While the cost of EHRs continues to be among the chief barriers to EHR adoption, the safe harbor and exception have, to date, made that cost more manageable for many physician practices. The problem of EHR investment cost will persist as a barrier to adoption as the Meaningful Use program continues and imposes additional requirements (e.g., patient portals and lab interfaces), and physicians continue to cite cost as a significant barrier in spite of program incentives. For these reasons, we believe that an indefinite extension of the safe harbor and exception would best facilitate continued physician adoption of EHRs, and strongly urge this course. However, should CMS and OIG choose to adopt a date certain for sunset of the safe harbor and exception, CMS and OIG should adopt their proposed alternate date of December 31, 2021.

We also caution CMS and OIG to proceed carefully as they consider whether to exclude certain types of donors from the scope of permissible donors, or to modify the conditions of the safe harbor or exception. We are aware of the concern of CMS, OIG, and others that donors may be attempting to use EHR donations to secure inappropriate referrals. We have the additional concern that donors and providers may not understand the limits of the safe harbor and exception for EHR donations, as we note that both the safe harbor and exception explicitly provide that the donor not take into account the volume or value of referrals or other business generated between the parties. Instead of narrowing the EHR safe harbor and exception, we think that CMS’ and OIG’s efforts should focus on education regarding the existing bounds of the safe harbor and exception, as well as appropriate enforcement, and we urge CMS and OIG to take that approach.

We appreciate the opportunity to provide our comments on the Agencies’ proposals. Should you have any questions in regard to our letter, please contact Mari Savickis, Assistant Director, Division of Federal Affairs, at 202-789-7414 or mari.savickis@ama-assn.org.

Sincerely,

James L. Madara, MD