AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
Executive Vice President, CEO

American Medical Association
515 N. State Street
Chicago, Illinois 60654

ama-assn.org

(p) 312.464.5000
(f) 312.464.4184

February 26, 2013

Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health & Human Services
Attention: OIG-121-N
Cohen Building, Room 5541
330 Independence Avenue, SW
Washington, DC 20201

Re: OIG Solicitation of New Safe Harbors and Special Fraud Alerts [OIG-121-N]

Dear Inspector General Levinson:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide the U.S. Department of Health & Human Services (HHS), Office of the Inspector General (OIG) with our comments and recommendations in response to the Solicitation of New Safe Harbors and Special Fraud Alerts.

Innovative Payment and Delivery Models

As a preliminary matter, we laud the OIG's establishment of waivers of the federal program integrity laws for physicians who seek to participate in the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs). We believe that these waivers will be instrumental in facilitating physician leadership and participation in the MSSP.

In the same vein, we ask that the OIG publish guidance regarding the waiver of the federal program integrity laws for those physicians who seek to participate in innovative delivery and payment model programs developed by the Center for Medicare & Medicaid Innovation (CMMI). For CMMI's programs to reach their potential for success, it is essential that applicants have up-front guidance regarding the program-specific applicability of the program integrity laws.

The OIG noted in the MSSP interim final rule that section 3021 of the Affordable Care Act includes waiver authority that may be exercised for CMMI programs. In that rule, the OIG stated, "We will address the exercise of that waiver authority in guidance relevant to those programs."[1] We ask that the OIG expeditiously publish such guidance for the programs currently offered by CMMI, and continue to offer such guidance as further programs are developed.

It is our understanding that CMMI means to address the applicability of the federal program integrity laws through the contract process on a case-by-case basis with each CMMI program applicant. In addition, CMMI

[1] Medicare Program, Final Waivers in Connection With the Shared Savings Program, Interim Final Rule, 76 Fed. Reg. 68007 (November 2, 2011).

has developed some preliminary guidance on what activities prospective applicants may engage in without running afoul of the federal program integrity laws. For example, the Bundled Payments for Care Improvement initiative lays out requirements that gainsharing arrangements must meet to be eligible for participation.[2]

While we strongly support CMMI's effort to lay out ground rules as they relate to specific initiatives, we believe that greater assurance would come from a concerted effort by both the Centers for Medicare & Medicaid Services (CMS) and the OIG to issue prospective, bright-line guidance regarding the applicability of the federal program integrity laws to CMMI models.

In addition, we strongly urge the OIG to consider that the federal program integrity laws present a barrier to the multitude of innovative payment and delivery reforms taking place outside the context of the models put forward by CMS. To support payment and delivery reform, clear guidelines are needed concerning the applicability of the federal program integrity laws to these emerging private sector arrangements so that innovators can prospectively assess how best to proceed and be successful.

We offer our assistance as the OIG considers the impact of federal program integrity laws on physician participation in innovative payment and delivery models, including those put forward by CMMI and those driven by the private sector. We note that in the context of the MSSP, on October 5, 2010, the OIG and the Federal Trade Commission held a workshop to examine the effects of the federal program integrity laws on physician participation in the MSSP. We encourage the OIG to hold a similar workshop to consider the implications for other innovative payment and delivery models, focusing on those put forward by CMMI, as we understand that the exercise was useful as the OIG developed waivers for the MSSP.

Electronic Health Records: Waiver of Sunset Date for Exception and Safe Harbor

We urge CMS and the OIG to waive the current sunset date of December 31, 2013 for the existing electronic health record (EHR) exception to the Ethics in Patient Referrals Act and safe harbor from the federal anti-kickback statute. An important part of EHR adoption is "knowing what the rules are" in advance because EHR adoption can be time consuming and expensive. Physicians who seek to adopt EHRs and utilize them in innovative delivery models should be assured that their systems will not run afoul of the federal program integrity laws when those protections expire after 2013. By making the exception and safe harbor protections permanent, CMS and the OIG would foster EHR adoption. The current expiration date of 2013, conversely, inhibits EHR adoption and the use of EHRs in the innovative delivery setting. We recommend an indefinite extension of the Ethics in Patient Referrals Act exception and safe harbor from the federal anti-kickback statute for the donation of EHR products and services.

Safe Harbor for Hospital-Sponsored Continuing Medical Education

We urge the OIG to establish a federal anti-kickback statute safe harbor for hospitals that provide free continuing medical education (CME) programs to physicians. There is widespread consensus that such programs enhance the quality of care received by patients and promote value in the delivery of health care. Such programs serve as a forum for hospital and physician collaboration on care coordination and responsibility, a key tenet of health system reform. It is essential that physicians and hospitals are not deterred from participating in hospital-sponsored CME activities that engender a vital dialogue and shared accountability for comprehensive care. We note that CMS has already established an exception to the Ethics in Patient

[2] See *Bundled Payments for Care Improvement initiative Request for Application*, the Centers for Medicare and Medicaid Innovation, at http://innovation.cms.gov/Files/x/Bundled-Payments-for-Care-Improvement-Request-for-Applications.pdf.

Referrals Act for CME activities as part of compliance training. We ask that the OIG provide corresponding guidance and establish a safe harbor from the federal anti-kickback statute for CME activities.

Hospital Exclusive Credentialing

We urge the OIG to issue a special fraud alert on hospital exclusive credentialing. We believe that the preservation of patient freedom of choice is a key objective as we embark on health reform implementation. A hospital credentialing policy that conditions a physician's privileges on his/her promise to practice (and hence to admit) exclusively at the credentialing hospital is contrary to this effort.

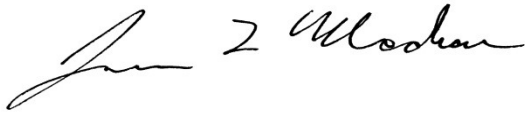
When a physician is able to have privileges at more than one facility, the physician-patient relationship and continuity of care can be preserved at whatever location the patient can be most appropriately treated based on factors such as clinical resources and patient convenience. However, when hospitals are permitted to enforce exclusive credentialing policies, patients can face the "take it or leave it" choice of either receiving care from their preferred physician in a non-preferred hospital setting, or receiving care from a non-preferred physician in a preferred hospital setting. In many cases, patients will utilize the exclusively credentialing hospital's facilities to receive care from their preferred physician, even though the physician and patient would rather have the services rendered at another location for a variety of reasons, including clinical factors.

Accordingly, the OIG should issue a special fraud alert on hospital exclusive credentialing policies that effectively force a physician, as a condition of maintaining privileges, to admit only to the credentialing hospital's facilities.

Conclusion

We appreciate the opportunity to provide our recommendations on waivers and safe harbors of the federal anti-kickback statute and other federal program integrity laws. We look forward to working with you further on our recommendations. Should you have any questions on this letter, please contact Carol Vargo, Assistant Director, Division of Federal Affairs, at carol.vargo@ama-assn.org or at (202) 789-7492.

Sincerely,



James L. Madara, MD