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February 27, 2012

Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
Attention: OIG-120-N
Cohen Building, Room 5541
330 Independence Avenue, SW
Washington, DC 20201

Re: OIG Solicitation of New Safe Harbors and Special Fraud Alerts [OIG-120-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 OIG's recent 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). In the MSSP interim final rule published by OIG and the Centers for Medicare and Medicaid Services (CMS), OIG and CMS issued broad waivers of the federal anti-kickback statute, the Ethics in Patient Referrals Act, the civil monetary penalties law prohibiting hospital payments to physicians to reduce or limit services (the Gainsharing CMP), and the CMP law prohibiting beneficiary inducements. As outlined in our comments on that rule, we believe that the waivers published therein will be instrumental in facilitating physician leadership and participation in the MSSP.

In the same vein, we ask that 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 and Medicaid Innovation (CMMI). As OIG noted in the MSSP interim final rule, Section 3021 of the Affordable Care Act (ACA) includes waiver authority that may be exercised for CMMI programs. In that rule, OIG stated, "We will address the exercise of that waiver authority in guidance relevant to those programs."[1] We ask that OIG expeditiously publish such guidance

[1] 76 Fed. Reg. 68007

for the programs currently offered by CMMI, and continue to offer such guidance as further programs are developed.

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 and potential waivers. Without prospective, bright-line guidance, physicians will be discouraged from making the resource and time investment that is necessary to apply and participate. Further, as many of the CMMI models have swiftly-approaching deadlines, and tight timelines between the programs' application and launch, preliminary guidance regarding the federal program integrity laws is needed as soon as possible to empower physicians to swiftly move forward with their applications and program adoption.

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 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]

We strongly support CMMI's effort to lay out ground rules regarding the applicability of the federal program integrity laws as they relate to specific CMMI programs. We believe that greater assurance would come from a concerted effort by both CMS and OIG to issue prospective, bright-line guidance regarding CMMI program-specific applicability of the federal anti-kickback statute, the Ethics in Patient Referrals Act, the civil monetary penalties law prohibiting hospital payments to physicians to reduce or limit services (the Gainsharing CMP), and the CMP law prohibiting beneficiary inducements.

We also urge OIG to consider that innovative payment and delivery reforms are taking place outside the context of the models put forward by CMS, and ask that OIG consider the chilling effect of the federal program integrity laws on the success of these non-governmental reforms. The MSSP and the models put forward by CMMI may also catalyze such private sector innovations, increasing the need for clear guidelines about the applicability of the federal program integrity laws to these emerging arrangements.

We offer our assistance as OIG considers the impact of federal program integrity laws on physician participation in innovative payment and delivery models, including those put forward by CMMI. We note that in the context of the MSSP, on October 5, 2010, the OIG and the Federal Trade Commission held a "Workshop Regarding Accountable Care Organizations and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws" to examine the effects of the federal program integrity laws on physician participation in the MSSP. We encourage 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 OIG developed waivers for the MSSP.

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

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

We urge CMS and OIG to waive the current sunset date 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 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.

Safe Harbor for Hospital-Sponsored Continuing Medical Education

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

Explicit Prohibition: Hospital Exclusive Credentialing

We urge OIG to establish an explicit prohibition 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. Nothing could be more antithetical to this effort than 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.

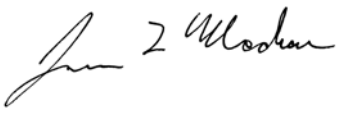
When a physician is able to have privileges at more than one facility, the physician-patient relationship and continuity of care can be preserved at whatever location the patient can be most appropriately treated based on factors such as convenience and clinical resources. However, when hospitals are permitted to enforce exclusive credentialing policies, patients often 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. The result is predictable: 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. In many markets, exclusive credentialing can also result in the maintenance of the credentialing hospital's monopoly, further decreasing choice and adding greater cost to the federal health care programs.

Accordingly, hospital exclusive credentialing policies that effectively force a physician, as a condition of maintaining privileges, to admit only to the credentialing hospital's facilities should be deemed unlawful. The AMA strongly urges OIG to formulate official guidance that would prevent hospitals from conditioning privileges on referral levels or on agreements not to seek medical staff privileges or to admit patients to other hospitals.

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 (202) 789-7492.

Sincerely,



James L. Madara, MD