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February 25, 2014

Daniel R. Levinson  
Inspector General  
Office of the Inspector General  
U.S. Department of Health & Human Services  
Attention: OIG-122-N  
Cohen Building, Room 5541  
330 Independence Avenue, SW  
Washington, DC 20201

Re: OIG Solicitation of New Safe Harbors and Special Fraud Alerts [OIG-122-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 recognize and appreciate that the OIG has established 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 are 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."<sup>1</sup> We ask that the

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

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 has addressed 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 laid out requirements that gainsharing arrangements needed to meet to be eligible for participation.<sup>2</sup>

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, including multi-payer models and others. 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 not participating in CMS programs. 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.

### **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 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.

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<sup>2</sup> 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>.

## **Electronic Health Records**

We would also like to take this opportunity to comment on the OIG's recent work in regard to electronic health records (EHRs), even though it is outside the scope of this solicitation. The OIG has released several reports in the recent past on EHR use, and has made some specific recommendations to CMS regarding potential avenues to curb potential overbilling through EHRs. We have significant expertise in the area of EHRs and would like to work closely with the OIG as the OIG formulates future reports or activities related to EHRs. As a starting point, we have attached the May 3, 2013 testimony of Steven Stack, MD, Immediate Past Chair of the American Medical Association, before the Office of the National Coordinator (ONC) convened Listening Session on Coding and Billing. We think that this testimony provides a valuable perspective on physician EHR use, and is a helpful resource for the OIG as they continue this work. We also welcome a continued dialogue on this issue.

In addition, while we understand that the OIG has focused on ensuring the accuracy of incentive payments paid through the EHR incentive program, we urge OIG to also review the program's penalties. In particular, our members have voiced concern that physicians are being issued a penalty under the E-Prescribing Program, despite having met and satisfied this requirement through the EHR program. Further, we know that the program's risk assessment requirements are one of the most challenging aspects for physicians, and recommend that the OIG urge CMS to provide educational resources and training to meet these technological requirements.

## **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 Cybil Roehrenbeck, Assistant Director, Division of Federal Affairs, at [cybil.roehrenbeck@ama-assn.org](mailto:cybil.roehrenbeck@ama-assn.org) or (202) 789-8510.

Sincerely,

James L. Madara, MD

Attachment