



**JAMES L. MADARA, MD**  
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org  
t (312) 464-5000

March 2, 2015

Daniel R. Levinson  
Inspector General  
Office of the Inspector General  
U.S. Department of Health & Human Services  
Attention: OIG-123-N  
Cohen Building, Room 5541  
330 Independence Avenue, SW  
Washington, DC 20201

Re: OIG Solicitation of New Safe Harbors and Special Fraud Alerts [OIG-123-N]

Dear Inspector General Levinson:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide the U.S. Department of Health & Human Services (HHS) Office of the Inspector General (OIG) with our recommendations in response to the annual Solicitation of New Safe Harbors and Special Fraud Alerts. The following outlines additional safe harbor provisions that we believe will promote innovation and allow physicians to modernize our nation's health care system.

### **Innovative Payment and Delivery Models**

The AMA recognizes and appreciates that the OIG has established waivers of the federal program integrity laws for physicians who participate in the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs). These waivers are instrumental in facilitating physician leadership and participation in the MSSP and have mitigated any confusion for program participants.

In the same vein, we ask that the OIG consider expanding these exemptions to encourage other forms of innovative delivery and payment models. Specifically, we encourage the OIG to publish guidance regarding the waiver of federal program integrity laws for those physicians participating in programs developed by the Center for Medicare & Medicaid Innovation (CMMI).

For CMMI's programs to succeed, physicians and other participants need to fully assess how care can and cannot be provided to patients under these new models. Without bright line guidance, program integrity provisions can deter the adoption of payment and delivery reforms, including bundled payments, medical homes, and other initiatives. Currently, CMMI has addressed the applicability of the anti-kickback and other fraud and abuse laws through the contract process on a case-by-case basis. Program applicants therefore do not have up-front guidance regarding the challenges and restrictions that will apply.

Programs run by the CMMI also pose little risk of fraud and abuse because they have built in safeguards, including careful monitoring by the Centers for Medicare & Medicaid Services. Accordingly, we urge the OIG to establish an explicit safe harbor to provide new models with the flexibility necessary to become successful.

### **Gainsharing Arrangements**

The AMA is supportive of the OIG's recent proposed rule that sought a more flexible approach to the Civil Monetary Penalty (CMP) gainsharing provisions. Under the CMP's current broad prohibitions, physicians are discouraged from using innovative incentive plans and other arrangements to improve care quality and reduce costs. To facilitate potentially beneficial arrangements, we urge the OIG to define a more explicit safe harbor that incorporates the following safeguards:

- Specific, identifiable, transparent, and verifiable cost savings;
- Arrangements of fixed duration;
- Provisions for participating physicians to make a patient-by-patient determination of necessary care and other patient-care safeguards;
- Disclosures to patients about the hospital and physician participation in cost-saving efforts;
- Equal distribution of cost savings among all participating physicians; and
- Maintenance of quality monitoring that has been mutually agreed upon, or developed, by participating physicians and the hospital to ensure that the quality of, and patient access to, health care services is not negatively affected.

These factors ensure that patients are aware of gainsharing programs, that physicians retain the right to use the most appropriate items and services for their patients, and that the programs are effective by achieving cost savings. Using these factors, we believe the OIG could provide more explicit guidance on when an arrangement will or will not prompt action under the CMP gainsharing provision.

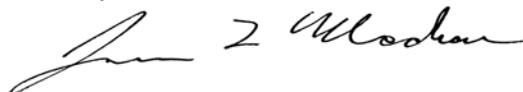
### **Continuing Medical Education**

Finally, we recognized that the OIG is not seeking additional recommendations related to the safe harbor proposals received and considered in its 2014 Semiannual Report to Congress. The AMA, however, wishes to reiterate that we believe the OIG could exempt hospital-sponsored continuing medical education (CME) programs from its enforcement actions. These programs enhance the quality of care received by patients and promote collaboration without posing significant program integrity risks. While we acknowledge these programs can seek advisory opinions prior to being implemented, we generally believe this case-by-case process hinders adoption of these important care coordination tools.

### **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 Kristen O'Brien, Senior Attorney, Division of Legislative Counsel at [kristen.o'brien@ama-assn.org](mailto:kristen.o'brien@ama-assn.org) or 202-789-7428.

Sincerely,



James L. Madara, MD