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

**Re: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing**

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 comments on the proposed rule entitled, *Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing.*

The AMA with other stakeholders has been diligently working to educate and encourage physicians to develop innovative health care payment and delivery models that will lead to improved care coordination and quality while reducing the rate of growth in health care spending. While well intended, the Anti-Kickback and Civil Monetary Penalty (CMP) statutes are broadly interpreted so as to prohibit or create uncertainties about these arrangements that could improve care for patients. In March 2012, the Government Accountability Office (GAO) issued a report that examined the barriers created by these program integrity laws to delivery system innovation. The GAO concluded that federal regulators' interpretation of these laws may "constrain the development of financial incentive programs that would align hospital and physician incentives to provide more cost-effective care." [1] The GAO report also noted that, while regulators have outlined some discrete exceptions, "constraints of existing exceptions and safe harbors make it difficult to design and implement a comprehensive program for all participating physicians and patient populations."[2]

Recognizing the concerns outlined by the GAO and identified by our members, the AMA has sought clarification of existing fraud and abuse laws and broader exceptions to encourage physician participation in new care models. We believe that appropriate safeguards can prevent quality and efficiency programs

[1] Government Accountability Office. *Implementation of Financial Incentive Programs under Federal Fraud and Abuse Laws* (GAO-12-355). Available at http://www.gao.gov/products/GAO-12-355.
[2] Id.

from becoming conduits for fraud and abuse, but worry that existing laws remain overly stringent. With this in mind, we offer the following comments on this proposed rule and our recommendations for potential improvements.

**Anti-Kickback Statute and Safe Harbors**

1. *Cost-Sharing Waivers*

   The AMA supports efforts to waive patient cost-sharing where there is a low risk of potential fraud and abuse. These programs can be important tools for patients who face financial hardships, especially in the context of drugs and other expensive items and services. We therefore support the Office of the Inspector General's (OIG) proposal to codify cost-sharing waivers for pharmacies and emergency ambulance services. Given the benefit of these programs to all patients, we would urge that these waivers not be limited to Medicare but be expanded to all Federal health care programs, where applicable.

2. *Local Transportation*

   The OIG also proposes a new Anti-Kickback safe harbor to protect free or discounted local transportation services for beneficiaries. **While the AMA is strongly supportive of this new safe harbor, we believe that certain definitions, as proposed, may be overly restrictive and would limit valid transportation arrangement for patients.**

   In particular, we agree that defining "nominal value" to mean no more than $10 per item or service or $50 in the aggregate over the course of a year is unreasonable given the typical cost of transportation services. We therefore support the elimination of that requirement. However, defining "local" as no more than 25 miles may be too restrictive since it may disadvantage those living in rural or underserved areas. Instead, we recommend a more general approach rather than creating strict definitions that result in a one-size-fits-all exception. A more flexible safe harbor would include defined cost and distances that the OIG could deem as being compliant with the new safe harbor; costs or mileage above these fixed amounts would not be prohibited but could be appropriate depending on the facts and circumstances of the arrangement.

   Similarly, we are concerned that the term "Eligible Entity" in the proposed safe harbor is too restrictive. While we acknowledge the OIG's concern that entities could use transportation arrangements to generate referrals, we do not agree that this concern can be imputed to all physicians in certain at-risk categories, such as home health. We therefore discourage the OIG from excluding whole categories of physicians or other providers. Such a broad exclusion may unfairly penalize legitimate entities, which should be able to furnish transportation services on the same terms as others in the industry. Patients who need these services should also be able to access them on similar terms. **We believe that the many other safe harbor requirements already protect against the possibility of abuse and would encourage a broader reading of the term "Eligible Entity."**

   The AMA also believes that the proposal limiting transportation services to established patients is vague and confusing. The rule states that safe harbor protection would not be available to "new

patients." Although CMS has defined the distinction between new and established patients with respect to billing for physician evaluation and management services, the distinction is not used or defined in other settings. In non-physician office settings under the proposed rule, it remains unclear if a patient would only need to have visited the entity once or if a more established relationship is necessary. It is also unclear how this distinction would, or even could, apply in certain care settings (e.g., if a patient was discharged from a hospital and selected a nursing facility but was not yet admitted to the facility). We urge the OIG to further clarify how it anticipates applying this term in different contexts and across different providers.

Overall, the AMA is very supportive of this safe harbor protection given its benefits to patients. We agree with the rule's proposal to allow transportation for nonmedical purposes that relate to the patient's health care (e.g., social services, food banks, etc.). We also support extending free or discounted transportation services to caregivers or a family member to ensure that patients can be accompanied by another person when necessary. We urge that the OIG include this new protection in its final rule, and strongly suggest that the new safe harbor incorporate our previously mentioned changes.

**Beneficiary Inducement CMP**

The AMA strongly supports exceptions to the CMP statute to allow programs that increase beneficiary engagement and access to care. Recognizing the need for these programs, we urge that the OIG limit its restrictions on these important efforts.

1. *Promotes Access/Low Risk of Harm*

The proposed rule seeks to define the phrases "promotes access to care" and "low risk of harm" to provide an exception for arrangements that benefit patients with little risk of fraud or abuse. The OIG proposes to define "promotes access to care as "the remuneration provided improves a particular beneficiary's ability to obtain medically necessary health care items and services." The AMA generally agrees with the broad approach taken by the OIG in defining this term; however, we believe that the focus should not be on only obtaining health care services, but encouraging patients to be informed about their health care. For example, free nutritional counseling services aimed at patients at risk of obesity or diabetes may not directly encourage patients to obtain specific items or services but may simply provide information on health and dietary risks. Such efforts may or may not eventually lead a patient to seek and obtain additional care since these activities are aimed at allowing patients to better manage their disease at home and lower their risk for hospitalizations, emergency visits, complications. Failure to include patient engagement or other similar activities in this definition may lead to continued confusion about application of the CMP statute and limit these important efforts. We also note that this definition should not be constrained to a particular beneficiary but should include efforts aimed at specific patient populations or care networks.

The OIG further proposes that the phrase "low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs" means that the remuneration: "(1) is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization;

and (3) does not raise patient-safety or quality-of-care concerns." Again, the AMA supports the broad definition suggested in the proposed rule but worries that it may be too general to properly inform what activities will be considered as interfering with clinical decision-making or raising quality of care concerns. The examples provided in the preamble of the rule are helpful but only offer a few instances in which the exception would or would not apply. **Overall, the AMA would support a more explicit exception for participants of delivery and payment models, including medical homes, bundled payment arrangements and other care coordination programs**. As mentioned in the rule, these programs have built in safeguards, including monitoring by CMS, which would protect against many of the program integrity concerns and limit unnecessary or low quality care. We therefore urge the OIG to consider including this exception to provide new models with the flexibility necessary to become successful.

2. *Retailer Rewards Programs*

Under the proposed rule, exception for retailer reward programs would be permitted if: (1) the items or services consist of coupons, rebates, or other rewards from a retailer; (2) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (3) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by Medicare, Medicaid or any of the other programs covered by the Beneficiary Inducement CMP. We recognize that physicians are generally not retailers and will not be directly impacted by this exception but encourage efforts that allow physicians to understand when these rewards programs would be available to their patients. We also agree with the proposed rule requirement that these reward programs be broadly available to patients to discourage cherry picking or other perverse incentives.

3. *Financial-Need-Based Exception*

**We generally support the OIG's proposal to allow financial-need exceptions that reflect case-by-case considerations of a patient's medical and financial circumstances**. We believe this approach reflects the variables posed by different medical and personal circumstances and does not limit the type of care or services that can be offered. When considering whether there exists a reasonable connection between the item or service offered and the patient's medical care, we believe that the physician's conclusion that the item or service would benefit the individual patient's treatment should carry significant weight. This conclusion would be appropriate to deem a "reasonable connection" for purposes of this exception because the physician is in the best position to understand the medical needs of his or her patient.

Although we generally support the approach taken by the OIG, we are concerned that the new exception will require physicians to extensively document the financial status of their patients. Financial information may not be readily available to the majority of physicians and, depending on what is required, may require extensive time and effort. If this is required, physicians may be deterred from offering these needed discounts. We urge the OIG to take a reasonable approach and consider other ways than requiring physician documentation to assess a patient's financial needs.

*4. Waivers of Cost-Sharing for the First Fill of a Generic Drug*

The AMA appreciates OIG clarification that it will not exercise its enforcement authority against plans that already waive cost-sharing for certain generic drugs, as we believe this practice can benefit patients. Moreover, we again support the OIG's efforts in this section of the rule to provide exceptions to the CMP authority when practices pose little risk of fraud and abuse and enhance the delivery of care.

**Gainsharing**

Since enactment of the CMP gainsharing provision, and even since the issuance of the OIG's gainsharing opinions, the health care landscape has dramatically evolved to place greater emphasis on accountability for providing high quality care at lower costs. Yet, the statute's broad prohibitions have discouraged the use of innovative incentive plans and other arrangements to promote these goals. The AMA believes that, when implemented appropriately, gainsharing has the potential to align hospital and physician incentives to provide more cost-effective care. For example, such arrangements can encourage appropriate use of services and more careful choice among available treatments. Accordingly, we are encouraged that the OIG is considering a more flexible approach that recognizes efforts to control costs can also have the potential to improve patient care.

We agree that limiting the scope of the gainsharing statute to services, and not items, is a step in the right direction. We also strongly support the OIG's suggestion to include an explicit definition of the term "reduce or limit services" to more clearly and narrowly define when the CMP authority applies. The rule then outlines specific safeguards that could be included in such a definition. Overall, the AMA urges the OIG to more clearly codify some of the new considerations outlined in the preamble of the proposed rule. And more specifically, we urge that gainsharing programs that incorporate the following safeguards be considered as not reducing or limiting services:

- 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.

Based on these factors, we believe the OIG could provide more coherent guidance on when an arrangement will prompt action under the CMP gainsharing provision. 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 those programs are effective by achieving cost savings. In general, we caution against taking an approach that would automatically deem certain practices as limiting care and encourage the OIG to recognize that waivers of the CMP gainsharing authority may be necessary to explore new care innovations. Otherwise, physicians and other providers may not adopt arrangements due to uncertainties regarding the law's application or may continue to devote significant time and

expense seeking advisory opinions. By proposing regulatory text that simply mirrors the CMP statute, we do not believe that this provides sufficient clarity to encourage physicians, hospitals, and other providers to implement new programs. We believe that the OIG could incorporate these considerations into its new regulatory text at 42 C.F.R. § 1003.700.

**Conclusion**

Currently, fraud and abuse statutes have unreasonably constrained physicians in their efforts to design and implement innovations to improve care. The AMA is committed to working closely with the OIG to find more appropriate ways to implement these statutes while protecting against fraud and abuse. We appreciate the OIG's ongoing effort to listen to our suggestions and make reasonable changes to reflect developments in health care. Should you have any questions regarding this letter please contact Cybil Roehrenbeck, Assistant Director, Federal Affairs, at cybil.roehrenbeck@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD