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December 2, 2014

Patrice Drew
Office of the Inspector General
Department of Health and Human Services

Attention: OIG-403-P

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 Ms. Drew:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide comments on the Office of Inspector General’s proposal rule, Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed.Reg. 59717 (October 3, 2014). The AAMC is a not-for-profit association representing all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC recognizes that the OIG has the difficult task of implementing laws that were drafted during a time when coordinated care was rarely considered. While it is possible to read the laws as being so restrictive that they prohibit many of the positive behaviors that our health care system is trying to encourage, we believe that it also is possible for the OIG to recognize—as it has attempted to do in a number of Advisory Opinions-- that these behaviors and changes in the health care system are intended to improve patient care, reduce costs, and increase patient satisfaction, goals that must be accommodated. As the OIG considers the best way to proceed, the Association encourages an approach that allows for maximum flexibility, as to do otherwise may discourage the innovation and changes that are needed to help us attain the type of health system that we all desire.

Our comments will be limited to the proposed safe harbor for local transportation; a suggestion about an expansion of the safe harbor for the beneficiary inducement CMP; and gainsharing.
Beneficiary Inducements

The AAMC asks the OIG to consider adding an exception under beneficiary inducements when there is payment for items or services, such as transportation, that allow beneficiaries to participate in clinical trials. Some institutional review boards (IRBs), bodies charged with ensuring compliance with all requirements related to human subjects research, require that research subjects incur no costs for participating in the research. In the past, when studies were funded by the National Institutes of Health (NIH), some of these costs may have been included, but as NIH funding has been reduced so has support for the cost of subjects in clinical trials.

The OIG could include in the interpretation of the phrase “promotes access to care” payment for costs related to participating in a clinical trial provided that the following criteria are met:

- The research is approved by an IRB.
- The IRB determines that expenses themselves must be incurred because the expenses are directly related to the research.
- All research subjects are given information about covered costs.
- There are no alternatives for the subject to participate in research where he/she would not incur these expenses.

Proposed Safe Harbor For Local Transportation

The AAMC supports the creation of a safe harbor for local transportation. The Association appreciates that the OIG:

[R]ecognizes that health systems, health plans, accountable care organizations, or other integrated networks of providers and suppliers might be Eligible Entities and might seek to establish a free or discounted local transportation program among only providers and suppliers within the system or network.

The AAMC believes it is essential that integrated systems of care be given the necessary protections to provide transportation to beneficiaries. Providing the assistance that many patients need to benefit from this type of care—which for certain populations could include free or discounted transportation—requires a large financial investment. The OIG should reject the notion of requiring such entities to provide free or discounted local transportation to non-network or non-participating providers or suppliers as such a requirement may discourage some hospitals from providing this type of beneficiary support. When care is integrated, providers work together to provide the best care for patients, including the support they need—such as transportation—to benefit from those services. We already have heard anecdotally that some members are reluctant to provide these types of services for fear of violating the fraud and abuse laws. The OIG should make clear that services that support patients and help them to receive appropriate care are not prohibited.
The AAMC suggests that provision of free or discounted transportation not be limited to established patients. It should be available to any patient once an initial appointment has been made. Attempting to differentiate between patients coming for an initial appointment and those coming for subsequent visits would be impractical and unnecessarily risk offending first-time patients.

**Gainsharing**

The OIG has not proposed any regulatory language regarding gainsharing except for language related to the imposition of penalties. The request for information in the proposed rule regarding the possibility of defining the term “reduce or limit services” and related matters is akin to an advanced notice of proposed rulemaking. Therefore, it would be premature at this time for the OIG to issue either an interim final or a final rule regarding these issues. On the other hand, the AAMC supports finalizing the proposed regulatory language in §1003.700 et seq. regarding the amount of penalties and determinations of the amount of penalties. The AAMC is providing additional comment about gainsharing below.

The AAMC was pleased to see that the OIG stated that:

> [A]s hospitals move towards using objective quality metrics, we recognize that a change in practice does not necessarily constitute a limitation or reduction of services, but may in fact constitute an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality. (79 Fed. Reg. 59730)

As was mentioned above, the health care system is going through enormous transformations in care, not with the goal of “reducing or limiting services” but with the goal of improving care. Medicare has imposed a number of quality-related programs that currently, or in the future, will result in payment penalties if certain metrics are not met. Hospitals are subject to the Hospital Acquired Condition (HAC) Reduction Program, the Hospital Readmission Reduction Program, the Value-Based Purchasing Program, and the Electronic Health Record Incentive Program (also known as “meaningful use”). In addition to “meaningful use,” physicians are subject to the Physician Quality Reporting System (PQRS), and the Value Modifier. It has become abundantly clear to both hospitals and physicians that quality is important to the bottom line. It is equally clear that physicians are key players in improving care and that it is reasonable to provide incentives to them.

Changes in practice that are well-supported by evidence are embraced by Medicare, Medicaid, and all payers. They are part of an effort throughout the health care system of continuous quality improvement. Should the OIG become aware of specific behaviors that thwart these goals, it would be appropriate to target them through its enforcement authority. The OIG should not impose barriers to these laudable activities, all of which involve substantial clinical judgment, something that is outside the scope of the OIG’s authority. It is worth noting that other Federal agencies stand squarely behind improving health care practice. For example, the Agency for Healthcare Research and Quality (AHRQ) has as its mission “to produce evidence to make
health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.” (www.ahrq.gov) The Affordable Care Act established the Patient-Centered Outcomes Research Institute (PCORI) which is intended to “close the gaps in evidence needed to improve key health outcomes. To do this, we identify critical research questions, fund patient-centered comparative clinical effectiveness research, or CER, and disseminate the results in ways that the end-users of our work will find useful and valuable.” (www.pcori.org).

Combined with the movement to use evidence-based medicine, is the movement toward care coordination and care management. The Centers for Medicare and Medicaid Services (CMS) has supported this movement by implementing payment for two types of services that recognize the value of care coordination. Transitional Care Management (TCM) codes pay for additional care coordination following the discharge from a hospital, skilled nursing facility, or similar institutional stay. In addition, starting in 2015, CMS will pay for a Chronic Care Management (CCM) code for certain beneficiaries who have two or more chronic conditions. For that service, CMS will pay once per beneficiary per month when clinical staff, working with the physician, spend at least 20 minutes on the patient’s care (outside of normal visits.)

In this rapidly moving environment, it is essential to avoid definitions or criteria that will soon be out of date. The AAMC suggests that the OIG not attempt to define the term “reduce or limit services.” Instead, there should be strong support for programs that encourage better patient care, report metrics, and work for continuous quality improvement, along with a recognition that attempts at too tightly defining the criteria for these activities may inadvertently impede them. Efforts such as these require a huge financial investment, one for which the financial return on investment is likely to be years away. However, these institutions that engage in transformative care see a more immediate pay-off: they are beginning to learn the process of delivering care in a new and better way, a knowledge base that will be necessary to survive and thrive in the health care system of the future.

Finally, the AAMC opposes a “requirement that the hospital and/or physician participating in a gainsharing program notify potentially affected patients about the program.” To require that a patient be informed about a gainsharing arrangement is to suggest that there is something wrong with such an arrangement. The Association supports transparency but fails to understand how knowledge about a gainsharing arrangement will aid a patient, particularly when such an arrangement is tied to improvements in quality and other desirable outcomes. Care and treatment decisions must be determined during a discussion between the physician and the patient, taking into account the physician’s clinical judgment but ultimately decided on the basis of the patient’s preferences.
Conclusion

Thank you for the opportunity to present our views. If you have any questions about our comments, please feel free to contact Ivy Baer, J.D., M.P.H., Senior Director and Regulatory Counsel, at 202-828-0499 or at ibaer@aamc.org.

Sincerely,

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Chief Health Care Officer