December 2, 2014

Daniel R. Levinson, Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P3
Cohen Building
330 Independence Avenue SW, Room 5269
Washington, DC 20201

RE: OIG Proposed Rule, 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 Mr. Levinson:

On behalf of AdvaMed, thank you for the opportunity to provide comments on the Proposed Rule which would amend the safe harbors to the anti-kickback statute and the civil monetary penalty (CMP) rules under the authority of the Office of Inspector General (OIG). This notice, published in the Federal Register on October 3, 2014, solicited public input on proposed revisions to existing safe harbors and regulatory language for new safe harbors.¹ In this letter, our comments primarily relate to the OIG’s proposal to add a gainsharing CMP provision to its regulations. We also briefly comment on the local transportation safe harbor proposal.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. These products and services improve patient care quality. In addition, they often improve efficiency by reducing lengths of stay, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

General Comments

Beneficiary access to the full range of treatment options appropriate for their medical conditions is critical to the health and well-being of Medicare beneficiaries. One of our overarching concerns with gainsharing arrangements is that they focus on short-term costs—those associated with a particular procedure or hospital admission—rather than looking at costs incurred across the whole episode of care or over a period of several years or the life of the patient. Savings on short-term costs could be illusory, if an appropriate treatment option and quality of care is reduced, leading to costs to Medicare outside the episode window. We also note the challenges in sustaining savings year after year and how the pressure to do so can put patients at risk. As discussed below, we believe that the OIG must continue to be extremely cautious when interpreting the Gainsharing CMP statute in order to ensure that the health of Medicare and Medicaid beneficiaries is protected and beneficiaries continue to have access to advanced medical technologies, services, and procedures that are critical to their health.

Sections 1128A(b)(1) and (2) of the Social Security Act, which have become known as the Gainsharing CMP statute, prohibit a hospital or a critical access hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician. A hospital or critical access hospital that makes such a payment, and the physician who knowingly accepts it, are subject to CMPs of not more than $2,000 for each beneficiary for whom the payment is made. This law helps to ensure that physicians make decisions based on their medical judgment and the patient’s clinical need and not on financial incentives provided by the hospital that can personally benefit the physician.

The Gainsharing CMP statute is a self-implementing statute and to date, the OIG has not finalized corresponding regulations. Instead the OIG has issued guidance in the form of a Special Advisory Bulletin issued in 1999 and individual determinations for specific arrangements through its Advisory Opinion process. As the OIG considers moving forward with regulations, AdvaMed urges caution and continued focus on and attention to the potential impact that such regulations could have on Medicare and Medicaid beneficiaries. While it is true that in the changing landscape of healthcare payment and delivery there is increasingly a greater emphasis on providing health care at lower costs, the goal of achieving lower costs should not be permitted to overcome the priority on providing high quality care.

Over the past decade, Congress has authorized, and the Secretary has implemented specific projects involving gainsharing—most recently and notably, the Medicare Shared Savings Program (MSSP) for accountable care organizations (ACOs) and the Bundling Payment for Care Improvement Initiative. In this context, the OIG has proposed codifying the Gainsharing CMP in regulations and has requested comments on whether, in addition to the proposed language, OIG should also define the term “reduce or limit services” in regulatory text.
In its 1999 Gainsharing Special Advisory Bulletin (SAB), the OIG stated generally that "gainsharing arrangements pose a high risk of abuse." Furthermore, the OIG noted that gainsharing arrangements, if approved on a case by case basis, would require “ongoing oversight both as to quality of care and fraud that is not available through the advisory opinion process,” and that “case by case determinations by advisory opinions are an inadequate and inequitable substitute for comprehensive and uniform regulation in this area.” Despite this, the OIG has issued 16 advisory opinions over the past 15 years since this SAB, recognizing that, in the OIG’s view, under certain circumstances “gainsharing can be beneficial.”

AdvaMed understands the desire of the OIG to update its guidance on the issue of gainsharing and to interpret the statute in a way that “reflects today’s health care landscape.” However, the OIG must also be able to ensure that any gainsharing programs and arrangements are carefully designed in order to prevent patients from being put at risk from inappropriate incentives that influence clinical decisions, leading to stinting on care or otherwise inappropriate choices. There must be adequate controls on the gainsharing payments and ongoing rigorous oversight with respect to quality of care and beneficiary access to clinically appropriate items and services.

While there is no “fixed” definition of gainsharing, the OIG has repeatedly described the term as typically referring to “an arrangement in which a hospital gives physicians a share of any reduction in the hospital’s costs attributable in part to the physicians’ efforts.” As an overarching comment, we believe that protection for gainsharing should be available with the safeguards discussed below, only in the context of formal ACO, bundled payment, and similar programs that are required to meet quality standards. Gainsharing applied in isolation or pursued in less formal ways, e.g., inappropriate hospital-physician co-management arrangements, increases the likelihood that decision-making will be based predominately on economic considerations rather than on a balance of quality and economic considerations.

Separately, with respect to the proposed modifications to the anti-kickback statute safe harbors, AdvaMed urges OIG to consider the appropriateness of excluding certain types of entities, including manufacturers of medical technologies, from protection under the safe harbors. If strong safeguards are in place, it may be entirely appropriate and beneficial for a manufacturer to engage in particular practices, including the provision of free or discounted local transportation to beneficiaries.

Specific Comments

In its October 3 Proposed Rule, the OIG proposes regulatory language to be added to 42 CFR §§ 1003.700 and 1003.710, which largely reflect the Gainsharing CMP statute. Thus, under the regulations, the OIG may impose a penalty against a hospital that “knowingly makes a payment,

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2 OIG, “Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries” July 1999 (the Gainsharing SAB).
3 Id.
4 79 Fed. Reg. at 59729.
directly or indirectly, overtly or covertly, in case or in kind, to a physician as an inducement to reduce or limit services provided to an individual who is eligible for Medicare or Medicaid benefits and who is under the direct care of the physician,” and to a physician who knowingly receives such a payment. The OIG also proposes § 1003.720, regarding the factors that the OIG will take into consideration when determining the amount of the penalties. These factors are based on the statute at § 1128A(d) and include:

- The nature of the payment designed to reduce or limit services and the circumstances under which it was made,
- The extent to which the payment encouraged the limiting of medical care or the premature discharge of the patient,
- The extent to which the payment caused actual or potential harm to program beneficiaries, and
- The financial condition of the hospital (or physician) involved in the offering (or acceptance) of the payment.

In addition, the OIG requests input from stakeholders with respect to the term “reduce or limit services,” noting that the OIG is considering a narrower interpretation of the term “reduce or limit services” than it has previously held.  As context, the OIG states that “hospitals [are] mov[ing] towards using objective quality metrics” and 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.”

OIG requests comment on its interpretation of the term “services” as including payments to limit items used in providing services, consistent with the definition of “services” found at 42 CFR § 400.202. We strongly believe that this interpretation is an appropriate and necessary interpretation of the term “services” – as noted in the Proposed Rule, it is consistent with CMS regulations at 42 CFR § 400.202 defining the term “services” as “medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.” (Emphasis added).

In addition, OIG requests comment on whether a hospital’s decision to standardize certain items be deemed to constitute reducing or limiting care. AdvaMed has concerns around the concept of “standardization” of items, and interpretations that could lead to blanket protection of hospital-physician arrangements to “standardize” items, such as implantable medical devices. “Standardization” has the potential of limiting physician choices and autonomy with respect to making medical decisions based on the medical needs of a patient. Our concern is that “standardization” raises the possibility that a physician may not choose – and a beneficiary may not have access to -- the most clinically appropriate and effective items depending on how a hospital’s list is developed and enforced. For example, a hospital’s list of “standard” items may

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6 Id. at 59730.
7 Id.
include a less expensive device that is appropriate for 85-year old relatively sedentary patients, but is not appropriate for an active 65 year-old. A hospital’s “standardized” list of items has the potential to limit physician options to less expensive or the least expensive products or older technologies, even if they are not the most clinically appropriate for particular patients. In addition, savings from standardization of products or devices could easily become the means to an end, the sole focus of cost reduction in care delivery, at the expense of more challenging improvements in the process of care that could result in enhancements to care outcomes and quality.

Even if “physicians were simply encouraged to choose from the standardized items, but other items remained available for use when deemed appropriate for any particular patient,” AdvaMed would have concerns. Additional detail and safeguards would still be necessary. We believe that where a hospital adopts a “standardized” list of items from which the physician is required or “encouraged” to choose, this is limiting. As the OIG considers regulatory language to interpret the Gainsharing CMP, the protections must not be relaxed in such a way as to allow for financial arrangements between hospitals and physicians that prioritize cost-saving measures (whether mandated or “encouraged”) at the expense of a physician’s freedom to choose the most clinically appropriate items and services for the patient.

To address this problem, AdvaMed recommends that, in the context of ACO, bundled payment, and similar programs, an entity such as the ACO or hospital, would be required to ensure that: (i) individual physicians participating in the gainsharing or shared savings program make a patient-by-patient determination regarding the most appropriate service, procedure or item and that the availability of the full range of services, procedures or items was not compromised by any aspect of the gainsharing or shared savings program; and (ii) individual physicians have available the same selection of services, procedures or items after implementation of the gainsharing or shared savings program as before, and that the efficiency gained through the gainsharing or shared savings arrangement result from both the clinical and economic value and not from restricting the availability of services, procedures or items based on cost. In their applications to participate in these programs, ACOs, bundled payment and other participating entities should be required to document how they will implement these policies and CMS should be required to determine their compliance with the requirements during a given agreement period.

The Proposed Rule also requests comment on whether a hospital’s “decision to rely on protocols based on objective quality metrics for certain procedures [should] ever be deemed to constitute reducing or limiting care...” and whether “hospitals deciding to compensate physicians in connection with the use of such protocols be required to maintain quality-monitoring procedures to ensure that these protocols do not, even inadvertently, involve reductions in care.” Our concern with the use of protocols is that the protocols could, if they are not properly structured with safeguards, be used to reduce or limit care. In our view, the concept of “objective quality metrics” can be difficult to define in many instances and the healthcare sector as a whole is a long way from reaching quality metrics and outcome measures that could consistently and

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8 The term “item” includes any device or supply.
9 Id.
adequately protect beneficiaries in cases where protocols impose significant pressure on physicians, impacting their ability to individualize care to the particular needs of their patients. Innovative technologies, in particular, would be vulnerable to strict protocols that do not allow for the use of new technology. This could impact, for example, not only new technology, but also newer iterations of the same technology, where an updated version clearly gives patients benefits, but is not incorporated into the protocols in place. Therefore, protocols should incorporate provisions for use of innovative technologies where a physician determines that they are the most appropriate options for patients. OIG should also evaluate how protocols accommodate the use of new technologies.

AdvaMed believes that certain arrangements involving standardization and protocols should be considered to “reduce or limit services,” and thus, fall under the scope of a prohibited gainsharing arrangement. If the OIG considers language that would allow for the use of standardization or protocols, AdvaMed, would recommend that any such arrangements be required to incorporate strong safeguards.

The Proposed Rule also asks for input into whether the hospital and/or physician participating in a gainsharing program should be required to notify potentially affected patients about the program. In general, we believe notification is important and that patients should be as informed as possible with respect to the care they receive and how their physicians made certain decisions with respect to the items and services prescribed to them. In this regard, patients should be explicitly told about the technology and treatment options available to them, e.g., that a particular device is not MRI-proof and that alternatives technologies are available and why the ACO or bundled payment practitioner is not recommending them. In addition, as we noted in our letter of September 5, 2013 to the Centers for Medicare & Medicaid Services (CMS) regarding the potential release of Medicare physician data, AdvaMed believes strongly that the agency should have a policy of transparency regarding physician payment and public disclosure applicable within ACO programs and any bundled payment initiatives. Applying requirements of notification to beneficiaries around the gainsharing arrangements and public disclosure of any shared savings or gainsharing payment amounts that physicians receive would help protect beneficiaries; however, notification and disclosure alone are not adequate protection against the potential harms that gainsharing payments and arrangements can have when such arrangements are permitted to improperly reduce or limit care.

We have argued for strong oversight and monitoring of care received by patients in ACOs and bundled payment program and believe that OIG should play the lead role in evaluating that care. Monitoring should include medical audits of patient records looking at the utilization of guideline-recommended care, i.e. diagnostic tests; specific procedures; referrals to specialists; excessive standardization of technology options; and changes in utilization of specific devices. It should also include making available to the public specific shared savings and gainsharing payments made to individual providers so the impact of gainsharing can be evaluated by all stakeholders. In addition, CMS should make periodic assessments for the clinical and economic impact of these payments on Medicare beneficiaries.
Finally, the Proposed Rule asks for input on modifications to the anti-kickback statute safe harbor for the provision of free or discounted local transportation. OIG describes the benefit that such transportation programs provide, describes safeguards that must be put in place to mitigate the risk of fraud and abuse, and proposes to exclude from the definition of “eligible entity” any entity that primarily supplies health care products. AdvaMed urges OIG to recognize that manufacturers may play an appropriate role in the provision or the funding of patient transportation programs. These programs promote adherence to therapies and rehabilitation from surgeries; the success of a therapy or a surgery, which may involve an implanted or other type of medical device or supply, can hinge on appropriate adherence and patient follow-up. Manufacturers have a strong interest in improving these patient outcomes, and so long as manufacturers implement the same controls and safeguards to mitigate against improper inducements, participation in programs to provide transportation services may be appropriate.

**Conclusion**

As the health care landscape shifts from a payment system that rewards based on volume to one that reward based on quality and efficiency, the OIG has an increasingly important role to play in ensuring that the pendulum does not swing too far and allow for providers and professional to limit patient care, use less effective or inappropriate products or methods of treatment, or delay or deny access to appropriate care in order to achieve greater savings. AdvaMed remains concerned that gainsharing arrangements have the potential to reduce physician choice, limit patient access to the most appropriate care, and reduce the quality of care, as well as hindering medical innovation. ACOs, bundled payment, and other similar programs offer a platform for evaluating the impact of gainsharing arrangements on beneficiary care and should be evaluated on an ongoing basis to determine the extent of this impact.

AdvaMed members continue to work diligently to develop medical devices that fill unmet medical needs and improve the health of patients. As the OIG considers regulatory language to codify the Gainsharing CMP statute, AdvaMed urges the OIG to ensure that such language does not inadvertently allow for arrangements that compromise physician choice and the quality of patient care and access to critical and life-saving technologies.

Again, thank you for this opportunity to comment. AdvaMed would be happy to answer any questions OIG may have or to further engage with the OIG as future regulatory language is considered. Should you have any questions or if we can provide additional information, please do not hesitate to contact Richard Price at 202-434-7227 or rprice@advamed.org.

Sincerely,

/S/

Donald May
Executive Vice President
Payment & Health Care Delivery Policy