December 2, 2014

Via Electronic Submission

Ms. Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P
Room 5269, Cohen Building
330 Independence Ave SW
Washington, DC 20201

RE: 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 Ms Drew:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments related to the proposed rule amending the safe harbors to the anti-kickback statute and the civil monetary penalty (CMP) rules. MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

Background

On October 2, 2014, the HHS OIG released its proposed rule to amend the Anti-Kickback Statute’s regulatory safe harbors (AKS Safe Harbors) and expand permitted gainsharing arrangements under the Civil Monetary Penalty law (CMP). The gainsharing CMP prohibits hospitals from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries who are under the physician’s direct care. In its proposed rule, the OIG noted that historically, this prohibition has been interpreted broadly and emphasized that the prohibition is not limited to medically necessary items or services.

The OIG has approved 16 gainsharing arrangements through its advisory opinion process and concluded “gainsharing can be beneficial” under certain circumstances. In addition under Section 5007 or the Deficit Reduction Act (DRA) of 2005, as amended by Section 3027 of the Affordable Care Act, the Secretary was required to conduct a qualified gainsharing

demonstration program “to test and evaluate methodologies” of gainsharing programs. The demonstration called for six hospitals to participate, two of which from rural areas. At the time of the DRA a number of policy makers, patient groups and innovators expressed concerns with the widespread adoption of gainsharing and the adverse impact it would have on patient care.

As part of the demonstration, CMS was required to provide Congress with status reports. On June 3, 2014, CMS issued its final Report to Congress entitled, “Medicare Gainsharing Demonstration: Final Report to Congress”. In this report, CMS states that only two hospitals participated in the demonstration. It further states that one hospital dropped out of the demonstration after year one. The one hospital that remained and concluded the demonstration was Beth Israel Medical Center (BMIC) in New York, New York. Therefore, the demonstration provided only feedback from a single hospital and no data from rural hospitals. Despite the lack of any meaningful data from the Gainsharing Demonstration, the OIG appears to want to accelerate the proliferation of gainsharing by creating a new safe harbor.

The OIG argued as payment and delivery reforms have focused on accountability for providing high quality care at lower costs, the agency is considering narrowing the gainsharing prohibition “in a manner that reflects today’s health care landscape.” Specifically, the OIG is considering a narrower interpretation of the term “reduce or limit services,” but acknowledged that it cannot read a “medically necessary” element into the prohibition without a legislative change.

Although there are a number of different types of gainsharing arrangements, one purpose of gainsharing is to align physician incentives with those of the hospital, and thereby encourage hospital cost reductions. Historically, the OIG has been wary of propagating gainsharing arrangements, noting in its testimony to the Ways and Means Committee in 2005 that the “Civil Monetary Penalties law is an intentionally broad prohibition reflecting congressional concern that under the prospective payment system hospitals would have an economic incentive to pay physicians to discharge patients too soon – quicker, sicker – or otherwise stint on care. Put simply, any hospital gainsharing plan that encourages physicians through direct or indirect payments to reduce or limit clinical services violates the law…. The potential risks to patients of poorly designed gainsharing arrangements would include giving physicians incentives… to skimp on devices or supplies that would be necessary for the care of the patient.”

The OIG requested comments on several of its proposals. Below are MDMA’s responses.

**Response to OIG Solicitation of Comments**

**OIG Solicitation**: The prohibition on payments to reduce or limit services has been interpreted as including payments to limit items used in providing services, which is consistent with the definition of “services” found at 42 CFR 400.202. Is this interpretation appropriate or necessary in the context of the Gainsharing CMP?

**MDMA Response**: This interpretation is appropriate and a narrowing of patient protections to exclude items from such protections is not warranted. The medical item provided is no less
important than the service provided. The sacred doctor-patient relationship would be undermined by permitting the physician to profit by administering items that are not clinically optimal for the patient. Physicians may be incented to prescribe older, less effective medical technology to produce revenue for their practice and the hospital in the short-term, rather than adopting a more holistic clinical approach that can save the entire health care system resources over the long-term. For example, a physician may be encouraged to implant a less costly orthopedic device that may need to be replaced in a shorter time period than a more expensive but more durable device that may last the patient years longer.

When the OIG was asked whether gainsharing arrangements could lead to a lessening of quality care at the aforementioned Ways and Means hearing, the OIG responded, “I think that is a real risk and why it is so important that there be a great number of safeguards and ongoing monitoring, to assure that patient care is not compromised through gainsharing.” Neither the OIG nor anyone else has presented compelling evidence explaining why those fundamental concerns do not continue to stand today. As such, gutting the definition of “health care services” by excluding items would reduce the current safeguards OIG has employed to ensure that patient care is not compromised.

**OIG Solicitation:** Does a hospital’s decision to standardize certain items (e.g., surgical instruments, medical devices, or drugs) constitute reducing or limiting care? Would the answer be the same if the physicians were simply encouraged to choose from the standardized items, but other items remained available for use when deemed appropriate for any particular patient?

**MDMA Response:** Eliminating physician choice of clinically significant medical devices to enable hospitals to kickback resources to practicing physicians is entirely inappropriate and contrary to best medical practice. Medical devices are not interchangeable commodities.

Product standardization does not recognize the growing importance of personalized medicine—the tailoring of medical treatment to the individual characteristics and needs of a patient during all stages of care. Certain medical devices work better in some patients than others, based on body type, comorbidities, configuration of patient’s anatomy and patient’s medical history. Standardization would incentivize physicians to ignore unique patient circumstances that may otherwise warrant the use of a non-standardized device, and instead follow the protocol for economic gain.

Certainly, requiring physician access to medical devices that are not on formulary is preferred to total exclusion. Yet this in no way negates the economic incentive of the physician to choose the standardize products, and is therefore unacceptable.

How would new technologies, where the data is not yet robust be assessed against older technologies if the economic incentives for physicians encourage utilization of the older technologies? Outcomes data is built over time through patient utilization and comparative effectiveness for different types of patients can be assessed only if patients have access to the new technology. Patients run the risk of not having a physician advocate by their side in terms of bringing forward new technology as a way of bettering outcomes.
Gainsharing undermines competition and harms small companies

Gainsharing will create an additional barrier for small companies. Fully 80 percent of medical device companies have fewer than 50 employees and 98 percent have fewer than 500 employees. Following FDA approval, these companies confront a maze of Medicare regulatory coverage, coding and payment requirements. They then must negotiate with powerful group purchasing organizations (GPOs), which predominate hospitals’ medical device acquisition and whose own statutory exemption from the anti-kickback law encourage the purchase of more expensive devices sold by large manufacturers who sell a portfolio of medical devices. GPO’s supplier-based model extracts a percentage fee for devices it acquires for hospitals – the higher the cost of the device, the higher the fee; the more devices a manufacturer sells the greater potential profit for the GPO. Numerous investigations have documented the anti-competitive nature of GPOs and how small companies selling less expensive and clinically superior devices are excluded because GPOs can extract more revenue from large manufacturers demanding exclusive and preferred contracts for their product portfolios.

Layering yet another distortionary economic incentive whereby physicians can garner kickbacks from hospitals to utilize the devices chosen by the GPO for the hospital would erect a barrier to entry that cannot be surmounted by many small medical device manufacturers. It will enhance the ability of large medical device manufacturers to consolidate market share and gain greater pricing flexibility over time by stamping out competition, thereby driving up costs.

Gainsharing will not reduce Medicare costs

While gainsharing proposals may result in improved hospital profits and physician revenue, they do not result in lower Medicare outlays. Because hospitals are paid on a prospective payment system any savings achieved by the hospitals are neither passed on to the Medicare program nor Medicare beneficiaries.

Conclusion

In conclusion, MDMA has strong concerns with creating a new safe harbor to permit gainsharing and we encourage the OIG not to move forward with this proposal.

Sincerely

Mark B. Leahey
President & CEO, MDMA