MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

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ACO Legal Issues
Mail Stop C5–15–12,
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore, MD
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Re: the Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self- Referral, Anti-Kickback, and Civil Monetary Penalty (CMP)

The Medical Device Manufacturers Association ("MDMA") appreciates the opportunity to provide comment for the Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self- Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws on October 5, 2010. 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.

The *Federal Register* notice, published on September 17, seeks comments regarding the establishment of Accountable Care Organization and the potential implication on laws related to anti-trust issues, including the physician self-referral, anti-kickback, and Civil Monetary Penalty ("CMP") laws.[1] Specifically, the notice seeks comments on how the Department of Health and Human Services ("HHS") Secretary's waiver authority of Title XVIII and sections 1128A and 1128B of the Social Security Act should be applied to section 3022 of the PPACA. In addition, there is also a request for comment on whether the Secretary should use her authority under

[1] 75 Fed. Reg. at 57039

section 1877(b)(4) of the Social Security Act to create a shared savings/incentive payment exception to the physician self-referral prohibition. Also, the notice seeks comment on whether the HHS, Office of Inspector General ("OIG") should consider a new safe harbor under 1128(B)(b)(3) of the Social Security Act.

MDMA's comments focus on the following issues in response:

- **Allowing the Secretary to waive requirements of 1128A and 1128B could harm patient access to innovative medical therapies by creating an incentive environment that encourages product standardization;**

- **If a shared savings/incentive payment exception to the physician self-referral prohibition, or the OIG creating a safe-harbor under the Social Security Act, is implemented, HHS and/or the OIG must clearly state that programs that satisfy the exception could implicate other state or federal laws;**

- **If any exception to the physician self-referral regulations is created, it should require programs to measure cost savings over at least a one year period; and**

- **Before any shared-savings program(s) moves forward, the current ongoing gainsharing demonstration projects must be completed and thoroughly evaluated.**

Waiver Authority under the PPACA

MDMA has commented in the past on similar proposals to accountable care organizations ("ACOs"), including the Centers for Medicare and Medicaid Services ("CMS") efforts to forward programs such as gainsharing. As with those proposals, MDMA has concern

with the waiving the requirements of sections 1128A and 1128B of the Social Security Act. This would likely give rise to greater product standardization in the hospital setting and could potentially limit patient access to innovative medical technologies.

MDMA believes that standardization cannot be achieved without limiting access to innovative items, supplies, and devices. By definition, standardization involves limitations on access to beneficial items, supplies, and devices that are not on the hospital's approved list. This list is likely to include devices from a single manufacturer. No single brand of medical device is best for all patients, however, because each patient requires different features and sizing. Physicians must have full access to any medical device that they determine is appropriate for their patient, and their choice of device should not be tainted by financial incentives.

In addition to denying access to the particular device that is best suited for the patient, standardization also could delay access to beneficial care by requiring physicians to be retrained on the use of devices other than the models they currently choose to use in their patients. This training period will be costly, and medical mistakes and patient injuries are more likely to occur during this learning period. Any purported benefits of standardization due to increased "efficiencies" likely would be substantially offset by the costs, both in terms of money and timely access to safe patient care that standardization of medical devices entails.

MDMA also believes waiving the authority under 1128A and 1128B of the program would adversely impact small device manufacturers. Although small manufacturers can compete on the basis of quality and utility, they may be less able to price their products as competitively as large manufacturers with economies of scale. In addition, large manufacturers of multiple devices are in a position to use pricing for one product to offset a lower price or a discount

offered on another product. In our experience, shared savings programs that include standardization tend to choose devices exclusively from large companies that negotiate with group purchasing organizations to provide exclusive and bundled contracts. Any program that seeks to standardize the use of a particular set of devices can follow this same pattern, and this would be a distinct disadvantage to small manufacturers.

Standardization not only places small manufacturers at a disadvantage during the duration of the shared savings program, it also harms these companies' ability to invest in continued research, potentially impeding improvements in patient care. Innovation in the medical device market is driven by small and new companies; entrepreneurial companies with fewer than fifty employees are estimated to offer more than 80% of device innovation. Thus, standardization risks trading short term savings for long term improvements in care.

If Any Exception to the Physician Self-Referral Regulations is Finalized, It Must Clearly State that Programs that Satisfy the Exception Could Implicate Other State or Federal Laws

MDMA would be concerned about the creation of additional exceptions to the physician self-referral prohibitions or the creation of additional safe-harbors for shared-savings programs, similar to ACOs. The authority to promulgate regulations is limited to the physician self-referral statute, however, and HHS acknowledges that incentive payment and shared savings programs may implicate the anti-kickback statute and the civil monetary penalty ("CMP) statute in addition to the physician self-referral statute. Any regulations promulgated HHS would not govern the interpretation of the anti-kickback statue or CMP statute by the Office of the Inspector General or the Department of Justice or state laws. Because an exception created by HHS could provide only limited protection for an incentive payment or shared savings program,

we urge HHS to explicitly state in any final rule that any programs meeting the regulations' exceptions could implicate other federal or state laws.

If Any Exception to the Physician Self-Referral Regulations is Finalized, It Should Require Programs to Measure Cost Savings over at Least One Year

Measuring the perceived cost savings achieve by ACO's or any shared savings programs must be accomplished in a manner that reflects an appropriate timeline to realize savings and preserve patient care. To show that savings have not resulted in adverse effects on quality, the program must measure savings over a long enough period to capture all of the costs of care provided under the program. Programs that encourage physicians to select medical devices based on cost rather than clinical appropriateness for the patient are likely to result in higher rates of medical complications, malpractice liability, and hospital re-admittance. Although these decisions may result in reductions in immediate healthcare costs, the decreased durability of lower-cost medical devices may cause a higher rate of medical complications and follow-up surgeries. If HHS finalizes any exception to the physician self-referral regulations for these programs, we urge the agency to require any programs to measure cost savings over a period of at least one year to attempt to ensure that the program does not harm the quality of care provided.

Exceptions Would be Premature Because CMS Has Not Completed the Demonstration Projects Required by Congress

Congress has authorized several demonstration projects that involve incentive payments and shared savings programs. Under the Deficit Reduction Act of 2005 (DRA), Congress expressly authorized CMS to move forward with a limited, six hospital, gainsharing demonstration program. Given the concerns that were raised by many stakeholders, including patients and innovators, Congress felt a small number of gainsharing projects should be

permitted "to test and evaluate methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of remuneration as specified in the project."[2] The carefully structured projects under the DRA attempted to address stakeholders concerns regarding payments that could compromise the patient/physician relationship. The limited number of hospitals expressly authorized by Congress also helps to limit harm to a broader group of Medicare beneficiaries before the program can be studied and analyzed in depth. Until these demonstrations have been completed and evaluated, HHS should not create new exceptions to the physician self-referral law.

Conclusion

MDMA appreciates the opportunity to provide comments for the Workshop and hope we can be resource moving forward.

Sincerely,

Thomas C. Novelli
Vice President of Government Relations
Medical Device Manufacturers Association

[2] DRA § 5007, Pub. L. No. 109-362.