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

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May 31, 2011

Department of Justice, Antitrust Division
Federal Trade Commission
Washington, DC

Re: Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program from the Department of Justice, Antitrust Division and the Federal Trade Commission

Dear Sir or Madam:

The Medical Device Manufacturers Association ("MDMA") appreciates the opportunity to provide comment for the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program from the Department of Justice, Antitrust Division ("DOJ") and the Federal Trade Commission ("FTC").[1] 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.

In September, 2010, MDMA provided comments for the October 5, 2010 joint Accountable Care Organization ("ACO") workshop hosted by the Centers for Medicare and Medicaid Services ("CMS"), Department of Health and Human Services Office of Inspector General ("HHS OIG"), and FTC. Our comments for the workshop focused on the establishment of ACOs and the potential implication on laws related to antitrust issues, including the physician self-referral, anti-kickback, and Civil Monetary Penalty ("CMP") laws. While those comments

[1] 76 Fed. Reg 21894 (April 19, 2011)

focused primarily on waiver authorities afforded to CMS for those relevant laws, our comments to the FTC and DOJ focus on ensuring a competitive landscape for manufacturers of innovative medical technologies.

The DOJ/FTC Policy Statement will likely have broad implications for many stakeholders throughout the healthcare system. Medical device manufacturers are cognizant of the vital role they play in the improvement of patient lives and reducing costs throughout the health care system. These objectives are achieved by producing innovative, life-saving medical technologies that reduce costs over time, leading to lowered readmission rates into health facilities, increased individual productivity within the workforce, and better overall outcomes. To this end, MDMA supports the goals of delivering the highest quality health care to Medicare beneficiaries under newly created ACO's. However, the DOJ and FTC must work to ensure that a competitive landscape exists for medical device manufacturers.

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MDMA agrees with the FTC and DOJ that beneficiaries in newly created ACOs should have access to the highest quality care possible and lowering overall costs. However, we also have concern with provisions outlined in the DOJ/FTC Policy Statement.

MDMA is concerned that under the proposed Policy Statement, there is insufficient clarity as to whether specific ACO's will wield an inordinate amount of dominant market power and unintentional harm medical device manufacturers, particular small companies, which are competing for critical market access to hospitals.

Under the proposed ACO review by the FTC and DOJ, the Agencies will use a streamlined analysis that evaluates the ACO's share of services in each ACO participant's Primary Service Area ("PSA"). According to the DOJ/FTC Policy Statement, the higher the PSA shared, the greater the risk the ACO will be anticompetitive, thereby reducing quality and choice for Medicare beneficiaries. Further, the DOJ/FTC Policy Statement outlines that there will be three types of review of ACO's by the FTC or DOJ. First, ACO's that have less than 30% companied share in each ACO participant's PSA for every common service will fall into the "safety zone" and have no required review by either agency. Second, ACOs outside the safety zone abut do have require mandatory review fall into "optional review" category and can request expedited 90-day review. Finally, ACOS that have greater than 50% combined shared in any ACO participant's PSA will fall into the "mandatory review" category and will be subjected to a 90-day expedited review.

While MDMA acknowledges the efforts of the DOJ and FTC to provide guidance regarding the competition risk assessment of various ACO's, we believe that additional and continual guidance will be needed. Specifically, DOJ and FTC should provide additional and continual guidance to ensure that an ACO, or group of ACO's, do not wield excessive market dominance in a geographic area and to ensure that manufacturers of innovative medical devices are not excluded from competition within those ACO's. An ACO that incorporates numerous health care providers within certain areas may dampen the competitive landscape for medical devices, thereby limiting the choices of patients to receive innovative treatments. Already, hospitals are limited in their choice of products to provide to patients due to the anticompetitive nature of hospital purchasing. Specifically, hospital group purchasing organizations ("GPOs") stifle competition in the medical device industry. Since GPOs are funded by manufacturers

themselves, and not the hospitals which utilize their services, they have an inherent conflict of interest in their purchasing decisions. Moreover, GPOs are wrongly afforded exclusionary treatment from anti-kickback laws under the Social Security Act. MDMA is concerned that this anticompetitive behavior could be exacerbated in an unbalanced ACO that yields significant market dominance. To this end, the DOJ and FTC should consider continuous reviews of ACO's, perhaps semi-annually, or annually, to ensure that ACO's do not wield dominant market power to the detriment of innovative medical device treatments for patients.

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MDMA appreciates the opportunity to provide comment to the DOJ and FTC regarding the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. We look forward to working with the Agencies as they work to ensure a competitive landscape within the Medicare Shared Savings Program.

Sincerely,

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