MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street ▪ Suite 1752
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

September 27, 2010

Donald Berwick, MD
Administrator, Centers for Medicare & Medicaid Services
Donald S. Clark
Secretary, The Federal Trade Commission.
Daniel R. Levinson
Inspector General.
Attn: ACO Legal Issues
Mail Stop C5–15–12
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws

Dear Dr. Berwick, Mr. Clark, and Mr. Levinson:

The Medical Imaging and Technology Alliance (MITA) appreciates this opportunity to comment on the October 5, 2010 workshop to be held by the Centers for Medicare & Medicaid Services (CMS), Federal Trade Commission (FTC), and Office of Inspector General (OIG) regarding accountable care organizations (ACOs) and implications regarding antitrust, physician self-referral, anti-kickback, and civil monetary penalty (CMP) laws.[1] As the leading trade association representing medical imaging and radiotherapy technology manufacturers, we have an in-depth understanding of the significant benefits to the health of Medicare beneficiaries that medical imaging, radiotherapy and proton therapy provides. MITA looks forward to working with you as you implement the Patient Protection and Affordable Care Act's provisions regarding ACOs to ensure that this payment model allows Medicare beneficiaries to continue to benefit from appropriate use of these technologies for the early detection, diagnosis, staging, therapy monitoring, and surveillance of many diseases.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, related image acquisitions, diagnostic ultrasound, and nuclear medical imaging (including positron emission tomography (PET)), and magnetic resonance imaging (MRI).

[1] 75 Fed. Reg. 57039 (Sept. 17, 2010).

Medical imaging is used to diagnose patients with disease, often reducing the need for costly medical services and invasive surgical procedures.[2] In addition, medical imaging equipment often is used to select, guide and facilitate effective treatment, for example, by using image guidance for surgical or radiotherapeutic interventions.[3] MITA's members also develop and manufacture innovative radiotherapy equipment used in cancer treatment.

MITA supports the goals of the Affordable Care Act's ACO provisions: to "improve the quality of care for Medicare beneficiaries and reduce unnecessary costs for the Medicare program."[4] Ideally, an ACO that allows participating providers to share the costs and benefits of the services they furnish would encourage efficient use of technology, including imaging services. We are concerned, however, that unless ACOs are established in a manner that encourages competition and includes adequate protections for the quality of care provided, this payment model could limit beneficiaries' access to appropriate imaging services. An ACO that limits access to care in its service area and restricts physicians' and beneficiaries' choices of technology based solely on the cost of the test likely would fail to improve quality and reduce cost, and over the long term, could discourage investment in beneficial new technologies.

During the FTC panel discussions at the workshop, the panelists will "explore ways to encourage formation of multiple ACOs among otherwise independent providers so that competition among ACOs in any given geographic market will drive improved quality and affordability of health care."[5] MITA agrees with the need for competition among ACOs in a given area. Allowing the formation of a single ACO would create an imbalance in market power between the providers and purchasers of health care. If patients have no other option but to receive care from the ACO, the ACO will have no incentive to improve care. The ACO could be encouraged to reduce costs to ensure that it remains profitable at the current Medicare payment rates, but such cost savings could come at the expense of the quality of care. MITA is particularly concerned that a single ACO also would have little incentive to invest in technologies that improve the quality of care over the longer term but have increased costs in the near term.

The panel will consider "ways to assess whether formation of an ACO among independent providers may allow the ACO to increase price and reduce the quality of care" and "the financial, utilization, outcome, and patient experience data necessary to monitor and measure the impact of an ACO on prices and quality in the relevant market."[6] We believe that assessment of the potential effect of an ACO on price and quality of care must be conducted before an ACO is established and that benchmarks need to be set, especially with regard to quality of care. If an ACO is established in a market, utilization of health care services, outcomes, and patient experiences must be monitored to ensure that the ACO truly improves care

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[2] See, e.g., Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005.
[3] See, e.g., Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731-737.
[4] 75 Fed. Reg. at 57040.
[5] Id.
[6] Id.

and reduces costs. Furthermore, the concept of utilization, as a measure, is of concern to us. The measure needs to be focused on whether or not the patient received the appropriate imaging test for their condition, not how many of a specific imaging test were rendered. Quality measures should have a clear basis in clinical research, and not be based solely on volume of procedures performed. The care provided by an ACO should be consistent with accepted clinical guidelines, such as those of the American College of Radiology and American College of Cardiology. Moreover, the assessment of access and quality must take place over a meaningful time period. Short term changes in utilization could affect the quality of care over the long term, and the assessment needs to cover a long enough period to fully capture the costs and benefits of services provided.

We also recommend that ACOs include patient protections that allow patients to understand how their care will be reimbursed and how payment might affect their access to care. Because a shared savings model would provide new incentives to reduce the cost of care, patients should be informed that their providers are participating in a new reimbursement system, be told about any limitations on their access to and choice of care, and be provided an appeals process if they disagree with the providers' treatment options.

MITA appreciates this opportunity to submit comments on the workshop regarding ACOs. As CMS, FTC, and OIG move forward on implementing the Affordable Care Act provisions, we would be pleased to answer any questions you might have about the efficient provision of quality imaging services. Please contact me at (703) 841-3279 if MITA can be of any assistance.

Respectfully submitted,

Dave Fisher
Executive Director, MITA
Vice President, NEMA