September 27, 2010

Donald Berwick, MD, MPP
Administrator
Centers for Medicare and Medicaid Services
Attention: ACO Legal Issues
Mail Stop C5-15-12
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Written Comment for Accountable Care Organization Workshop

Dear Dr. Berwick:

In light of the upcoming Accountable Care Organization ("ACO") workshop, the American Society for Radiation Oncology ("ASTRO") appreciates this opportunity to reiterate some of its ongoing concerns related to physician self-referral in the provision of radiation therapy services and how the development of ACOs may address those concerns. ASTRO is the largest radiation oncology society in the world, with 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology, and physics, ASTRO is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving healthcare environment.

We are very concerned that radiation therapy is frequently abused under a guise of legitimacy offered by the in-office ancillary services ("IOAS") exception to the physician self-referral ("Stark") law, which permits physicians to provide most health services in their offices as long as certain exceptions are met. We urge the Federal Trade Commission, the Centers for Medicare and Medicaid Services ("CMS"), and the Office of the Inspector General to implement changes to end these abuses in the practice of radiation therapy, which may be accomplished through changes to the Stark Law's implementing regulations and the utilization of ACOs.

Consistent with the foundational principles of ACOs, ASTRO's highest priority is excellence and efficiency in the use of radiation and other therapies for cancer patient care. When a patient's medical condition requires a referral for specialized care like radiation therapy, the treatment decision must be based on quality care and patient choice, not financial incentives. ASTRO believes it is wrong to create business enterprises centered on rewarding physicians for making referrals, yet we are increasingly seeing business ventures across the country designed to generate additional revenues within a group practice by incorporating radiation therapy. This practice may lead to adverse outcomes for patients, especially where certain alternative therapies to radiation are avoided, delayed, or otherwise ignored. The result of the abuse of radiation

therapy by way of the IOAS exception not only harms patients, but it also leads to unnecessary Medicare spending.

One way of addressing the potential abuse of the IOAS exception is to amend the exception itself to allow only individual physicians and group practices that are themselves ACOs (*e.g.*, robust, multispecialty physician group practices that provide primary care services for more than 5000 Medicare beneficiaries) to utilize the exception's protection. By doing so, CMS and the public would be comforted that, while physicians and group practices would continue to be able to utilize the IOAS exception to perform radiation therapy services, group practices could only do so by becoming an ACO, which would combat the current abuse that leads to increases in unnecessary Medicare spending and potential harm to patients. In other words, group practices seeking the protection of the IOAS exception would be unavoidably part of an integrated healthcare delivery system with appropriate oversight, incentives, and controls for the quality and efficiency of patient care.

It is clear that the IOAS exception is being abused in various ways, and the Medicare Payment Advisory Commission ("MedPAC") recently acknowledged this reality. *See* MedPAC Report to the Congress, "Aligning Incentives in Medicare," June 2010. MedPAC commented in its report on "the rapid growth of services covered by the IOAS exception" as well as the continuing "evidence that these services are sometimes furnished inappropriately." In fact, MedPAC was merely revisiting a previous finding by CMS, in conjunction with its issuing the 2008 physician fee schedule proposed rule, that imaging equipment, pathology services, and therapy services were being increasingly migrated to physicians' offices. At that time, CMS asked whether the IOAS exception should be changed in order to eliminate certain services from its protection, including those services that are not needed at the time of an office visit or to help immediately with diagnosis. Though no changes have since been made, it is clear the IOAS exception was originally intended to apply mainly in situations where quick results -- such as with X-rays or laboratory tests -- were needed in order to speed patient care. As time has gone on, the exception has taken an entirely new direction, ironically providing Stark law protection for the overutilization of health services.

While ASTRO supports MedPAC's potential solution of excluding radiation therapy from the IOAS exception altogether, we also strongly believe that limiting the use of the IOAS exception to individual physicians and group practices that are themselves ACOs (*e.g.*, robust, multispecialty physician group practices that provide primary care services for more than 5000 Medicare beneficiaries) would dramatically reduce the amount of abuse seen in the radiation therapy industry. Since the physician self-referral of ancillary services frequently creates an improper incentive to increase volume under the Medicare fee-for-service system, limiting the IOAS exception to use by ACOs would eliminate inappropriate financial motivations. By limiting the IOAS to truly integrated, multidisciplinary group practices, this proposal would meet two primary ACO objectives, which are (1) promoting accountability for patient populations and coordinating items and services covered by Medicare, and (2) rewarding physician practices and other physician organizational models for quality and efficiency. In fact, MedPAC's June 2010 report echoed these benefits: "By making providers jointly responsible for the quality of care and

cost of a population, ACOs are designed to improve the coordination of care and reduce duplication of services."

We urge CMS and others to enhance accountability and patient care by ending the inappropriate use of radiation therapy under the IOAS exception. We believe that the ideal long-term solution for ending healthcare fraud and abuse is to develop payment systems that reward quality over volume, including through the use of integrated care systems like ACOs. One way to move closer to this goal is to allow only ACOs to take advantage of the Stark Law exception for in-office ancillary services -- it is a change that will ensure the elimination of abusive radiation therapy practices and curb spending by the Medicare system.

Sincerely,

Laura I. Thevenot
Chief Executive Officer