

# Regulatory Review: Physician Self-Referral Updates

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For years, certain healthcare industry stakeholders have argued that increased utilization of diagnostic imaging studies is directly tied to physician self-referral. A heightened focus, however, has recently come to light with respect to physician self-referral generally, and in the advanced imaging and radiation oncology services arena, in particular. This is evident in a number of recent developments, including the 2010 healthcare reform bill, a request for government study focusing on the imaging utilization self-referral connection, reimbursement and other regulatory changes, and future accreditation standards. This article will focus solely on the new disclosure requirements contained in the healthcare reform bill and a newly requested government study focusing on self-referral and advanced imaging and radiation oncology services.

## **Advanced Imaging: Disclosures Now Required for Physician Self Referrals**

Pursuant to the healthcare reform bill that was signed into law by President Obama on March 23, 2010 (the Patient Protection and Affordable Care Act, referred to as the Act going forward), physicians who furnish MRI, CT, or PET tests through their practices are now required to provide their patients with a written disclosure at the time of the referral.

By way of brief background, the Stark Law prohibits physicians from referring Medicare patients for certain “designated health services” (including MRI, CT, and PET) to an entity with which the referring physician (or any of his/her immediate family members) has a direct or indirect financial relationship, unless an exception is met. Physicians who furnish designated health services within their practices typically rely upon Stark’s In-Office Ancillary Services Exception (the IOASE) in order to avoid running afoul of the Stark Law’s self-referral prohibition.

Notably, Section 6003 of the Act imposes a new requirement that physicians who furnish MRI, CT, or PET testing services for their Medicare patients by way of the IOASE must inform the patient in writing at the time of the referral so that the patient may obtain the MRI, CT, or PET test elsewhere. Pursuant to the Act, these physicians are also required to provide a written list of suppliers who furnish those services in the area where the patient resides. Section 6003 allows the Secretary of Health and Human Services (HHS) to require similar notices for other

categories of imaging services that fit within the definition of designated health services. Note that, the disclosure requirement applies solely to physician groups whose self-referrals of MRI, CT, and PET comply with Stark on the basis of the IOASE; this requirement does not apply to physician groups comprising of solely radiologists.

This new disclosure provision of the Act applies to services furnished on or after January 1, 2010 (but the disclosure requirement appears to have taken effect on March 23, 2010, the date President Obama signed the bill into law). Section 6003 of the Act suggests that regulations will be issued to implement the new disclosure requirement. However, physicians who furnish MRI, CT, or PET tests pursuant to the IOASE should immediately begin to provide the required written disclosure and list of suppliers to their Medicare patients.

## **Advanced Imaging and Radiation Oncology Services: GAO Requests Study of on Physician-Self Referral Arrangements**

In a related development, physician self-referral concerns prompted Congress, via an April 16, 2010 letter, to request the General Accountability Office (GAO) to conduct a study to evaluate the extent of physician self-referral arrangements for advanced imaging and radiation oncology services provided to Medicare beneficiaries and their effects on Medicare spending.

Supporters of the Stark IOASE argue that the ability for physicians to self-refer improves patient access to medically necessary services and leads to more efficient and better coordinated treatment for patients. Conversely, opponents argue that financial incentives tied to self-referral arrangements often lead to overutilization of imaging and radiation oncology services. These concerns prompted the Chairs of the Committee on Ways and Means, Subcommittee on Health Committee on Ways and Means, and the Committee on Energy and Commerce to send a written request to the GAO on April 16, 2010 calling for an examination of self-referral arrangements involving advanced imaging and radiation oncology services.

Specifically, the request calls on the GAO to focus the study on (1) prevalence, patterns, and trends in physician self-referral for advanced imaging and radiation oncology services, (2)

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Medicare spending on these physician self-referral services, and (3) the extent to which self-referral may have lead to increases in the provision of, and Medicare spending for, advanced imaging and radiation oncology services.

## **Conclusion**

At the present time, physician self-referral of advanced imaging and radiation oncology services is permitted under the

Stark IOASE. However, as noted above, physicians (other than radiology groups) that furnish MRI, CT, and/or PET in-office are now required to make certain disclosures to their Medicare patients. Further, physicians involved in self-referral arrangements in connection with advanced imaging or radiation oncology services should remain attentive to potential future changes that might restrict the scope of the Stark IOASE in these areas.