

STARK LAW IMPOSES ADDITIONAL DISCLOSURE REQUIREMENTS FOR CERTAIN IMAGING SERVICES

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Section 6003 of the Patient Protection and Affordable Care Act of 2010 (PPACA), part of the health reform legislation commonly known as “Obamacare” enacted March 23, 2010, revises the in-office ancillary services exception of the physician self-referral statute (the “Stark Law”) effective (retroactively) on January 1, 2010.

True to government form, however, the federal government enacted the prohibition without providing the necessary detail to explain how to comply with the rule. On July 13, 2010, HSS issued proposed regulations to implement Section 6003 of the PPACA. Those proposed regulations were finalized on November 29, 2010 to be implemented effective January 1, 2011.

In essence, Section 6003 amended the Stark Law to require a written patient notice in order to comply with the elements of the in-office ancillary services exception at least with respect to MRI, CT and PET imaging, plus any other designated health services (DHS) that the Department of Health and Human Services (HSS) deems appropriate.

By now, most physician practices that provide MRI, CT and/or PET recognize (or had better recognize!) that in order for them to legally do so, they must comply with the in-office ancillary services exception. Put simply, the Stark Law provides that with respect to Medicare patients, a physician may not make a referral for DHS to an entity to which such physician (or immediate family member of such physician) has a financial interest, unless an exception to such financial relationship applies.

The in-office ancillary services exception is likely the broadest exception in use by physician practices. When one physician of a practice refers a Medicare beneficiary to his or her own practice (with which he or she obviously has a financial relationship), for DHS, whether the physician is aware of it or not, compliance with the in-office ancillary services exception is what usually permits the referral to take place.

Most physicians recognize that they may usually refer to their own practice for services to be provided to their own patients. Section 6003 of the PPACA, because of the affirmative written notice requirement it imposes, may now require physicians to focus on *why* that it is permissible and the limits of such permissibility.

The Stark Law is a strict liability statute (think speeding ticket). Accordingly, the failure to comply, regardless of intent, is a violation. If the Stark Law is violated, the referral is prohibited. If the referral is prohibited, the physician practice may not bill Medicare for the DHS in question. There are also huge potential financial penalties that may come along with a wrongful referral. In addition, wrongful referrals may form the basis of a whistleblower case under the federal False Claims Act. In other words, failure to comply with the Stark Law has the potential for draconian repercussions.

The final regulation issued in connection with Section 6003 of the PPACA requires that in order for a physician to make a referral for a MRI, CT or PET imaging service in accordance with the in-office ancillary services exception, at the time of such referral, the physician must provide the patient with a written notice that contains the following information:

- That the patient may receive the same services from someone other than the physician's practice;
- A list of at least five other suppliers of such service located within a 25 mile radius of the referring physician's practice location (if less than five exist, must list them all, but if no other suppliers exist within 25 mile radius, then no written notice is required)
- The list must contain, at a minimum, the alternative supplier's name, address and telephone number.

A key component of the final regulation is that the written notice must be provided, not just for the initial service, but for each and every referral. While the government makes clear in the regulation that no written acknowledgment is required by the patient, it also indicates that "as a matter of prudent business practice, physicians should be able to document [compliance] with the disclosure requirement."

For purposes of the notice, only Medicare "suppliers" must be included. That definition excludes hospitals and is meant to generally mean other private physician practices (but does include private radiology practices). The regulation does "encourage" physicians to list hospitals if there are less than five alternative suppliers within 25 miles.

Bringing the required list down from 10 alternatives to 5 alternatives was a positive change made between the proposed regulation and the final regulation. Another change was removing the requirement that the list include the distance of the alternative supplier from the physician's office. Arguably, therefore, although certainly not recommended, the physician may list only the 5 suppliers that are farthest away within the 25-mile radius.

There is no specific form in which the notice must take so long as it contains the required elements. The regulation expressly provides that the physician practice may indicate that the suppliers on the list are not endorsed by the physician. The list might also indicate that the physician is not aware whether the alternative providers participate with the patient's insurance. The regulation does suggest the physician review the list at least annually to ensure accuracy of the information provided in such notice.

The notice must only be given when required to comply with the in-office ancillary services exception. Therefore, it only applies with respect to Medicare beneficiaries pursuant to Title 18 of the Social Security Act and only where that particular exception is required. Because this is often not so easy to determine in the course of operating the typical medical practice, and because the penalties of not-complying can be so draconian, it is often suggested that a practice should provide the notice to all patients as a matter of course. Practices that wish to do otherwise, are strongly advised to consult their health care legal counsel.

The regulation contains an important note for pathologists, radiologists and radiation oncologists. Many of them believe that they are "excepted" from the Stark Law. That is only partially true. So long as a pathologist is making a referral for pathology services, a radiologist is making a referral for radiology services or a radiation oncologist is making a referral for radiation therapy, as a result of a consultation pursuant to the special exception of the Stark Law for such practitioners, such request is not considered a "referral" for Stark Law purposes and practitioners need not rely on the in-office ancillary services exception, and therefore, need not provide the written notice.

Similarly, to the extent that a radiation oncologist makes a referral for CT services that are necessary for and integral to the provision of radiation therapy, the request for those services is also not considered a "referral" for Stark Law purposes.

Another nuance of the Stark Law surrounds radiology services that are integral to the performance of a non-radiological procedure or immediately performed either during the non-radiology procedure or immediately after to confirm placement of an item. In those specific limited circumstances, the radiology services is excluded from the definition of DHS, and therefore, no exception is required, including the in-office ancillary services exception. Thus, no notice is required.

Finally, the final regulation makes clear that the notice is still required even if the referral is time-sensitive or emergency in nature. The government believes the likelihood of such a circumstance is too rare to warrant the exception with respect to the in-office ancillary services exception.

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