

HEALTH REFORM IMPACT

What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Putting the Squeeze on Ancillaries: New Disclosure Requirements For Physicians Providing Advanced Imaging

April 6, 2010

The newly enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "Health Reform Legislation"), requires referring physicians¹ who provide MRI, CT or PET scans/services (and any other designated health services that CMS ultimately deems appropriate) under the in-office ancillary services exception of the federal Stark law² to inform the patient in writing at the time of the referral that the patient may obtain the specific imaging services (MRI, CT and PET) from other "suppliers" in the "area in which the patient resides."³ The disclosure notice must contain a written list of such other "suppliers."

For your reference, the statutory text of this new disclosure requirement is set forth below.

SEC. 6003. DISCLOSURE REQUIREMENTS FOR IN-OFFICE ANCILLARY SERVICES EXCEPTION TO THE PROHIBITION ON PHYSICIAN SELF-REFERRAL FOR CERTAIN IMAGING SERVICES.

(a) IN GENERAL. -- Section 1877(b)(2) of the Social Security Act (42 U.S.C. 1395nn(b)(2)) is amended by adding at the end the following new sentence: Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual

¹ For purposes of the federal Stark law, "physicians" include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry and chiropractors.

² If a physician, or an immediate family member of a physician, has a financial relationship with an entity (such as the physician's practice) that furnishes designated health services, including MRI, CT and PET services ("DHS"), the Stark law strictly prohibits the physician from referring patients to the entity, and the entity from submitting a claim for payment, for the furnishing of DHS that may be paid for by Medicare and Medicaid, unless an exception applies. 42 U.S.C. § 1395nn(a)(1). Penalties for Stark law violations may include denial of payment to the DHS entity, civil money penalties of up to \$15,000 per prohibited referral, up to \$100,000 for a circumvention scheme, exclusion from Medicare, recoupment of amounts paid pursuant to each prohibited referral, and potential federal and state False Claims Act liability.

³ Pub. L. No. 111-148, Section 6003 of the Health Reform Legislation.

with a written list of suppliers (as defined in section 1861(d)) who furnish such services in the area in which such individual resides.

(b) EFFECTIVE DATE. -- The amendment made by this section shall apply to services furnished on or after January 1, 2010.

Effective Date of Change

Note that this change is technically effective January 1, 2010. However, the informal consensus among the healthcare bar appears to be that the government will not pursue enforcement against physicians for periods prior to March 23, 2010, the date of the Health Reform Legislation's enactment (and perhaps not prior to the time that implementing regulations for the law are issued). Nonetheless, it is advisable for affected physicians to begin complying immediately with this new patient notice requirement to avoid exposure.

When Must the Written Notice Be Provided and What Must It Contain?

The written notice must be given to the individual patient by the referring physician "at the time of the referral" for the MRI, CT or PET services and must contain "a written list of suppliers (as defined in section 1861(d)) who furnish services in the area in which the individual resides." The term "supplier" is specifically defined in Section 1861(d) of the Social Security Act to mean "unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title." Importantly, the term "supplier" does not include hospitals, which are defined in the context of Medicare and Medicaid as "providers." (However, physicians are not prohibited from including hospitals in the written list of alternative facilities as long as the written notice contains a list of other "suppliers," such as freestanding imaging facilities, independent diagnostic testing facilities (IDTFs), and radiology groups and practitioners.)

It is not entirely clear in the absence of implementing regulations whether the list of other suppliers must include all of the suppliers in the area in which the patient resides (and how to measure the "area" in which the patient resides). However, a reasonable interpretation and practical approach is to give the patient several meaningful options throughout the geographic area in an effort to provide the patient with real freedom of choice.

Practical Implementation

We recommend that physicians maintain copies of the written notice in their records. It is preferable (though not required) to have the written disclosure signed and dated by the patient at the time of the referral to evidence compliance with this requirement with respect to each patient referred, if ever challenged.

We anticipate that the scope of this new requirement will continue to evolve. CMS may issue "frequently asked questions" (FAQ) guidance and will ultimately issue clarifying regulations.

It is also important to keep in mind that some states, including Tennessee⁴, have pre-existing physician ownership disclosure requirements. Those laws should be carefully considered when drafting the new Stark law disclosure notice.

⁴ Tennessee's Physicians' Conflict of Interest Disclosure Act of 1991, Tenn. Code Ann. § 63-6-501 et. seq.

Again, affected physicians should begin to comply immediately with this new patient notice requirement.

If you would like assistance in drafting the required notice of alternative suppliers, please contact any of the attorneys in our Healthcare Practice Group listed below.

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