

HEALTH REFORM IMPACT

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

Part II of Putting the Squeeze on Ancillaries: Proposed CMS Rule Specifies Disclosure Requirements for Physicians Providing Advanced Imaging

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As we first mentioned in our April 6th issue of *Health Reform IMPACT*,¹ Section 6003 of the Patient Protection and Affordable Care Act (the "Act") requires referring physicians who provide MRI, CT or PET scans under the in-office ancillary services exception of the federal Stark law to inform a patient in writing at the time of the referral that the patient may obtain the service from a person other than the referring physician and to provide the patient with a list of suppliers who furnish the service in the area in which the patient resides. The Centers for Medicare & Medicaid Services ("CMS") has now released a highly anticipated proposed rule implementing these disclosure requirements as part of the proposed 2011 Medicare physician fee schedule (the "Proposed Rule").² Comments to the Proposed Rule are due August 24, 2010.

Effective Date of Change

CMS proposes that the new disclosure requirements shall apply only to services furnished on or after January 1, 2011, which will be the effective date of the final regulation implementing Section 6003 of the Act. Note that this proposed date is one year later than the date of January 1, 2010, listed as the effective date in Section 6003 of the Act. CMS states in the preamble to the Proposed Rule that it considered whether the disclosure requirements should apply retroactively to all services furnished on or after January 1, 2010, but decided that retroactive rulemaking is not required.

Services that Trigger the Disclosure Requirement

The Proposed Rule limits the new disclosure requirement to MRI, CT and PET services. CMS, however, has the statutory authority to expand the scope of the disclosure requirement and is seeking comments regarding whether other radiology and imaging services that fall under the definition of "designated health services" for purposes of the federal Stark law should be included in this requirement.

¹ For more information about Section 6003 of the Patient Protection and Affordable Care Act, please [click here](#).

² See "Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule," available at <http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf>.

General Disclosure Requirements

Under the Proposed Rule, the disclosure notice must be written in a manner sufficient to be reasonably understood by all patients and must be given to the patient at the time of the referral. The notice must also make clear that the services may be obtained from a person other than the referring physician or his or her group practice and include a list of 10 other suppliers who provide the referred service within a 25-mile radius of the referring physician. Further, the notice cannot indicate that the patient must obtain services from a supplier on the list.

List of Alternate Suppliers

Under the Proposed Rule, the disclosure notice must include the name, address, phone number, and distance from the referring physician's office of the 10 other suppliers of the ordered imaging service that are within a 25-mile radius of the referring physician.³ If there are fewer than 10 other suppliers within a 25-mile radius of the referring physician's office location, all suppliers in the radius should be listed. If there are no other suppliers of the imaging services ordered within the 25-mile radius of the physician's office, the physician need not provide a list of alternative suppliers. Nonetheless, the physician must still disclose that the patient may receive the imaging service from another supplier. The Proposed Rule does not propose an exception to the disclosure requirement for MRI, CT or PET services furnished under exigent circumstances.

Importantly, under the Proposed Rule, only "suppliers" are to be included on the written list. CMS specifically states that it is not proposing to permit or require the list to include "providers of services," which include hospitals and critical access hospitals, among other facilities. Apparently, then, physicians may list only freestanding, nonhospital-based imaging alternatives in the 25-mile radius. The language of the Proposed Rule raises the issue of whether, if there are no freestanding, nonhospital-based suppliers within a 25-mile radius of the referring physician's office, but there are hospital-based alternatives, the referring physician must provide a list of the hospital-based alternatives or is instead exempted from providing the list.

Finally, CMS is concerned that physicians in urban areas will draft a list of suppliers located at the edges of the 25-mile radius to increase the chances that the patient will choose to receive imaging services from the referring physician's practice. CMS is soliciting comments regarding this concern and each of these proposed requirements, including whether providing a list of 10 suppliers is sufficient or too burdensome or susceptible to abuse.

Documentation of Disclosure

Finally, the Proposed Rule requires that a record of the patient's signature on the disclosure notification be maintained as part of the patient's medical record. CMS is soliciting comments regarding the burden of this recordkeeping requirement and is seeking alternate means of memorializing that the disclosure requirement was made to the patient at the time of referral.

³ Note that Section 6003(a) of the Act requires that the alternate suppliers specified in the notice provided to the patient must furnish the relevant services "in the area in which [the patient] resides." The Proposed Rule, however, proposes that suppliers included in the required notice should be located within 25-miles of the *physician's office location* at the time of the referral. CMS believes that if the patient has traveled to see the referring physician, then a referral within a certain distance of this location for advanced imaging services would also be convenient for the patient.

If you have any questions regarding this issue of *Health Reform IMPACT*, please contact any of the attorneys in our Healthcare Practice Group listed below.

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