Health Care Reform Alert: Stark Law Update: CMS Finalizes Rule Regarding Disclosure Requirements for Certain In-Office Ancillary Services

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In its 2011 annual Physician Fee Schedule update ("2011 PFS"), posted November 2, 2010 on its website,[1] the Centers for Medicare & Medicaid Services (CMS) finalized disclosure requirements for the in-office ancillary services exception to the prohibition on physician self-referral mandated by the Affordable Care Act (ACA). CMS commonly uses its annual PFS regulatory process—a publication required by the physician fee schedule law—to make changes to the self-referral, or "Stark Law," provisions. For example, each year the PFS regulation provides the yearly list of those services that are specifically identified as "designated health services" (DHS) under the Stark Law.

Section 1877(b)(2) of the Social Security Act (the "Act"),[2] entitled "In-office Ancillary Services," sets forth the exception that permits a physician to order and provide DHS in the office, provided that certain criteria are met. The requirements are described at 42 C.F.R. § 411.355(b).

Section 6003 of ACA amends section 1877(b)(2) of the Act by creating a new disclosure requirement for in-office ancillary services pertaining to certain high-cost "advanced imaging services." Specifically, section 6003 provides that, with respect to referrals for magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and any other DHS to be later specified, a referring physician must inform a patient in writing at the time of the in-office referral that the patient may obtain the service from another person, and must also provide the patient with a list of other suppliers who furnish the service in the area where the patient resides.

In the 2011 PFS, CMS, with some modifications, finalized its proposed rule concerning implementing this provision of the ACA.[3] The highlights of the final rule, which becomes effective on January 1, 2011, include:

- The written disclosure must be made at the time of referral for each service.
- The geographic area for the listing of alternative suppliers is within a 25-mile radius of the physician's office location.
- The number of alternative suppliers listed must be at least five, except where fewer than five exist within that geographic range.
- Physicians *may* add to this list (but not substitute other suppliers) by including providers, such as nearby hospitals.
- The listing of alternative suppliers must include suppliers of MRI, CT, and PET services.
- The disclosure notice should be written in a manner sufficient to be "reasonably understood by all patients," and is to be given to the patient at the time of the referral.
- The information about these suppliers must include name, address, and phone number.
- Although physicians need not obtain the patient's signature on the written notice, they must be able to demonstrate compliance with this rule.
- CMS advises physicians to annually update the list of alternative suppliers to make sure it is reasonably current and accurate.
- CMS will not issue a prescribed form of disclosure, and so physicians must determine for themselves how to develop the list of alternative suppliers and the wording of the disclosure statement.

Comment

The genesis of this disclosure requirement was the widespread recognition that in-office ancillary testing, especially high-cost services like MRI and CT scanning, has become a measurable driver in health cost inflation. While undoubtedly some in Congress may have preferred to launch a more direct attack at the Stark Law in-office ancillary services exception as a means to control this cost curve, political realities led to this more moderate first step. At the same time, it is hard to see that this measure will realistically lead patients to leave their physician, let alone actually forego the recommended test. And so it is more likely that this new requirement will simply impose a new compliance burden on physicians while yielding few system-wide benefits. Nevertheless, the significance of this requirement may be that it represents the crossing of a line, and a Congressional willingness to reexamine this once-sacred exception.

Endnotes

[1] Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011 ("2011 PFS") at 874-894, 1499-1500. The PFS will appear in the Federal Register on November 29, 2010. All references are to the hard copy version available on CMS's website at: http://www.cms.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=descending&itemID=CMS1240932&intNumPerPage=10 (last visited 11/4/10)

[2] 42 U.S.C. 1395nn(b)(2).

[3] The relevant provision is located at 42 C.F.R. § 411.355(b)(7).
