Summer 2008

Topics

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Stark Law Update: Recent Developments

Over the past several months, the Centers for Medicare & Medicaid Services (CMS) has issued various proposed rules and advisory opinions on issues related to the Stark Law provisions. Most notably, CMS is currently revisiting one of the provisions in the Stark II, Phase III rule it finalized in September 2007, i.e., the provision requiring physicians with financial interests in physician organizations to "stand in the shoes" of such organizations for the purposes of complying with self-referral laws. Additionally, CMS has issued an advisory opinion dealing with the Stark implications of providing customized software to members of hospital medical staffs for the purpose of remote access to patient information.

Status of the "Stand in the Shoes" Provision

In September 2007, CMS issued the third installment of the federal self-referral law, more commonly referred to as Stark II ("Phase III").1 In the Phase III installment, CMS included a provision that would now consider physicians who have an ownership interest in a physician organization to "stand in the shoes" of the physician organization for the purpose of Stark laws, i.e., the physician would "collapse" into the physician organization, resulting in the the physician organization no longer being considered an intervening entity for the purpose of establishing an indirect compensation arrangement with a designated health service ("DHS"). Under the new provision, any physician member, employee or contractor of the physician organization will be considered to have the same compensation arrangement with the DHS that the physician organization has as a whole. The effect of the "stand in the shoes" provision is that many more physicians will considered to have direct compensation arrangements with DHS entities, therefore falling under a different set of exemption provisions to Stark.¹

The final implementation of the "stand in the shoes" doctrine that concerned academic medical centers ("AMCs") and nonprofit integrated health system settings was delayed in November 2007, until December 2008, so that CMS could address such concerns as: (1) compensation arrangements between a faculty practice plan and another component of the same AMC; and (2) compensation arrangements between an affiliated DHS entity and the affiliated physician practice in the same

nonprofit integrated health care system.¹ Following this delay, CMS issued the proposed rule regarding the Hospital Inpatient Prospective Payment System ("IPPS") for FY 2009 ("Proposed Rule"), in which CMS solicited comments on two alternatives to address the "stand in the shoes" provisions for AMCs and integrated health systems going forward. The first alternative would create exceptions from the provision for physician-employees or contractors compensation arrangement satisfies the *employment*, personal services, or fair market value exception, or where the compensation arrangement is between an AMC component and a physician organization affiliated with the AMC through a written agreement to provide services required to satisfy the AMC's obligations under the Medicare Graduate Medical Education rules. 1 The second alternative provides that CMS would not change the current "stand in the shoes" provisions, but instead would develop a new exception for certain mission support and similar payment arrangements between and among DHS entities, physician organizations, and physicians.¹ The Proposed Rule also provides for revising the Stark Law such that a DHS entity would be deemed to stand in the shoes of any organization in which it has a 100% ownership interest so that the DHS entity would be deemed to have the same compensation arrangements (i.e., with the same parties and on the same terms) as does the organization that it owns.¹ The Proposed Rule also clarified how to apply physicianand entity-side collapsing rules so that the referring physician and the DHS entity will not ever become the same person/entity for analytical purposes.¹

With the revisions of the "stand in the shoes" provision, CMS also proposed revising the definitions of "physician" and "physician organization" so that the determination as to whether a direct or indirect compensation agreement exists would be clearer. Under the proposed definitions, physicians will be deemed to "stand in the shoes" of: (1) another physician who employs the physician; (2) his or her wholly owned professional corporation; (3) a physician practice that employs or contracts with the physician or in which the physician has an ownership interest; or (4) a group practice of which the physician is a member or independent contractor. ¹

Advisory Opinion: Remote Electronic Access of Patient Information

Additionally, CMS has recently published a new Stark Law advisory opinion on the topic of remote electronic access of patient information by the medical staff of a hospital system. CMS advised an inquiring hospital system that providing customized software to members of the medical staffs would not give rise to a compensation arrangement between and among the physicians and the hospital under the Stark Law. Under section 1877 of the Social Security Act, a compensation arrangement includes all arrangements between a physician (or immediate family member) and an entity which involve remuneration, except those arrangements which involve only "the provision of items, devices, or supplies that are used solely...to order or communicate the results of tests or procedures for such entity."1 Because the provision of free equipment solely to communicate the results of exams does not have independent value apart from the service being provided, it does not constitute prohibited remuneration.

64161 (Nov. 15, 2007).

- ¹ "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23686 (Apr. 30, 2008).
- ¹ "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23687 (Apr. 30, 2008).
- ¹ "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23689 (Apr. 30, 2008).
- ¹ "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physicians Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians," 73 Fed. Reg. 23689 (Apr. 30, 2008).
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- ¹ "Advisory Opinion No. CMS-AO-2008-01" By Jeffrey B. Rich, M.D., Director, Center for Medicare Management, May 28, 2008, http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-AO-2008-01.pdf (Accessed 6.30.08).
- ¹ 42 U.S.C. 1395nn(h)(1)(A)-(C)(ii)(II) (2003).

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¹ "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)," 72 Fed. Reg. 51012 (Sept. 5, 2007).

¹ "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)," 72 Fed. Reg. 51028 (Sept. 5, 2007).

¹ "Medicare Program; Delay of the Date of Applicability for Certain Provisions of Physicians' Referrals to Health Care Entities With Which they Have Financial Relationships (Phase III)," 72 Fed. Reg.



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