Health Law Advisory: Federal Court Holds that It Lacks Jurisdiction to Hear Challenge to the New Definition of "Entity" Under the Stark Law Regulations

4/30/2009

On April 20, 2009, the United States District Court for the District of Columbia issued an important ruling that will significantly affect the ability of physicians to challenge the Centers for Medicare & Medicaid (CMS) regulations under the federal physician self-referral law, more commonly referred to as the "Stark Law." Last fall, a group of physicians and their physician-owned cardiac catheterization laboratories challenged CMS's Stark Law revision of the regulatory definition of "entity" furnishing designated health services ("DHS Entity").[1] In brief, the Court held that it could not entertain the substance of the plaintiffs' complaint because they had not exhausted their administrative remedies, even though the court found that plaintiffs could not directly bring an administrative challenge to the regulations' revisions because they do not directly bill or receive payments from Medicare for designated health services (DHS). Instead, the Court held that the physicians must rely on their local hospitals, with which they contract but which are not parties to this lawsuit, to bring an administrative challenge on their behalf.

Background on the Stark Law and its Implementing Regulations

Generally, the Stark Law

- prohibits a physician from making referrals for certain DHS payable by Medicare to an "entity for the furnishing of designated health services" when the physician (or an immediate family member) has a direct or indirect financial relationship with the entity, unless an exception applies; and
- prohibits the DHS Entity from filing claims with Medicare for those DHS rendered as a result of a prohibited referral.[2]

The Stark Law establishes specific exceptions to this prohibition and authorizes the Secretary of Health and Human Services (HHS) to create additional regulatory exceptions for financial relationships that pose no risk of program or patient abuse.[3]

Changes to the Stark Law Regulations

Definition of "DHS Entity"

On August 19, 2008, CMS issued the final changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates final rules ("Final Rules"). The Final Rules included a number of important regulatory changes to the Stark Law, including the definition of the key term "entity" furnishing DHS, or DHS Entity.

Currently, CMS interprets the term "DHS Entity" to mean a person or entity that "furnishes DHS" and "to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf." However, effective October 1, 2009, an "entity" will be considered to be furnishing DHS "if it is the person or entity that has performed services that are billed as DHS" or it is "the person or entity that has presented a claim to Medicare for the DHS."[4] This means that the Stark Law prohibition will apply not only to the entity that submits a claim and receives Medicare payments for DHS, but also to the entity that "performs" the DHS for which it does not directly bill the Medicare Program.

Effect of Revised Definition

In an "under arrangements" relationship, a hospital contracts with a third party to provide services, including DHS, to the hospital, and the hospital bills for the services. Although the third party actually provides the service to the Medicare patient, subject to oversight by the hospital, the hospital is required to bill for the service because the patients in question are hospital patients, not patients of the "under arrangements" service provider. "Under arrangements" relationships may be a purely contractual arrangement between a hospital and a physician or physician group practice, or may be a joint venture arrangement in which the hospital and physician or physician group take ownership interests in a company that, in turn, contracts with the hospital to provide the services.

Under the current Stark Law regulations, only the hospital is considered to be the DHS Entity, and therefore the Stark Law analysis focuses on the compensation arrangement between the hospital and the physician-owned entities. Under the Final Rules, however, the "entity" that "performs" the DHS includes the physician-owned company. Thus, the new definition of "DHS Entity" will make it virtually impossible for providers to find a Stark law exception[5] to protect physician ownership in "under arrangements" service providers.

The Plaintiffs' Challenge

Under the revised definition of "DHS Entity," both hospitals and the "under arrangements" providers with which they contract will be considered DHS Entities. Consequently, CMS's revision was challenged by a group of cardiologists and the cardiac catheterization laboratories they own, who claimed that the change would effectively put the cardiac labs out of business.

On December 17, 2008, the plaintiffs filed for summary judgment, arguing, among other things, that CMS's definition of "entity furnishing DHS" is contrary to the statutory authority found in the Stark Law; is arbitrary and capricious; and was issued in excess of CMS' administrative authority. Mintz Levin represented the plaintiffs in this case.

No Decision on the Merits

The Court refused to address the merits of the case, holding that it lacked subject matter jurisdiction to hear a claim arising under the Medicare law until all administrative remedies have been exhausted through HHS. The plaintiffs countered that their claim was excepted from the administrative exhaustion requirement because they do not directly bill or receive payment from Medicare, and therefore cannot bring an administrative challenge before HHS. The Court rejected this argument, finding that the hospitals with which the plaintiffs contract could, "if they so choose," challenge the regulations on their behalf, and the fact that the plaintiffs did not have "a direct avenue to administrative review through an assignment does mean that they could not get their claim heard."

The plaintiffs are considering whether to appeal this decision, and will also be asking CMS to reconsider this rule as it affects physician-owned cardiac catheterization labs.

Implications of the Court's Decision

The implications of the Court's decision are that no physician who has an agreement with a provider who bills Medicare will *ever* be able to challenge a Stark Law regulation related to that agreement. Instead, the hospital (or other Medicare-billing DHS Entity) will have to bring the challenge on the provider's behalf, and the court will not need to analyze whether the hospital would have sufficient incentive to do so. In this regard, the Court recognized that the Fifth Circuit has looked to see not only whether the plaintiff's claim could be heard administratively, but also whether the third party with access to the review process has the *necessary incentive* to do so. Nevertheless, the Court expressly found that this is not the law in the D.C. Circuit; even if it were, hospitals have the necessary incentive in this case because the plaintiffs provide the cardiac catheterization services "at a lower cost than could be provided by the hospitals," and "the hospitals profit by having these services under arrangement."

This decision, if allowed to stand, imposes significant barriers to any attempt by physicians to challenge Stark Law regulations. This impact is particularly noteworthy given the penalties physicians face for violating the law.

Looking Ahead

The revised definition of DHS Entity, which becomes effective October 1, 2009, will cause most physician-owned "under arrangements" relationships to fall out of compliance with the Stark Law. As a result, it is important that these arrangements be reviewed to determine whether they need to be dismantled or restructured by, for example, converting the relationship between the hospital and the "under arrangements" provider to a pure leasing arrangement that does not constitute "performing" the DHS. In light of the potential penalties, as well as the time it may take to restructure these arrangements, parties should work now to identify their restructuring options so as to remain in compliance with the Stark Law.

Endnotes

[1] *Colorado Heart Institute LLC v. Johnson, DDC,* No. 08-1626 (April 20, 2009).

[2] 42 U.S.C. § 1395nn; 42 C.F.R. § 411.353(a),(b).

[3] 42 U.S.C. § 1395nn(b)-(e); 42 C.F.R. §§ 411.352-411.357.

[4] *See* 73 Fed. Reg. 48434 (revising 42 C.F.R. § 411.351) (effective October 1, 2009).

[5] The only under arrangements ownership relationships that will survive the new rule will be those that can meet the Stark Law's "rural provider" exception.

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