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Colorado Heart Institute, LLC v. Johnson: Revised definition of "entity" under Stark survives court challenge; case may impact other pending litigation on related topic

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A challenge to the new definition of "entity" under the Stark Law,[1] brough by physicians and physician-owned entities that furnish cardiac catherization services to hospitals that bill for them "under arrangements," was dismissed for lack of jurisdiction. *Colorado Heart Institute, LLC v. Johnson*, No. 08-1626 (RMC) (D.D.C. Apr. 21, 2009). As explained below the decision also may have some effect on pending litigation challenging the revision to the related Stark rule on "per click" lease arrangements.

The Stark law generally prohibits a physician from referring designated health services (DHS), including inpatient and outpatient services to an "entity" with which the physician (or an immediate family member) has a financial relationship (ownership or compensation), and prohibits the entity from billing Medicare for the DHS, unless an exception applies. The law and regulations have numerous exceptions for compensation relationships, but relatively few exceptions for ownership relationships.

In 2008, CMS revised the definition of "entity" so that, effective October 1, 2009, it includes a person or entity that performs services billed as DHS, regardless of whether the person or entity bills the services or whether some other person or entity bills the services.[2] Currently, the definition of what constitutes an "entity" includes only the person or entity that bills Medicare fo DHS. The October 1, 2009, revision was intended to address "under arrangements" situations in which a physician refers a patient for services furnished by the physician's owned service provider (such as a freestanding MRI center or a cardiac catherization lab), which are then sold t a hospital and billed by the hospital as outpatient or inpatient services to Medicare. The revision' effect requires that a referral from a physician owner in such an arrangement meet an ownership exception. As a practical matter, if the rural provider exception is not available, the arrangement will have to be unwound or restructured (e.g., the service could be billed by the referring physician's group practice and protected under the in-office ancillary services exception). [3]

In *Colorado Heart Institute*, the court noted the general rule that the Medicare Statute precludes federal question jurisdiction to hear pre-enforcement challenges to Medicare regulations and instead requires that a claim first be presented to the Secretary of DHHS and that the claimant exhaust its administrative remedies prior to filing suit.[4] The court also noted a narrow exception to this general rule, for the situation in which the claimant cannot get his or her claim heard administratively. In that situation, the Medicare Statute will not bar a challenge brought on federal question jurisdiction grounds. However, in this case, the court ruled that the exception di not apply, despite the fact that the plaintiffs would not have standing to present a claim to the Secretary for services billed by a hospital. Relying on *American Chiropractic Association, Inc. v Leavitt*, 431 F.3d 812 (D.C. Cir. 2005), the court focused on whether the plaintiffs could get the challenge heard, even indirectly, and not on whether they could present the challenge. The plaintiffs argued that *American Chiropactic* was not applicable because in that case the court found that the plaintiff association of chiropractics could get its claim heard because its members had direct access to the administrative appeals process as the assignee of their patients. The plaintiffs also argued that they had the right to immediate review because, although hospitals would have standing to bring an administrative claim, hospitals were not adequate proxies

because hospitals did not have the incentive to present a claim and seek administrative review.

The court disagreed with both contentions. First, it stated that if *American Chiropractic Association* was based solely on the right of the association members to obtain administrative review as assignees of their patients' appeal rights, there would have been no reason to discuss how the chiropractors could get their claim heard indirectly. Second, the court was unpersuaded by the plaintiff's argument that, under *American Lithotripsy Society v. Thompson*[5], a court has jurisdiction if the plaintiffs themselves cannot bring a claim and there is no other party that can serve as an adequate proxy for the plaintiffs. The court noted that in *American Lithotripsy* the court relied on the reasoning of the district court in *American Chiropractic* in finding jurisdiction due to an inadequate proxy, and that this reasoning was omitted by the D.C. Circuit when it reversed the district court in *American Chiropractic*. Further, the court stated, even if the law of the D.C. Circuit is that the presence of an adequate proxy is necessary to defeat jurisdiction, here there is an adequate proxy for the plaintiffs. In this regard, the court found that hospitals would have the necessary incentive to challenge the rule if, as the plaintiffs alleged, hospitals profited through services furnished "under arrangements" because the plaintiffs could provide the cardiac catherization services at a lower cost than the hospitals could provide directly. In addition, the court also noted that the Secretary assured the court that hospitals could bring an administrative challenge without risk of incurring sanctions. The government's representation that a claim could be brought without risk of being accused of filing a false claim was also a factor in the court's denial of jurisdiction in *Atlantic Urological Associates, P.A. v. Leavitt*, 549 F. Supp. 2d 20 (D.D.C. 2008), which was decided by the same judge (Collyer, J.) as in *Colorado Heart Institute*.[6]

The *Colorado Heart Institute* court's reasoning, if adopted by other courts, could make it difficult for plaintiff's to bring pre-enforcement challenges to Medicare rules, including other Stark rules. For example, it may affect *Council for Urological Interests v. Johnson*[7], a recently-filed case challenging the recent prohibition on "per-click" leasing arrangements. In 2008, CMS revised its Stark regulations to prohibit, effective October 1, 2009, a physician lessor of equipment, such as lithotriptors and lasers, from receiving a "per-click" (per-unit of service) fee from the lessee (typically a hospital) to the extent that the equipment is used in treating a patient referred by the physician lessor to the lessee.[8] The rule was designed to cover not only referrals from a physician who is the sole owner/lessor of equipment, but also referrals from a physician who has an ownership in an entity that is the lessor of the equipment. CMS amended its regulations partly out of concern that physicians who receive a separate payment each time equipment owned by them is used to treat a patient referred by them would have the incentive to over-refer.

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1 Section 1877 of the Social Security Act, 42 U.S.C. §1395nn.

2 *See* 73 Fed. Reg. at 418721-33.

3 The Stark law and regulations provide relatively few ownership exceptions, and the rural provider exception at 42 C.F.R. §411.356(c)(1) would seem to be the only one potentially available to protect referrals from a physician owner to a service provider that sells services to a hospital that then bills for them "under arrangements."

4 *See* 42 U.S.C. §405(h), incorporated into the Medicare Statute by 42 U.S.C. §1395ii.

5 215 F. Supp.2d 23 (D.D.C. 2002).

6 Cf. *American Lithotripsy Society*, 215 F. Supp.2d at 29-30 (federal question jurisdiction not precluded because of risk of serious sanctions in bringing administrative claim, which risk of sanctions was not contested by the government).

7 No. 1:09-cv-00546-HHK (D.D.C. complaint filed Mar. 23, 2009).

8 *See* 73 Fed. Reg. at 48713-21.

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