

## Cardiologists Sue Over Stark Changes

As mentioned in the Fall 2008 issue of Health Capital Topics, the 2009 IPPS Final Rule has redefined the definition of “an entity furnishing designated health services [DHS]” to include any entity that provides DHS, rather than the original definition which only included an entity that bills for DHS.<sup>1</sup> In response to this new definition, a group of cardiologists and vascular surgeons in Colorado filed a class action lawsuit on September 23, 2008 in the U.S. District Court for the District of Columbia, claiming that, by expanding the definition of “entity furnishing DHS services,” the cath labs in which they perform services (and have an ownership interest in) are now considered an “entity” under the Stark Law will, thereby prohibiting them from making referrals to the cath labs in which they have an ownership interest.<sup>2</sup>

The Plaintiffs provide services in physician-owned cath labs, located in hospitals, through an “under arrangement” contract with the hospitals. An “under arrangement” agreement occurs when a hospital contracts with a third party (e.g., a physician-owned entity such as a cath lab) to provide services to the hospital patients on behalf of the hospital. The hospital pays the third party and is then responsible for billing and collecting from third-party payors.<sup>3</sup>

While “under arrangement” agreements are allowable, they are heavily regulated by the governments, i.e., services provided must be inpatient and outpatient hospital services that are provided on behalf of the hospital; the hospital accepts and takes authority over the professional services; the hospital cannot merely serve as a “billing mechanism” for the third party performing the services; and, the hospital must bill third-party payors directly for services provided under the agreement.<sup>4</sup> Consequently, the only revenue the physician-owned cath labs receive for cardiac cath services performed is those provided directly by the hospital. Even though Stark Law prohibits self-referrals, CMS had previously stated that “physician ownership of any under arrangements provider...created a compensation arrangement, not a prohibited ownership interest,” and had determined that “under arrangements” relationships did not classify as “impermissible ownership interest.”<sup>5</sup> To regulate these agreements further, Congress created a “compensation exception” to Stark Law, which provides that physician referrals to a

DHS entity where the physician has a compensation agreement are not prohibited, as long as all aspects of a compensation exception have been met.<sup>6</sup> By creating the exception, Medicare can ignore the referring physician’s ownership in the entity that provides the services and focus on the compliance compensation standards in the under arrangement services. Accordingly, prior to the 2009 IPPS Final Rule, individual physicians were allowed to refer Medicare patients and provide services to them at local hospitals as long as physicians complied with “compensation exceptions.”

However, the new regulation of an “entity furnishing DHS” labels the physician-owned cath labs as an “entity,” ignoring the under arrangements agreements and compensation exception set forth by Congress as well as CMS’ own interpretation. Consequently, under the new definition, Stark Law will prohibit them from referring their Medicare patients to local hospitals thereby forcing the physician-owned cath labs to close their business. Given this information, the Plaintiffs argue that the new definition of “entity furnishing DHS” ignores Congress’ interpretation as well as CMS’ own interpretation of Stark Law. Furthermore, the lawsuit stipulates that by redefining “furnishing DHS,” CMS voids Congress’ Under Arrangements Exception.<sup>7</sup>

Furthermore, the Plaintiffs argue that CMS has no evidence of fraud or abuse – the supposed reason for the expanded definition of “furnishing DHS.” Given that there is no evidence to support such findings, the Plaintiffs argue the contrary that eliminating under arrangement agreements for cath lab services will force hospitals to unbundle their services and will be providing these services as a higher cost than the Cardiac Cath Plaintiffs.<sup>8</sup>

The Plaintiffs also argue that the new definition is contrary to Stark Law definitions in that the new definition of “furnishing DHS” states that even providers who cannot bill Medicare are still considered to be providing DHS. Given that Stark Law prohibits entities from billing Medicare for prohibited services, Medicare’s jurisdiction to enforce Stark Law lies in recovering improper billing. Since, the physician-owned entities cannot bill Medicare directly, Medicare cannot regulate these actions. The Plaintiffs therefore argue that

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if Congress had intended to include this expanded definition of “*furnishing DHS*” in Stark Law, they would have not have Medicare regulating it.

Additionally, the Plaintiff’s argue that the new definition ignores the fact that the physicians merely act as vendors and do not have an ownership interest in the hospital. In fact, the general public believes the services are provided by the hospital. Furthermore, the hospital sets the prices for the services, as well as exercising professional responsibility and overseeing credentialing standards for physicians. Finally, Plaintiff’s claim that the 2009 IPPS Final Rule is contrary to CMS’ existing interpretation that a referral from a physician who will perform the referred service is not considered a referral under Stark.<sup>9</sup>

Plaintiffs seek relief declaring that the definition of the an “entity furnishing DHS” in 2009 IPPS Final Rule as applied to the Plaintiffs is contrary to the statutory

authority found in the Stark Law; is arbitrary and capricious; and, was issued in excess of CMS’ administrative authority, thereby invalidating the definition of “*entity furnishing DHS*” contained in the 2009 IPPS rule and leaving the current definition as contained in the Stark Law in full effect, as applied to Plaintiffs.<sup>10</sup>

<sup>1</sup> *Colorado Heart Institute, LLC et al v. Leavitt* at 23, 1:2008cv01626 (D.C. Cir.)

Filed September 23, 2008

<sup>2</sup> *CHI v. Leavitt* at 28

<sup>3</sup> *CHI v. Leavitt* at 17

<sup>4</sup> *CHI v. Leavitt* at 18

<sup>5</sup> *CHI v. Leavitt* at 22

<sup>6</sup> *CHI v. Leavitt* at 20

<sup>7</sup> *CHI v. Leavitt* at 21-22

<sup>8</sup> *CHI v. Leavitt* at 26-27

<sup>9</sup> *CHI v. Leavitt* at 26

<sup>10</sup> *CHI v. Leavitt* at 31

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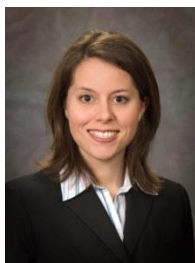
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