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Appeals Court Ruling Sets Stage For Challenge to 2008 Stark Ban

A popular type of joint venture may get a new lease on life in light of a Dec. 23 federal appellate court decision. The U.S. Court of Appeals for the District of Columbia Circuit has cleared the way for a challenge to the 2008 Stark law regulation that essentially put an end to "under arrangements."

The under arrangements provision was contested by the Council for Urological Interests. The upshot of the decision: even though the council and its members don't submit Medicare claims, the appellate court ruled the organization can fight CMS over the substance of the regulation. The battle will resume in federal district court.

In a typical under arrangement, a physician entity (e.g., group practice) provides the soup-to-nuts of a hospital service — including the equipment, staff and management — but the patient belongs to the hospital and is billed to Medicare accordingly. The hospital then pays the physician entity, which essentially functions as a subcontractor.

The Stark law bans Medicare payment to entities that perform designated health services (DHS) stemming from referrals by physicians who have a financial relationship with the DHS entity. Because it was concerned about abuses, CMS orchestrated the end of under arrangements by changing a Stark definition in the 2008 regulation, which took effect Oct. 1, 2009. Before then, only the entity that bills for DHS could run afoul of the law. That worked beautifully for under arrangements because the hospital did the billing while the physician entity provided the services, which meant referrals between them were protected.

But since the new reg took effect, the physician entity triggers the Stark ban if it performs services, such as cardiac catheterization, open MRIs or nuclear cameras. The same Stark regulation put an end to per-use (per-click) fees for equipment or space leased by physicians to hospitals if the per-click charges reflect patients referred by the physicians to the hospitals.

"These rules, along with a related ban on percentage-lease arrangements, were some of the most significant changes to the Stark regulations" since CMS first spelled out the law in Phase One, says Macon, Ga., attorney Alan Rumph, with Smith Hawkins.

Hospitals never challenged the Stark ban on under arrangements. In 2009, the Council for Urological Interests, an association of physician-owned equipment providers, argued that the 2008 Stark rules affecting under arrangements effectively outlaw the business ventures of its members. The council also argued it had the right to seek relief from the civil court system because administrative review under the Medicare Act is unavailable for entities that don't submit claims.

The federal district court dismissed the case on the grounds that hospitals — the other half of the under-arrangement — had standing to challenge the Stark regulations the usual way, through administrative review. So the council appealed to the second-highest court in the land.

In this particular case, the appeals court ruled that the council "may invoke the district court's general federal question jurisdiction without first seeking administrative review under the Medicare Act." Otherwise, there would be no access to judicial review because hospitals aren't challenging the Stark regulation. Rumph says there's a good reason why no hospitals have challenged the 2008 Stark rule. "With under arrangements, as well as per-click or percentage leases, hospitals often share with referring physicians the profits that the hospitals would otherwise keep for themselves," he says.

Urologists have a lot at stake in under arrangements with hospitals. As the court decision notes, 75% of patients who undergo urologic surgery are covered by Medicare, which throws providers in Stark's path. In addition to laser-surgery arrangements — the topic of the council's lawsuit — urologists perform lithotripsy to blast kidney stones in hospital settings.

But lithotripsy is the one service for which referring physicians remain able to own the under arrangements entity, notwithstanding the 2008 regulation. "The American Lithotripsy Society case, which was brought by a predecessor to the council, established the principle that lithotripsy is not a [Stark] DHS, even when provided and billed by a hospital," Rumph says. CMS agreed, and explained in its answer to a frequently asked question on a Stark issue (FAQ 9556) that physician lithotripsy entities that perform services and don't just lease equipment may receive percentage or per-click payments from hospitals.

Contact Rumph at Alan@shhrlaw.com. View the FAQ at https://questions.cms.hhs.gov/app/answers/detail/a_id/9556/kw/lithotripsy/session/L3NpZC9FYUN6WW9Oaw%3D%3D. ✧