Self-Referral Rule Marks Return to Earlier Policy

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In issuing the third phase of the final regulations implementing the physician self-referral rule, also known as the Stark law, the Center for Medicare and Medicaid Services has returned to a stance it held in the first phase.

The Stark law governs whether, how, and when it is acceptable for a physician to refer patients to hospitals, laboratories, imaging facilities, or other entities in which the physician may have an ownership interest.

Under the new rule, known as Stark III, to be published in the Federal Register on Sept. 5, physicians will be considered to be "standing in the shoes" of the group practice when their investment arrangements are evaluated for compliance, according to several attorneys.

This reversion back to the initial Stark policy is among the most important changes in the 516-page document, said Daniel H. Melvin, J.D., a partner in the health law department of McDermott, Will & Emery's Chicago office.

CMS came to see the indirect compensation analysis as a loophole that allowed potentially questionable investments to slip through.

As a result, "the application of exceptions will be different going forward," Mr. Melvin said in an interview.

That means that most physicians who have referral arrangements will have "a lot of contracts that will have to be looked at and possibly revised," said Amy E. Nordeng, J.D., a counsel in the government affairs office of the Medical Group Management Association. Ms. Nordeng agreed that the return to the "stand in the shoes" view was the most significant component of Stark III.

Under Stark II—an interim policy that began in 2004—physicians were considered to be individuals, outside of their practices.

Exceptions to the law were evaluated using an indirect compensation analysis, which ended up being onerous and was the subject of many complaints to CMS. In comments on Stark II, physician groups, hospitals, and other facilities (called designated health services, or DHS entities, under the Stark law) urged CMS to revert to the old policy.

CMS itself came to see the indirect compensation analysis as a loophole that allowed potentially questionable investment arrangements to slip through, Mr. Melvin said.

In the Stark III rule, CMS wrote that the change in policy means that "many compensation arrangements that were analyzed under Phase II as indirect compensation arrangements are now analyzed as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements."

There were several other notable changes in Stark III.

The regulations clarify that physicians who administer pharmaceuticals under Medicare Part B (such as chemotherapy or infusions) or who prescribe physical therapy, occupational therapy, and speech-language pathology, are entitled to get direct productivity credit for those orders, Mr. Melvin said.

The clarification applies to those two ancillary services only, not to radiology or laboratories, or other services typically offered in-house, he said.

CMS also lifted the prohibition on noncompete agreements. Under Stark II, practices could not impose noncompete agreements on physician recruits. Now, practices can bar competition for up to 2 years, but it's not clear how far, geographically, that noncompete can extend, Mr. Melvin said.

With the new rule, practices have to "go back and look at everything," including how their physicians are being compensated and the arrangements the practice may have for equipment and leasing or services with hospitals or other DHS entities, he said.

"At the very least, they're going to want to do a review of the arrangements in place," to see if any of the exceptions being relied on will change with Stark III, Ms. Nordeng added.

The final Stark rule goes into effect on December 5, 2007. ■