Appeals court ruling in Hanlester case adds to physician self-referral tumult

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Congressional hearing on Stark II set for May 3 A U.S. Court of Appeals panel this month significantly raised the standard that federal investigators must meet to successfully prosecute cases of physician self-referral under Medicare anti-kickback laws. The decision was considered a major blow to federal efforts to crack down on self-referral using the anti-kickback rules. It may also offer peace of mind to non-physician-owned companies forming joint-venture arrangements with imaging centers. The case stemmed from a Department of Health and Human Services effort that began in 1988 to prosecute the Hanlester Network, a group of clinical laboratories that relied heavily on physician investors. The government alleged that Hanlester broke federal anti-kickback laws by recruiting physician investors and compensating them through profit distributions to induce them to refer Medicare and Medicaid patients to Hanlester labs. The anti-kickback rules were passed in the 1970s to rein in self-referral abuses.

On April 6, however, the U.S. Court of Appeals for the Ninth Circuit in San Francisco ruled against the government. The court said that in order for the conviction to stand, prosecutors had to prove that the parties involved in joint-venture arrangements had specific intent to induce investor referrals. The ruling is a serious setback for the feds, according to Gary Fields, an attorney with Proskauer, Rose, Goetz and Mendelsohn in New York City. "It is going to make the enforcement of the anti-kickback statute with regard to joint ventures and other ventures between physicians, hospitals and integrated delivery systems much more difficult for the government," Fields told SCAN. "They now have to prove that there was actual intent on the part of the participants to induce referrals."

The ruling will primarily impact joint ventures that do not directly involve physicians, who are already banned from self-referral arrangements in Medicare and Medicaid by the provisions of Stark I and Stark II, according to Fields. Stark I and Stark II were passed after the government began its investigation of the Hanlester case. "I don't think this will have a profound impact on what physicians can do, but it will have an effect on all the other players: public companies, hospitals, not-for-profit institutions," Fields said. "It will give them greater latitude in structuring transactions, but when they are structuring with physicians, they still have to be concerned about the Stark statute."

Stark II hearing scheduled. Concerns about Stark II continue to build in Washington, DC. Rep. Bill Thomas (R-CA), chair of the House of Representatives subcommittee on health, is examining Stark II and may propose changes to the law (SCAN 3/15/95).

A hearing on Stark II has been scheduled for May 3. As the date approaches, parties on both sides of the fence are preparing for a legislative cat fight. One group that opposes Stark II, the Medical Group Management Association, this month released a set of changes to the law that it would like to see implemented. Among the proposed revisions is a change in the list of designated health services covered by Stark II. MGMA is proposing that some health services including radiology -- except for MRI and CT -- be removed from the list. MGMA's exemption of MRI and CT is significant. MRI services were frequently cited as an area of self-referral abuse when the debate over Stark II was raging, and since then the modality has become a symbol for the perceived excesses of high-tech medicine. The exemption may indicate that there is a lack of political momentum for removing the services from Stark II's mandate. Indeed, Randy Teach, director of MGMA's Washington, DC, office, said MRI and CT were removed after meetings with other groups that advocate revisions to Stark II.
"There seemed to be a feeling among participants in our discussion that (MRI and CT) are areas that could be controversial on their own," Teach said. "We've tried to create a list that is defensible."

There is political support to spare for revising the rest of the law, however. Stark II's ambiguities, which have been exacerbated by a lack of implementing regulations, have baffled the health-care industry since the law took effect Jan. 1, according to Fields.

Implementing regulations for Stark I appear to be on the way, and may help clarify the situation. The Health Care Financing Administration initially targeted late April for promulgation of the rules. It appears that they will miss that deadline, but the agency is believed to be close to finishing its work. Proposed Stark II rules are expected to follow by the end of the year.

Disclosures:

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