Lead Report

Fraud and Abuse

AHLA Stark Reform Proposals Welcome, Have Little Chance of Success, Attorneys Say

American Health Lawyers Association proposals to restructure the physician self-referral law to address the statute's complexity and unintended consequences are a significant contribution to policy discussions about the Stark Law but appear to have only a small chance of passage by Congress, according to health law attorneys interviewed by BNA.

Released Aug. 10, the AHLA Public Interest Committee white paper is the product of a two-part session where a broad spectrum of health care attorneys discussed Stark's problems and benefits in light of the U.S. health care system's current structure and pending health insurance reform proposals.

Difficulties with the law were summarized succinctly for BNA by Karl A. Thallner of Reed Smith LLP in Philadelphia: ''The Stark law is extraordinarily complex, the scope of its self-referral prohibition is uneven and too often counter-intuitive, its enforcement is haphazard, it leaves providers with no palatable solutions to compliance problems when discovered, and its sanctions are frequently disproportionate.'' As the white paper put it, the risk that violating Stark, a strict liability statute, ''might result in a level of exposure that could effectively bankrupt a hospital is a scenario that haunts administrators.''

The Stark Law is simple on its face, prohibiting—unless an exception applies—physician referrals of Medicare patients for certain designated health services to a provider with which the physician (or an immediate family member) has a financial relationship. It prohibits billing the Medicare program for any service that violates this prohibition.

''No one doubts the need for a law that protects patients from financial arrangements (whether by ownership or compensation) that provide incentives to enrich referring physicians without regard for or with potential adverse impact on patient health,'' Jack Rovner of The Health Law Consultancy in Chicago told BNA. Stark itself is complicated, not because this goal is complicated, but because its operation is and necessarily will continue to be exceedingly ''complex, confusing and challenging,'' he added.

The white paper warned that applying today's Stark in a post-health-care-reform world could significantly impede efforts to align hospital-physician financial incentives such as pay-for-performance, gainsharing, or bundled payment or outcomes measures.

Robert G. Homchick, with Davis Wright Tremaine LLP in Seattle, a member of the panel and the principal author of the white paper, told BNA that the paper and the two-day ''convener session'' of representatives of the health care industry, each branch of government, academics, patients, and consumers were intended to provide an overview of the self-referral law and regulations and propose ways in which Congress could improve it. Thallner said that, because of the panel's composition, its work product has ''especial credibility,'' unlike earlier critiques advanced by groups having a particular stake in the outcome. The white paper presents an ''objective, balanced view of the Stark law that hopefully will facilitate reasoned consideration of changes to the law,'' he said.

''It is the application of the Stark law that is and will continue to be exceedingly complex.''

JACK A. ROVNER,
THE HEALTH LAW CONSULTANCY, CHICAGO

Reece Hirsch of Morgan, Lewis & Bockius LLP in San Francisco said the white paper is important because it draws attention to ''just how convoluted and burdensome the statute has become and refocuses public policy objectives on abuses the law was originally intended to address.''

Homchick said he believes that some of the recommendations from the convener session could be handled by the Centers for Medicare & Medicaid Services, but that most were aimed at Congress. The white paper has been distributed to lawmakers, he said, but he does not expect that body to address its recommendations in the first round of health care reform legislation. He does hope, however, that attention to technical health law regulations like Stark's that are so ''challenging to apply and difficult to explain'' will come up in later health care legislation. Compliance with the current Stark law and regulations, several conveners said, is exceedingly difficult ''even for the best-intentioned providers.''

Restructuring Recommendations. Among suggestions in the white paper was to change the law so that it prohibits certain types of physician financial relationships, rather than creates exceptions into which all financial relationships must fit.

Some panel members were skeptical, as was Thallner, that lawmakers or CMS regulators would be able to define a list of illegal arrangements that would effectively control inappropriate behaviors. Thallner said that any such list, even if it could be developed, would have to change often enough to counter the new kinds of relationship that likely would emerge, perhaps in response to the list of prohibited relationships. This would only create a new uncertainty for providers.

Rovner said specifying illegal arrangements would be unlikely to reduce Stark's complexities. ''It would only shift complexities from determining if an arrangement is allowed because it meets an exception to determining if an arrangement is within the ban. New arrangements

that might be designed also could be abusive to patient interests, but since only those specified would be illegal and amending the law or regulations would take ''far too long to stay in step,'' these abuses could continue for some time before being stopped, he said.

Ownership, Compensation Interests. The paper also included a recommendation to limit the referral prohibition to ownership interests. For example, the panel agreed that so-called passive ownership interests where a physician ''does nothing more than refer patients and collect a check'' are susceptible to abuse, but that compensation arrangements are less susceptible to inappropriate referrals and could be eliminated from the statute. The Anti-kickback Statute still would be available to address truly abusive compensation arrangements, the panel said.

But not all panel participants agreed with the recommendation, arguing that eliminating compensation arrangements from the law would ''eviscerate'' the statute.

A recommendation to narrow the scope of compensation arrangements covered by the law also produced reservations. The health care industry's ability to design compensation arrangements that replicate the benefits and dangers of physician ownership without technically involving ownership was acknowledged. But panelists also noted that Stark was enacted when the government was in the process of litigating whether a kickback violation could be a false claim. Given the evolution of False Claims Act case law, there is less need for the Stark law's compensation provisions, the paper said.

The panel also suggested that Congress add an intent requirement to the Stark law.

''Under this approach, a physician referral or the submission of a claim by an entity would not be prohibited unless the action was taken with the knowledge that it was prohibited,'' the paper stated.

While some panel members said an intent requirement would ''avoid exposing innocent parties to significant sanctions'' for inadvertent technical violations, others argued that requiring proof of intent to show a violation would undermine the efficacy of the law and make it look more like the kickback prohibition that already exists in the Anti-kickback Statute. Rovner and Thallner agreed, saying an intent requirement's high standard of proof would weaken the ability of the Stark law, which now is a strict liability statute, to police potentially abusive relationships.

Other suggestions were to carve out small-dollar arrangements through a broad de minimis exception and to adopt a technical violation exception, a change that Thallner said is the ''minimum that should be done.'' This would avoid potentially major consequences for fairly innocuous transgressions such as failing to secure a physician's signature when all other elements of the relevant exception are satisfied, he said. Opponents pointed out that the tension between the Stark and anti-kickback laws would make it difficult for the government to accept a broad de minimis Stark exception without undercutting its ability to pursue anti-kickback claims. The paper also noted that if covered Stark compensation arrangements were limited to those where compensation varies with the volume or value of referrals, there should be no need for a broad de minimis exception.

A recommendation to give CMS broader rulemaking discretion to simplify Stark regulations caused Thallner to question whether CMS actually would use any additional discretion to alleviate the current burden and risks on the industry to any significant degree.

Homchick noted that the panel identified positive results of the law as well as making recommendations for improvements. The law has encouraged compliance programs, restricted improper physician investment in certain ancillary services, and aided in FCA enforcement, the paper said.

Political Backdrop to Debate. Not surprisingly, political considerations were a constant backdrop to the comments made by BNA interviewees. Patrick D. Seiter of Adams and Reese LLP in Baton Rouge said Congress probably will not initiate changes to the Stark law just to reduce the complexity or compliance burdens on providers, but might take action if Stark is seen as complicating payment reforms.

Mark R. Thompson of Seigfreid Bingham in Kansas City, Mo., for example, said several of the panel recommendations, such as listing illegal arrangements, ''would be ideal for simplification and clarity'' but are not likely to ''fly politically,'' he said.

Hirsch said reform may be difficult because ''it involves acknowledging that Stark regulations developed and amended over the course of many years have veered down the wrong path.''

Rovner said he does not believe any of the major changes proposed by AHLA is legislatively or administratively feasible. ''It is the application of the Stark law that is and will continue to be exceedingly complex,'' he said. While the white paper clearly explains the difficulties in applying Stark, he told BNA that conveners' own disagreements about how to reduce the confusion reflect the real problem with trying to strike a balance between protecting Medicare beneficiaries and permitting physician financial arrangements that may improve care for patients—like the in-office ancillary services exception—or at least make things more convenient for them. These are ''very elusive tasks,'' he said.

Thompson suggested that legislators seeking to improve the Stark law keep another fact in mind. As the white paper observed, valuation firms have benefited greatly from Stark's fair market value requirements, Thompson said. Law firms, too, ''have earned handsome fees advising our clients how to comply and how to address the inevitable noncompliance mistakes that occur. Lawyers' and valuators' energies would be better spent on legal (and valuation) issues associated with improving access and quality. Much of what Congress addresses through laws like Stark and the AKS could be better dealt with by changing the payment incentives to focus on prevention, wellness, and disease management rather than on episodes of care.''

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The white paper is available at http://www.healthlawyers.org/Resources/PI/Policy/Documents/Stark%20White%20Paper%2008.03.2009%20FINAL.pdf.

  HLR ISSN 1064-2137