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HHS Goal: Be Bold With Physician Self-Referral Reforms

A groundswell of detailed industry comments on the physician self-referral law will lead to bold reform from the Trump administration, the No. 2 official in the Department of Health and Human Services told Bloomberg Law.

''We're going to try to be as bold as we can within the restrictions of the law'' to make changes to the self-referral or Stark law that can help foster coordinated care, Deputy HHS Secretary Eric Hargan said Sept. 6 in an interview.

The HHS plans to focus on a number of achievable reforms that can have the highest impact, not a fundamental overhaul of the law's restrictions, Hargan said.

Hargan said he recently spoke with doctors and hospital administrators, and when he brought up Stark reform, he was surprised to get spontaneous applause. ''There has been a lot of pent-up interest in reforming'' the Stark law, he said, and the HHS plans to put reforms in place ''as swiftly as we can.''

The Stark law, named after its congressional sponsor and first enacted in 1989, prevents physicians from referring patients to medical facilities where they or their immediate family members have financial interests. Penalties for violating the law can include $15,000 for each medical service and three times the amount of Medicare payments received for services.

The comments came to the HHS in response to a late June request for information or RFI about Stark. The department's Centers for Medicare & Medicaid Services asked for comments by Aug. 24. The HHS is asking for input on other areas of health regulation, including anti-kickback restrictions, through RFIs.

In July, another Trump administration official, Centers for Medicare & Medicaid Services Administrator Seema Verma, said she hopes to address barriers to care coordination from the Stark law by the end of the year.

Flexibility The HHS has heard from commenters that they want more flexibility on the relationships between hospitals and doctors, laboratory service use, diagnostics, and evaluations, Hargan said. Stakeholders are especially concerned about rental and leasing agreements involving health-care providers.

The department is also looking at potential changes to how certain Stark law terms are defined, as well as exceptions to the law, Hargan said.

The stakeholders that commented cited concerns about the Stark law having strict liability, which means a doctor can violate the law without intending to do so, Hargan said. The ''agency can make things clearer than they have been,'' Hargan said, and intends to do that.

It will ''require thoughtfulness to make sure we don't take away the good parts of the law that have got to be operative to address the issue that is still out there . . . and don't stand in the way of us actually being able to coordinate care,'' Hargan said.

''The law itself has inbuilt a lot of deliberate restrictions that we are going to continue to enforce . . . but that doesn't mean we don't have a good amount of flexibility in how we are going to be able to interpret the law or allow some kinds of relief,'' Hargan said.

Reflecting Coordinated Care The Stark law has been a problem for the industry in a way that was not intended by the agency, Hargan said. When Stark was put into place, it was addressing an active problem of getting more money by feeding patients into a system a healthcare provider owns, but that is less of a problem with the focus on coordinated care.

As efforts to coordinate care expand, ''it doesn't matter as much if you send somebody into a particular institution'' because a payer is compensating for an outcome, Hargan said. Doctors won't be making extra money by having a patient go through multiple procedures.

''It's probably not the best situation'' to need to pay a lawyer to navigate day-to-day issues like leasing space in an office, employing a person, renting equipment, or renting space in a hospital, Hargan said.

The System Has Changed The consequences of violating the Stark law can be devastating, Hargan said, and it's ''relatively easy for the agency to go out and find a violation.'' He said, ''The industry doesn't necessarily know when they're developing a model'' that it could be violating the Stark law.

Coordinated care is ''an idea whose time has come,'' Hargan said. ''The system has changed. People are able to coordinate more closely'' because of changes in information technology, computer systems, and the ability to assess value and outcomes.

Agencies were ''open to taking a fresh look'' at the Stark law, and Hargan said he saw it as an issue when he joined the administration. ''If we can enable [coordinated care] without enabling the bad parts of the system, that's a pretty good goal,'' he said.

Congress Congress is also looking at potential changes to the self-referral law. Companion bills have been introduced in the House and Senate to create alternative financial penalties for procedural violations of the Stark law. Rep. Kenny Marchant (R-Texas), a House Ways and Means Committee member, intro-

duced H.R. 3726 while Sen. David Perdue (R-Ga.) introduced S. 3054.

The Ways and Means Committee has Medicare jurisdiction, and Stark law reform has come up at four roundtables the Ways and Means Health Subcommittee has hosted this year, according to a June 20 statement from the committee's chairman, Rep. Kevin Brady (R-Texas).

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