Bloomberg Law News 2020-11-24T12:50:57394-05:00

Changes to Anti-Fraud Laws Spur ‘Paradigm Shift’ in Health Care

By Lydia Wheeler 2020-11-24T12:19:27000-05:00

- Changes received bipartisan support
- Existing law stops doctors from coordinating

Recent major changes to how anti-fraud health laws are enforced pave the way for payment systems that create incentives for doctors to focus on the whole health of the patient rather than on individual treatments.

Final rules released by the Department of Health and Human Services Nov. 20 carved out new exemptions to the Physician Self-Referral law and Anti-Kickback statute, which have long been seen as barriers to paying doctors based on patient outcomes rather than for each isolated service. One rule provides new shields under the criminal kickback law, among other things, and another spells out exceptions under the civil self-referral law.

The administration’s unusual decision to expand its initial proposed anti-fraud rule to cover more industry sectors and transactions signals a bipartisan recognition that the law has stopped many health systems from going as far as they’d like in providing holistic care.

The final rules together “reflect a paradigm shift in the payment for and delivery of health-care away from the historical fee-for-service model and into a value-based service model,” said Samantha Gross, an associate at Saul Ewing Arnstein & Lehr LLP. They “reflect HHS’s recognition that value-based arrangements carry a low risk of fraud and abuse.”

Notable Changes

The Physician Self-Referral law, known as the Stark law, prohibits physicians from referring patients for certain health services paid by Medicare or Medicaid if the physician or an immediate family member has a financial relationship with that hospital and health-care facility. The Anti-Kickback statute prohibits doctors from paying or receiving money—or anything of value—for referrals that result in an item or service that’s paid by a federal health care program.

Both laws carry big fines for violators, which explains health providers’ hesitance to move forward

with coordinated care arrangements between facilities or specialists.

“Value-based arrangements have been finding their way into the health-care industry despite the safe harbor absences, but I think the breadth with which these rules describe what value-based arrangements are is likely to give people a lot more comfort,” said Thomas Bulleit, a partner at Ropes & Gray LLP.

Several pharma-related sectors are still subject to more scrutiny under the Anti-Kickback law even with the final rule. The HHS excluded a laundry list of entities from Anti-Kickback safe harbors for value-based arrangements, including pharmaceutical companies; pharmacy benefit managers, laboratory companies, compounding pharmacies, manufacturers of devices or medical supplies, durable medical equipment companies, and medical device distributors and wholesalers.

But in a notable change from the proposed to final rule, the agency set specific conditions under which medical device makers or suppliers can qualify for protection: when care coordination involves the exchange
of digital health technology, like cloud storage services, to monitor patients. For example, blood sugar measurement device suppliers can take advantage of the safe harbor if they’re coordinating with a digital health technology company to monitor blood sugar in people with diabetes.

The agencies “didn’t want to throw the doors wide open right out of the gate,” said Karen Lovitch, chair of the health law practice at Mintz. “It opened the door a crack for the medical device manufacturers and suppliers.”

In the Stark Law rule, the Centers for Medicare & Medicaid Services also pulled back on earlier plans to narrow an existing exception for isolated financial transactions that have saved hospitals from getting slapped with steep fines if they fail put a financial relationship with a physician in writing.

The CMS originally wanted to limit the exception to payments that total no more than $3,500 annually but expanded that figure to $5,000 in the final rule. Commenters had asked for the agency to settle on a figure between $5,000 and $10,000.

“The fact they increased it a little bit is beneficial, but I don’t know that there are a significant amount of arrangements that will get the protection,” said Randi Seigel, a partner at Manatt, Phelps & Phillips LLP. “It’s not really supposed to be an exception that you rely on in structuring your relationship.”

Bonus for Biden?

The rules’ release date—so late in the Trump administration that they’ll barely be in effect when President-elect Joe Biden takes office—means the next administration could subject them to further review. But leaving them untouched gives the incoming Biden administration new tools to a move toward value-based care goal that started in the Obama administration.

“This is not controversial stuff from a political point of view,” Bulleit said. “This is the career professionals making decisions.”

Sen. Mark Warner (D-Va.) applauded the agencies for the rules and said he looks forward to working with them and Virginia medical providers to properly implement the changes.

“Reducing long-term health care costs requires a health care system that encourages coordinated care, value-based healthcare, and outcomes-based payment,” he said.

Sen. Michael Bennet (D-Colo.) is also supportive of the new rules, according to a spokesperson. The rules will help improve coordination of care and prevent fraud, the spokesperson said.

—With assistance from Alex Ruoff

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