

Fraud and Abuse

## Doctors Say Fraud and Abuse Law Needs Major Surgery

### BNA Snapshot

- Physicians say fraud and abuse law blocks value-based payments
- CMS is considering some regulatory reforms to Stark law

By James Swann

Physicians are demanding wholesale changes to a federal fraud and abuse law they say is putting a straitjacket on efforts to roll out innovative payment models and provide better patient care.

The calls for change come amid growing indications that the Centers for Medicare & Medicaid Services is prepared to make significant changes to the physician self-referral law, also known as the Stark law.

Physicians should be encouraged to partner with other doctors and hospitals to provide more coordinated patient care, but those arrangements are mostly blocked by the Stark law, Gary Kirsh, president of the Urology Group in Cincinnati, told Bloomberg Law.

These so-called value-based care arrangements can help lower health-care costs by providing bundled payments to physicians instead of standard fee-for-service payments, but Stark needs a face lift before that can happen, Kirsh said. Bundled payment arrangements refer to making a single payment to several health-care providers for coordinating a patient's medical services rather than paying for each individual service.

Any changes to how the Stark law functions in the traditional Medicare fee-for-service program would be a much heavier lift, Kirsh said, though he did say it would be nice to bring care coordination to the fee-for-service space.

The Stark law generally requires that financial arrangements among health-care providers be based on fair market value, not paid based on the volume or value of referrals, and be commercially reasonable, Troy Barsky, a health-care attorney with Crowell & Moring LLP in Washington, told Bloomberg Law.

"Yet value-based payments are by definition payments based on the value of referrals, and therefore don't fit within existing Stark exceptions," Barsky said. Prior to joining Crowell & Moring, Barsky served as director of the division of technical payment policy at the CMS where he was responsible for Stark law policy.

Many value-based arrangements also won't meet the definition of being fair market value, Barsky said, citing the practice of a hospital locating care coordinators in physician offices.

Even though the care coordinators can facilitate high-quality care, they're provided to physicians at no cost, which means the physician is receiving a benefit below fair market value and therefore violating the Stark law, Barsky said.

### A Trickle, Not a Flood

A flood of alternative payment models was expected to materialize after Congress passed the Medicare Access and CHIP Reauthorization Act in 2015, but it's been more like a trickle due to Stark constraints, Kirsh said.

MACRA repealed the sustainable growth rate formula that determined Medicare reimbursement rates for physicians and created new payment models to reward value-based care.

Regulators realized that Stark was a problem when the Affordable Care Act became law and created a Stark law waiver for accountable care organizations (ACOs), but independent physicians were left out in the cold, Kirsh said.

ACOs were designed to provide coordinated patient care but have been dominated by hospitals and haven't worked very well in realizing cost savings, Kirsh said.

"We've created an alternative payment model but we can't test to see if it works financially because of Stark, which is a real Catch-22," Kirsh said.

CMS Administrator Seema Verma has spoken publicly about Stark reform several times over the past year, and the agency recently asked the public for comments on how to improve the Stark law and reduce the burdens it places on health-care providers. Congress has also shown interest in Stark reform, and a House Ways and Means health subcommittee hearing in mid-July was focused on whether the law needed to change.

### **Stark Changes**

Congress needs to step up and make several changes to the Stark law, Kirsh, who testified at the hearing, said. The CMS can make some regulatory changes on its own, but fundamental changes that can open up alternative payment models (APMs) have to be made at the statutory level, Kirsh said.

Specifically, Congress needs to create a mechanism that will let physicians test APMs without violating the Stark law, Kirsh said.

Physicians should be able to go to the Department of Health and Human Services, present a proposal to test an APM, and then proceed with a waiver from the Stark law, Kirsh said.

Congress should also rewrite the Stark law to remove the section that covers financial compensation related to the value and volume of referrals, Kirsh said. The section says that compensation arrangements between physicians have to be fair market value and not based on the volume or value of referrals, going against the very nature of a value-based payment system.

Value-based payment arrangements work under the idea that a number of caregivers, such as physicians, hospitals, and post-acute providers, will work cooperatively to provide better care more efficiently, Karl Thallner Jr., a health-care attorney with Reed Smith LLP in Washington, told Bloomberg Law. Thallner has represented many clients in Stark law cases.

"The kinds of incentives that drive collaborative behavior and care coordination, such as shared savings or other incentives, could be found to run afoul of these constraints because they result in payments not consistent with fair market value for a physician's personally performed services, and/or because they vary with or take into account the volume or value of referrals," Thallner said.

The looming midterm elections are likely to draw attention away from congressional Stark reform. Waiting until next year will run into the problems inherent in a new Congress, where legislative efforts have to start over and momentum for change is lost, Kirsh said.

### **Waivers**

While the CMS does offer certain Stark law waivers, each program has a different waiver, governed by separate requirements, Anders Gilberg, senior vice president for government affairs at the Medical Group Management Association in Washington, told Bloomberg Law.

This can complicate matters when a physician practice participates in multiple alternative payment models, such as a bundled payment model and an accountable care organization, Gilberg, a Bloomberg Law advisory board member, said.

For example, a Stark waiver for a bundled payment model permits gainsharing payments, while an ACO waiver doesn't, Gilberg said. Gainsharing refers to arrangement in which physicians and hospitals share in cost savings.

Furthermore, the waivers only apply to service covered by Medicare, and it's unclear if any protection extends to commercial arrangements.

"CMS can only do so much and we don't simply want more exceptions and waivers for physician practices," Gilberg said.

Doctors Say Fraud and Abuse Law Needs Major Surgery, Health Care Daily Report (BNA)

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