

## How Health Cos. Have Responded To Anti-Kickback Reform

By **Troy Barsky and Barbara Ryland** (January 20, 2022, 3:12 PM EST)

In the beginning of 2021, the Office of Inspector General for the U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services issued regulations that revised anti-fraud and abuse regulations in order to facilitate value-based care arrangements.

In this article, we review these regulatory reforms and reflect on how the health care industry has reacted to these changes. We conclude with some recommendations for needed further reform that may come from either OIG and CMS or potentially from Congress.

The OIG finalized multiple safe harbors under the Anti-Kickback Statute, which prohibits anyone from knowingly or willfully offering or receiving remuneration in exchange for ordering or referring an item or service covered by a federal health care program, which includes Medicare and Medicaid.[1]

CMS finalized similar exceptions to liability under the Physician Self-Referral Law, or Stark Law, which prohibits a physician from making a referral to an entity for designated health services payable by Medicare if the physician or an immediate family member has a financial relationship with the entity.[2]

Both the AKS and Stark Law are considered key to combating health care fraud, as well as providing a strong deterrent to providers from succumbing to undue financial influence in making health care related decisions for Medicare and Medicaid beneficiaries. In addition to potential criminal and civil penalties and program exclusion, violations can result in liability under the False Claims Act.

However, as the federal government has tried to move Medicare and Medicaid reimbursement away from a fee-for-service model, regulators and providers view the fear of being penalized under these laws as a significant barrier to the kind of provider collaboration that is required to effectuate innovative global or value-based reimbursement models.

To date, the OIG and CMS have provided enforcement waivers to the Stark Law and AKS on a case by case basis for CMS value-based demonstration programs, but have not offered protection for any other value-based arrangements.



Troy Barsky



Barbara Ryland

Historically, AKS safe harbor and Stark Law exception status for provider arrangements has been limited to payment for the provision of items or services by capitated managed care plans and their downstream contractors, or the provision of items and services by at-risk provider groups.

The existing safe harbors and exceptions do not clearly protect financial incentives or payments among providers for attaining superior outcomes or meeting optimal standards of care.

The new value-based AKS safe harbors and Stark Law exceptions protect three types of value-based arrangements if safe harbor and exception criteria are met:

- Care coordination arrangements to improve quality, health outcomes and efficiency, or value-based arrangements;<sup>[3]</sup>
- Value-based arrangements with substantial downside financial risk, or meaningful downside risk to physicians;<sup>[4]</sup> and
- Value-based arrangements with full financial risk.<sup>[5]</sup>

Each of the AKS safe harbors and Stark Law exceptions requires a value-based arrangement to meet significant organizational and operational criteria, including a number of interrelated regulatory definitions such as value-based entities, value-based activities, and value-based purposes.

The number of regulatory requirements imposed on different arrangements decrease based on an increased level of financial risk assumption. However, the new safe harbors and exceptions give providers the opportunity to establish arrangements under which they can provide and share financial incentives that are intended to spur or reward better patient outcomes or more effective or efficient patterns of care.

### **Observations and Experiences**

Health care entities, including providers, payers, technology companies and population management companies have adopted different positions and approaches regarding the new value-based exceptions and safe harbors. These entities generally fall into three different categories: (1) the not-yet group; (2) the interested-but-waiting group; and (3) the early adopters.

The not-yet group are those entities that perhaps see the promise of the new safe harbors and exceptions, but are making no move now to use them.

Some entities enjoy protection under existing managed care safe harbors or exceptions like the AKS safe harbors at Title 42 of the Code of Federal Regulations, Sections 1001.952 (t) and (u), or the Stark Law exceptions at Title 42 of the Code of Federal Regulations, Sections 411.354(c) and 357(n).

Still other entities are participating in CMS alternative payment programs, like the Medicare Shared Savings Program, and enjoy protections under broad fraud and abuse waivers.<sup>[6]</sup> The OIG and CMS have stated that they will not eliminate existing fraud and abuse waiver requirements, but will not create new ones for new Center for Medicare & Medicaid Innovation models.

Because the existing fraud and abuse waivers are significantly less onerous than the new safe harbors and exceptions, health care entities have continued to be attracted to models that offer the existing

fraud and abuse waivers.

The second category of entities is interested in the protection that the safe harbors and exceptions have to offer, but are unable or unwilling to engage in protections afforded by these regulatory reforms. Providers and other entities need to invest significant up-front resources as well as ongoing resources to ensure compliance.

Yet many entities do not have the funding to invest in these endeavors, nor a clear roadmap to ensure compliance. The new safe harbors and exceptions use untested terms of art like value-based activities and value-based purposes, and providers and other entities do not have an enforcement history or government interpretation of these provisions that can be relied upon.

Until there is more clarity or track record of industry compliance, many entities will continue to wait before using these protections.

The last category of entities is early adopters. They see the value of these safe-harbors and exceptions, they have the resources to set up an infrastructure to ensure compliance, and they are willing to accept a certain amount of risk that the government and False Claims Act whistleblowers will not engage in enforcement actions against activities that are lowering the cost of care while improving health care quality and outcomes.

We have observed health care technology companies, population-management companies, and health care providers or payors who have already invoked the protection of the new AKS safe harbors, and in some cases, the Stark Law exceptions.

How have these health care entities successfully engaged the new safe harbors and exceptions?

As noted above, these new regulations are complex and require advanced planning to ensure compliance. Health care providers seeking to implement arrangements that take advantage of value based safe harbors typically have internal protocols for business teams to answer the many questions that are implicit in the regulatory definitions.

For example, what entity is the value-based enterprise as required by both the OIG and CMS regulations? If the value-based enterprise is not an entity, but instead is created between two contracting value-based enterprise participants, who is the individual or accountable body that is responsible for the value-based enterprise?

Parties wishing to enjoy the protection afforded by the new regulations must address every regulatory definition to assist their attorneys in drafting contracts that will demonstrate regulatory compliance.

Certain companies, especially health care technology companies and population management companies, are designing models of care that take advantage of these new safe harbors and exceptions.

They have studied these new regulations and are offering business models to providers specifically tailored to comply with the many regulatory requirements set forth by the OIG and CMS.

Sharing the administrative burdens between these technology and management companies and providers offer the promise of regulatory compliance that would not be achievable if providers were acting alone. Most importantly, these novel business offerings are beginning to grow outside of CMS'

established innovative payment models, but are still providing coordinated and improved care at lower costs.

Finally, we have seen early adopters not only develop internal protocols at the beginning of value-based arrangements, but they are establishing processes to maintain compliance with the value-based safe harbors and exceptions.

Both the OIG and CMS have offered regulatory protection with no financial risk requirement.[7] Yet, in order to ensure compliance with these regulations, the government has mandated ongoing compliance monitoring. And if the value-based arrangements do not continue to meet the value-based purposes of the arrangements, the value-based enterprise is required to terminate the arrangement or modify the arrangement to ensure compliance.

Value-based enterprise participants have established new compliance mechanisms or have incorporated these monitoring requirements into their existing compliance plans. While it is too early to tell whether failure to monitor and revise arrangements will lead to technical violations of these regulations, the compliance mechanisms that value-based enterprise participants are employing will significantly lower risk of violations.

### **Potential Problems In Need of Correction**

The OIG and CMS recognized that their value-based fraud and abuse regulatory reforms were similarly designed, but had key differences. They explained that since the AKS and the Stark Law are two different statutes, it was impossible for them to create identical regulatory safe-harbors and exceptions.

Even though the fraud and abuse waivers for CMS innovative payment models were substantially the same as applied to the AKS and the Stark Law, the OIG and CMS could not attain the same alignment in fraud and abuse regulatory reforms.

These differences create some compliance headaches for health care entities wishing to adhere to both AKS safe harbors and Stark Law exceptions. For example, in the no risk arrangement safe harbor the OIG requires a 15% contribution from recipients of value-based nonmonetary compensation.

Yet, the CMS' value-based exception does not require a 15% contribution. What should a value-based enterprise do in a situation where care coordination tools are provided by the value-based enterprise to participants and thereby create risk under the AKS and the Stark Law?

Does the value-based enterprise simply rely upon the Stark Law exception and not ask for any financial contribution? At what point is the remuneration significant enough where the value-based enterprise believes that it needs AKS safe harbor protection? Or perhaps the Stark Law exception's more lenient standard is simply a mirage, and the AKS safe harbor 15% contribution requirement is the appropriate standard?

Finally, while CMS did not exclude any entities from protection under the Stark Law exceptions, the OIG chose to all but exclude safe harbor protection for certain entities, like drug and medical device manufacturers. This was obviously disappointing to device and drug manufacturers.

While there is a significant focus on improving outcomes and lower costs in the health care industry, especially for drugs and medical devices, it seems to be a lost opportunity to completely exclude

manufacturers from protection under these safe harbors. If the OIG does not feel that it has the regulatory authority to issue broader safe harbor protection, perhaps Congress needs to step in to fill the gap.

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*Troy Barsky is a partner and Barbara Ryland is senior counsel at Crowell & Moring LLP.*

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[1] 42 U.S.C. § 1320a-7b(b).

[2] 42 U.S.C. 1395y.

[3] 42 CFR 1001.952(ee) and 42 CFR 411.357(aa)(3).

[4] 42 CFR 1001.952(ff)) and 42 CFR 411.357(aa)(2).

[5] 42 CFR 1001.952(gg) and 42 CFR 411.357(aa)(1).

[6] <https://www.cms.gov/medicare/physician-self-referral/fraud-and-abuse-waivers>.

[7] See 42 CFR 411.357(aa)(2); 42 CFR 1001.952(ee).