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How New Kickback Rules Benefit Health Care Industry: Part 1

By **Karen Lovitch and Rachel Yount** (December 16, 2020, 7:21 PM EST)

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Just in time for the holidays, the U.S. Department of Health and Human Services gifted the health care industry with historic, sweeping changes to the regulations implementing the Anti-Kickback Statute, the Physician Self-Referral Law — commonly known as the Stark Law — and the civil monetary penalty rules regarding beneficiary inducements.

The changes come through corresponding final rules — one issued by the HHS Office of Inspector General addressing changes to the AKS and the beneficiary inducements civil monetary penalty rules,[1] and one issued by the Centers for Medicare & Medicaid Services addressing changes to the Stark Law.[2]

The final rules go in effect on Jan. 19, 2021, and offer a number of industry-friendly changes that will have a far-reaching impact on the health care industry.

In this two-part article, we provide a comprehensive discussion of the final rules' key provisions, along with practical examples of how the industry can take advantage of these significant changes.

Part one covers the primary focus and main goal of the final rules — to advance the health care industry's transition to value-based care.

Part two concern the numerous changes and clarifications of the AKS and the Stark Law, which generally reduce regulatory burdens and offer health care entities more flexibility.

Some examples include:

- HHS finalization of a new safe harbor and new exception for cybersecurity technology and related services;
- A new Stark Law exception for limited remuneration, not to exceed $5,000, provided to a physician without the need for a written agreement or compensation that is set in advance; and
- Deletion of two of the more challenging conditions for the personal services and management contracts safe harbor.

These are just a few of the many changes and clarifications that are bound to be well-received holiday gifts for the health care industry.

Value-Based Care — the Primary Focus of the Final Rules

The final rules are part of HHS's Regulatory Sprint to Coordinated Care initiative. The rules are designed to offer the health care industry more flexibility, and to reduce the regulatory burden associated with the AKS and the Stark Law, particularly with respect to value-based arrangements and care coordination.

Value-based care, often referred to as pay-for-performance, is a payment model where payors offer health care providers and suppliers financial incentives to meet certain performance measures that improve quality of care or appropriately reduce costs, as opposed to traditional fee-for-service or capitated payments health care reimbursement.

For example, payors might withhold a certain percentage of a hospital's reimbursement and then use the reduction to fund a value-based incentive awarding the hospital for reducing adverse events.

Hardly a new concept, value-based care is a commonly used payment mechanism in the health care industry, and CMS and the OIG are finally now catching up.

The rules establish three new AKS safe harbors and four new Stark Law exceptions that offer protection for remuneration exchanged between participants in a qualifying value-based arrangement.

Both the safe harbors and the Stark Law exceptions are broken down by the amount of financial risk assumed under the value-based arrangement, and the level of flexibility increases with the level of risk assumed.

Hospitals and physician groups are the big winners here because the agencies designed the safe harbors and exceptions to offer them a lot of flexibility to enter into innovative value-based care arrangements that are protected under the AKS and comply with the Stark Law.

Manufacturers, pharmacy benefit managers, laboratories and pharmacies, on the other hand, are generally ineligible for protection under the value-based safe harbors and exceptions.

There is a limited option for manufacturers of digital health technology, and suppliers of durable medical equipment, prosthetics, orthotics and supplies, or DMEPOS, to exchange digital health technology with other participants in a value-based care arrangement.

For example, a medical technology company could partner with physician practices to better coordinate and manage care for patients discharged from a hospital by providing digitally equipped devices that collect and transmit data to the physicians, helping to monitor the patients' recovery and flag the need to intervene in real time.

Value-Based Terminology from the OIG and CMS Final Rules

Despite comments requesting clearer definitions that do not incorporate and rely on other defined terms, the agencies finalized a complicated set of definitions for the value-based terminology that is difficult to wade through. It is necessary to do so, however, in order to understand the safe harbors and

exceptions. Fortunately, the value-based definitions finalized by the OIG and CMS are aligned in nearly all respects.

A value-based enterprise, or VBE, is an enterprise with two or more participants that: (1) are collaborating to achieve at least one value-based purpose; (2) are each a party to a value-based arrangement with the other — or at least one other participant in the same VBE; (3) have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) have a governing document describing the VBE and how its participants intend to achieve the VBE's value-based purposes.

A value-based arrangement is an arrangement entered into between a VBE and one or more of its participants, or among VBE participants in the same VBE, for the provision of one or more value-based activities for a target patient population.

A value-based purpose is:

- Coordinating and managing the care of a target patient population;
- Improving the quality of care for a target patient population;
- Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
- Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality for care and control of costs of care for a target patient population.

In its proposed rule, the OIG sought comments on whether to exclude certain entities, such as pharmaceutical manufacturers and laboratories, from the definition of a VBE participant.[3]

The final rule modifies the proposed definition of VBE participant by defining it as an individual or entity that engages in at least one value-based activity as part of a VBE, other than a patient acting in their capacity as a patient.

Although the VBE participant definition in the final rule has been modified such that it no longer excludes any particular entity types, the OIG instead finalized the value-based arrangements safe harbors to exclude a number of stakeholders in the health care supply chain including:

- Pharmaceutical manufacturers, distributors and wholesalers;
- Pharmacy benefit managers;
- Laboratory companies;
- Pharmacies that primarily compound drugs or primarily dispense compounded drugs;
- Manufacturers of devices or medical supplies;

- Entities or individuals that sell or rent DMEPOS — other than a pharmacy or a physician, provider, or other entity that primarily furnishes services; and

- Medical device distributors and wholesalers.

However, there is a limited pathway for medical device and supply manufacturers and suppliers of DMEPOS to provide digital health technologies — discussed below.

OIG Safe Harbors for Value-Based Arrangements

The OIG implemented three new AKS safe harbors, all designed to protect certain arrangements entered into with or by a VBE, which is broadly defined to capture any number of network arrangements where the participants have agreed to collaborate for value-based purposes:

Care Coordination Arrangements

This safe harbor protects in-kind remuneration exchanged between VBE participants, provided that the remuneration is used predominately to engage in value-based activities that are directly connected to care coordination for a target patient population.

For example, a hospital and physicians could engage in care coordination, and the hospital might provide the physician group with care managers to ensure patients receive appropriate care post-discharge, and remote monitoring technology to alert the group when a patient needs a health care intervention to prevent an unnecessary emergency room visit or hospital readmission.

Under this safe harbor, there does not need to be an assumption of any financial risk. However, it is the most stringent, least flexible value-based safe harbor, and it may be difficult to fully satisfy its technical requirements, particularly for small or rural health care providers with limited resources.

Value-Based Arrangements Where Value-Based Enterprise Assumes Substantial Downside Financial Risk

This safe harbor covers both monetary and in-kind remuneration exchanges between a VBE and a VBE participant in an enterprise that assumes substantial downside financial risk from a payor if the VBE participant assumes a meaningful share of the risk. This safe harbor offers greater flexibility than the care coordination arrangements safe harbor.

The OIG finalized this safe harbor with industry-friendly modifications. For one of the three different payment methodologies used to determine substantial downside financial risk, the OIG reduced the risk threshold — i.e., the VBE has repayment obligation of 30% of shared losses rather than 40%.

While the proposed rule defined "meaningful share of the risk" to mean at least 8%, the OIG reduced this amount, requiring the VBE participant to share at least 5% of the financial risk to qualify.

Value-Based Arrangements Where the Value-Based Enterprise Assumes Full Financial Risk

This safe harbor protects monetary or in-kind remuneration from a VBE to a VBE participant, provided that the VBE assumes full financial responsibility for the costs of all items and services covered by a payor for each patient in the target population for a term of one year and is paid prospectively.

This safe harbor is designed to afford the most flexibility. But this safe harbor may have limited utility because there are a very limited number of providers that currently assume the required level of risk.

Big winners under the final rules are manufacturers of medical devices and DMEPOS suppliers who provide digital health technologies. While the proposed rules offered these entities no safe harbor protection, the final rules gave them a limited pathway via the OIG's new digital health technology provisions under the care coordination arrangements safe harbor.

DMEPOS suppliers who provide digital health technologies can receive protection under the care coordination safe harbor for exchanges of digital health technology as part of a VBE.

For example, a medical device manufacturer could furnish another VBE participant with a software product that pairs with implantable devices that transmit medical data to health care providers as part of a VBE. Another example is cloud storage services to monitor blood sugar levels.

But the care coordination arrangements safe harbor, which involves the least amount of financial risk assumed from the payor, comes with a number onerous safeguards, including, but not limited to the following:

- The arrangement must be reduced to writing;
- The parties must establish legitimate outcome or process measures;
- The recipient of the digital health technology must contribute at least 15% of the cost of the digital health technology, and
- The parties are required to maintain and make available to HHS, upon request, material and records sufficient to establish compliance with the safe harbor.

Safe Harbor for Patient Engagement and Support Arrangements

The OIG also finalized a new safe harbor for patient engagement and support arrangements, which is closely related to value-based arrangements. This safe harbor allows certain health care entities to provide patients in a target patient population of a VBE with certain tools and supports in order to improve quality, health outcomes, and efficiency.

For example, assuming all the safe harbor's onerous requirements are met, VBE participants could give patients smart watches that monitor patient health and transmit health data to the patients' physicians, smart pill bottles that dispense medications to patients at preset times, and parking vouchers or free child care during medical appointments.

The safe harbor sets a fairly generous $500 cap on the amount of in-kind remuneration that can be provided to patients, although it may prove insufficient with respect to digital health technologies that could easily exceed the cap.

Unfortunately for some health care entities looking to take advantage of this safe harbor, it is limited to entities participating in a VBE. Moreover, it includes a number of intricate and often technical requirements, including, but not limited to:

- The tool or support must be recommended by the patient's health care professional;

- The VBE participants must retain records related to the tools or support sufficient to establish compliance with the safe harbor; and

- The availability of the tool or support must not be determined in a manner that takes into account the patient's type of insurance coverage.

Keep in mind that compliance with safe harbors is not mandatory, and so VBEs may start adopting patient engagement and support arrangements that do not fully satisfy the safe harbor's technical requirements, and/or exceed the $500 cap if they can get comfortable that the arrangements nevertheless pose low risks under the AKS.

Stark Law Exceptions for Value-Based Arrangements

Similarly, CMS implemented four new exceptions to the Stark Law for value-based arrangements that apply based on the level of risk assumed by the VBE or the physician:

Full Financial Risk

This exception applies to value-based arrangements between VBE participants in a VBE that has assumed full financial risk for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population during the entire duration of the value-based arrangement.

Because the risk of ordering unnecessary services or steering patients to higher-cost sites of service are low when a VBE bears full financial responsibility for patient care, this exception includes fewer technical requirements compared to the other value-based exceptions.

Also, VBE participants can rely on this exception during the prerisk period, which is 12 months prior to the VBE assuming the financial risk.

Meaningful Downside Financial Risk to the Physician

This exception applies to remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose of the VBE for the entire term of the value-based arrangement.

While the proposed rule set "meaningful downside financial risk" to mean that the physician is responsible to pay or forgo no less than 25% of the total value of the remuneration they receive under the value-based arrangement, CMS lowered the threshold to 10%. This exception imposes more onerous technical requirements as opposed to the full financial risk exception.

Value-Based Arrangements Regardless of the Level of Risk Undertaken

The most onerous exception for value-based arrangements, this exception applies to value-based arrangements regardless of the level of risk undertaken by the VBE or any of the VBE participants.

Because the exception potentially applies to arrangements where neither party has assumed any

financial risk, CMS included a number of additional requirements to satisfy this exception compared to the exceptions for full financial risk and meaningful downside financial risk, in an effort to guard against patient and program abuse.

Indirect Compensation Arrangements That Include a Value-Based Arrangement.

CMS finalized its proposal to make value-based exceptions applicable to indirect compensation arrangements that include a value-based arrangement to which the physician or physician organization is a direct party.

CMS did not include in these exceptions the typical Stark Law requirements that compensation be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of a physician's referrals, or other business generated by the physician for the entity.

However, these exceptions do require that the compensation arrangement be commercial reasonable. Note that CMS also added a definition for commercially reasonable — a key Stark Law term not previously defined. We discuss this in part two of this article.

The AKS and the Stark Law have for many years posed obstacles, and placed great regulatory burdens and enforcement risk on the health care industry.

The final rules are a welcome relief to health care providers and payors who have long argued that these laws often hinder value-based arrangements that could facilitate improved quality of care as well as lower costs.

The impact of these substantial changes remains to be seen, but we expect to see the health care industry continue to adopt innovative value-based care arrangements now with a little more flexibility thanks to these final rules — a wonderful holiday gift from HHS.

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[1] https://www.federalregister.gov/public-inspection/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

[2] https://www.federalregister.gov/public-inspection/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations.

[3] https://www.hhs.gov/sites/default/files/oig-nprm.pdf.