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How New Kickback Rules Benefit Health Care Industry: Part 2

By **Karen Lovitch and Rachel Yount** (December 17, 2020, 6:28 PM EST)

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The U.S. Department of Health and Human Services recently gave the health care industry a host of holiday gifts in the form of significant 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]

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

Part one focused on the final rules' many changes to promote the health care industry's transition to value-based care, including three new AKS safe harbors and four new Stark Law exceptions that offer protection for value-based arrangements.

Part two focuses on the numerous changes and clarifications to the AKS and the Stark Law that are bound to be well-received by the health care industry.

While new safe harbors and exceptions related to value-based health care delivery and payment have garnered the most attention from the health care industry, the final rules also include a number of industry-friendly changes. Some of the highlights include:

- A new safe harbor and exception for cybersecurity technology and related services that will allow, for example, hospitals to provide cybersecurity technology to providers with access to the hospitals' electronic health record systems;

- A new Stark Law exception for limited remuneration, not to exceed $5,000 in the aggregate per calendar year, provided to a physician without the need for a written agreement or compensation that is set in advance; and

- The deletion of the two most challenging conditions for the personal services and management contract safe harbor — (1) that the aggregate compensation be set in advance and (2) that if services are to be provided on a periodic, sporadic or part-time basis, the agreement must specify the schedule, length and exact charge for the intervals.

Below is a high-level discussion and analysis on (1) new safe harbors and exceptions; (2) modifications to existing safe harbors and exceptions; (3) changes to fundamental Stark Law terminology; and (4) changes to the scope and application of the Stark Law exceptions.

Creation of New Safe Harbors and Exceptions

Cybersecurity Technology and Related Services

In the face of mounting concerns about the financial losses and risks to patients caused by cyberattacks against hospitals and other health care providers,[3] the agencies finalized a new safe harbor and a new exception for donations of cybersecurity technology and services.

The health care industry — particularly hospitals — should welcome this new flexibility to donate cybersecurity technology and services to physicians and other providers who often cannot afford sufficient protection against cyberattacks and therefore weaken the entire health care information ecosystem.

Under the safe harbor and the exception, covered technology and services must be "necessary and used predominantly to implement, maintain, or reestablish cybersecurity," which is the same standard applied under the safe harbor and exception for electronic health record donations.

Because the agencies did not finalize the proposed deeming provision, the parties have great discretion to decide what technology and services qualify for protection, which is a benefit as well as a risk. The parties should carefully document all decisions regarding compliance with this requirement.

The technology can have multiple uses, but the core functionality must relate back to cybersecurity. Covered technology may include malware protection software, data protection and encryption tools, and email traffic filtering. However, donation of a virtual desktop that includes features beyond cybersecurity software — e.g., word processing — likely would not be protected.

In contrast to the safe harbor and exception for electronic health record donations, this safe harbor and exception consider hardware to be protected technology, but the agencies made clear that the donation of physical infrastructure improvements, such as locks on doors, upgraded writing, and physical security systems, is not permitted because such items do not qualify as technology and offer other valuable benefits.

Similarly, a broad range of services would qualify for protection, including cybersecurity training services, risk assessment or analysis services, and services associated with developing, installing, and updating cybersecurity software. CMS mentioned that a donor could potentially provide a full-time cybersecurity officer to a physician recipient's practice.

In deciding what services to provide, donors should consider the level of risk presented when placing employees or contractors in physician offices because the possibility exists that such individuals could perform other duties that are the responsibilities of the physician's staff.

When determining eligibility, or the amount or nature of a donation, donors cannot directly take into account the volume or value of referrals or other business generated between the parties. The agencies chose not to include a list of deeming criteria as they did for electronic health record donations.

Donors are therefore free to determine eligibility and the scope of donations as they see fit. For example, a hospital may choose to donate to physicians on its medical staff or to physician practices identified in greatest need through risk assessments.

The most important difference between the exception and safe harbor is the writing requirement. Under the safe harbor, the arrangement must be set forth in writing and signed by the parties, and it must include a general description of the donation and the contribution amount, if any.

In contrast, CMS merely requires that the arrangement be documented in writing. The parties could satisfy the requirement with a memorandum to file or with a compilation of contemporaneous documents — such as emails — that would permit a reasonable person to verify compliance. The OIG also permits a collection-of-documents approach but notes that a single, written approach is a best practice from a compliance perspective.

Both agencies considered whether to restrict the scope of potential donors but ultimately declined to do so. Various laboratory industry organizations recommended the exclusion of laboratories, but the agencies decided there is no need to do so because recipients cannot make the receipt of cybersecurity technology or services, or the amount or nature of such technology or services, a condition of doing business with the donor.

Limited Remuneration to a Physician

While the new exception for limited remuneration provided to a physician is flexible in that it does not require a written agreement or compensation that is set in advance, it only allows for payments for services actually provided by the physician — or through certain individuals or entities — that do not exceed $5,000 in the aggregate per calendar year, to be adjusted for inflation.

This exception will likely be used by parties who have historically relied upon the isolated financial transaction exception to make a single payment for multiple services without a written agreement, as discussed below.

CMS provided an example in which a hospital's medical director resigns unexpectedly, and the hospital quickly arranges for a new medical director who starts performing services before a written agreement is drafted or the compensation is set.

If the aggregate compensation provided to the new medical director does not exceed the annual limit, the parties could rely upon this exception if all other conditions are met. This exception also may protect space or equipment lease payments, as long as the payments are not per-unit of service charges or based on a percentage of revenue.

Modifications to Existing Safe Harbors and Exceptions

Safe Harbor and Exception for the Donation of Electronic Health Records Technology and Related Services

While the use of electronic health record technology is far more widespread than when the safe harbor and exception for electronic health record donations became effective in 2006, the agencies believe that protection for electronic health record donations is still necessary to encourage continued adoption and use. To that end, the agencies finalized certain changes intended to offer more flexibility and clarity to parties seeking to donate electronic health record items and services.

Among other things, the agencies deleted the prohibition on donating replacement technology, and made the safe harbor and exception permanent by removing the sunset date of Dec. 31, 2021. While they considered eliminating the 15% cost-sharing requirement applicable to recipients, they ultimately decided not to do so, but relaxed the timing requirements for items or services received after an initial or replacement donation by allowing payment of the cost-sharing amount at reasonable intervals.

Donors seeking to avoid cost sharing can consider whether and to what extent the new safe harbors and exceptions for cybersecurity technology and related services, or for value-based health care delivery and payment, might apply.

In a surprise move, the agencies also deleted the prohibition on the donor taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other e-prescribing or electronic health record systems — which is now known as information blocking.

When the safe harbor and exception were implemented in 2006, HHS had few legal avenues to prevent information blocking, but the 21st Century Cures Act has now given the Office of the National Coordinator for Health Information Technology and the OIG more direct authority to address HHS' concern with this practice.

Further, the proposed information blocking regulations allow for exceptions, while the prohibition in the safe harbor and exception was absolute. The agencies believe that, taken together, the interoperability requirement and the deeming provision encourage an interoperable health system and prevent electronic health record donations intended to lock in referrals by limiting the flow of electronic health information.

Rental of Office Space and Rental Equipment Exceptions

CMS made slight changes to these exceptions to clarify that they do not prohibit multiple lessees from using the space or equipment ,or prevent a lessee from inviting another party other than the lessor to use the office space or equipment rented by the lessee.

Providers should welcome these modifications because many previously believed the exceptions prohibited the lessee from sharing the space or equipment with any other party, which could be problematic because multiple physicians typically use the same space or equipment at the same time when treating patients.

Fair Market Value Compensation Exception

The fair market value compensation exception is used to protect arrangements that do not fit within other exceptions, often because it places no time limit on the parties' arrangement. Historically, CMS prohibited application of the exception to the rental of office space, but it reversed course in the final rule for arrangements that do not involve compensation based on (1) a percentage of the revenue

attributable to the services performed or business generated in the office space; or (2) per-unit of service rental charges, where the charges reflect services provided to patients referred by the lessor to the lessee.

The same limitations already apply to equipment rentals.

Parties can now rely upon this exception to cover a short-term rental of office space.

Personal Services and Management Contracts Safe Harbor

A particularly welcome change is the OIG's decision to no longer require that aggregate compensation be set in advance under the personal services safe harbor, and instead require only that the methodology for determining compensation be set in advance.

This change allows an arrangement to comply even if the compensation is set on a per-unit or an hourly basis, which are typical compensation mechanisms already permitted under the Stark Law.

The OIG further simplified compliance by eliminating the requirement that, if services are to be provided on a periodic, sporadic or part-time basis, the agreement must specify the schedule, length and exact charge for such intervals. Satisfying the requirement presented difficulty because contracting parties often need part-time services on an as-needed basis.

Changes to Fundamental Stark Law Terminology

Commercially Reasonable

The Stark Law regulations now define "commercially reasonable," which is used in multiple commonly used exceptions. The definition permits the parties to consider their own characteristics, such as size, type, scope and specialty, and it specifically recognizes that the arrangement does not necessarily need to be profitable, which many previously believed to be true.

While the new defined term is welcome, it poses some risk because it contains an undefined term — "legitimate business purpose" — and requires the parties to make subjective judgments when determining compliance, which could make it easier for enforcement authorities to second-guess the parties after the fact.

Designated Health Services

The definition of "designated health services" now makes clear that services furnished by hospitals to inpatients do not constitute designated health services if the furnishing of those services does not increase the amount paid to the hospital under the Acute Hospital Inpatient Prospective Payment System and other prospective payment systems applicable to hospitals.

For example, if a specialist who did not admit the patient orders an x-ray for an inpatient, the x-ray would not qualify as a designated health service under the new definition, which means that the specialist can have a financial relationship with the hospital that does not satisfy a Stark Law exception, and the hospital can bill Medicare for the inpatient hospital services without violating the Stark Law.

This change could significantly decrease the number of hospital-physician relationships subject to the

Stark Law, and it is likely to have the most utility when determining potential overpayment amounts rather than when making contract decisions because it may be difficult to know in advance whether the services will result in an increase in payments.

Isolated Financial Transaction

While most of the final rule's changes are provider-friendly, the new definition of "isolated financial transaction" is intended to prevent parties from using the isolated transactions exception to protect a single payment for services provided without a written, signed agreement, which typically cannot comply with any other exception because compensation is not set in advance.

The regulation now expressly states that an isolated financial transaction does not include a single payment for multiple or repeated services — such as payment for services previously provided but not yet compensated.

The exception for isolated financial transactions does, however, protect forgiveness of an amount owed in settlement of a bona fide dispute related to a compensation arrangement, but the parties must be able to show that a bona fide dispute must in fact exist.

Changes to the Scope and Application of the Stark Law Exceptions

Volume or Value Standard

Numerous Stark Law exceptions require that compensation paid to referring physicians must not take into account the volume or value of referrals or other business generated between the parties. For the first time, the regulations will include bright-line, objective tests to determine when compensation meets this standard.

Compensation from an entity to a physician is problematic only if the physician's compensation positively correlates with the number or value of the physician's referrals to the entity. Conversely, compensation from a physician to an entity cannot negatively correlate with the number or value of the physician's referrals to the entity.

For example, if a physician leases medical office space from a health system, and the rental charges are reduced for each diagnostic test ordered by the physician and furnished in the health system's outpatient departments, then the compensation would take into account the volume or value of referrals.

While these formulas provide clarity for Stark Law compliance purposes, no such rules apply in the AKS context. This is not surprising given that the Stark Law is a civil strict liability statute rather than a criminal, intent-based law like the AKS. In addition, these special rules do not apply in the context of the new value-based enterprise exceptions.

AKS Compliance Requirement

CMS eliminated from most – but not all – Stark Law exceptions the requirement that an arrangement must comply with the AKS. Providers have always struggled with this requirement because it introduced intent into a strict liability statute and allowed enforcement authorities to claim Stark Law violations based solely on a claim of noncompliance with the AKS. Health care providers will undoubtedly welcome

the added certainty and increased flexibility resulting from this change.

Writing and Signature Requirements

Many Stark Law exceptions require that the compensation arrangement be set forth in a writing signed by the parties, which can present a variety of operational challenges. For example, physicians often perform services before the parties have a signed, written agreement, whether due to necessity or oversight.

Recognizing that such technical noncompliance presents a low risk of abuse if it otherwise complies with an applicable exception, CMS has sought to relax the writing and signature requirements for several years. The final rule allows the parties to obtain the required writing or signature within 90 consecutive calendar days after the date on which the arrangement fell out of compliance.

The highly anticipated AKS and Stark Law final rules came as a bit of a holiday surprise, given that CMS had announced that it was extending its deadline to finalize the Stark Law changes until August 2021, and had many speculated that the OIG's final rule would be similarly delayed.

While the focus of the final rules centered on the transition to value-based care, the rules also include a number of welcome changes and clarifications, and offer the health care industry much needed relief from the regulatory burdens imposed by the AKS and Stark Law.

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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.nytimes.com/2020/10/28/us/hospitals-cyberattacks-coronavirus.html.