

Regulatory Changes Affecting Physicians' Referral Practices

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Physician-patient relationships are influenced by surrounding legislative climates. Recent rulemaking by the Centers for Medicare and Medicaid Services (CMS), which went into effect on January 19, 2021 and intended to facilitate value-based treatment, has made significant changes to the regulations underlying the *Ethics in Patient Referrals Act*, also known as the *Stark Law*, and the *Anti-Kickback Statute*. (See Background)

The new rules, which modify and expand the regulatory exceptions of the *Ethics in Patient Referrals Act* and the *Anti-Kickback Statute*, are part of a larger concerted effort launched by the U.S. Department of Health and Human Services (HHS) to stimulate innovative, collaborative arrangements in the healthcare system. These modifications remove previously existing regulatory red tape and obstacles to the adoption of promoting value-based models in modern clinical care.

Patient referrals

Among other things, the changes in the rules modify and expand the regulatory exceptions that pertain to healthcare providers and institutions in connection with patient referrals. The anti-kickback rules applicable to patient referrals are of exceptional clinical significance because their prohibition on billing for patient referrals to related health services directly affects physicians' ability to deliver quality, coordinated and efficient care. The new rules are intended to provide relief for value-based enterprises and the value-based arrangements between participants in a given value-based enterprise.^{2,5-7}

When the *Stark Law* was first introduced, Medicare operated primarily on fee-for-service models, prior to value-based payment models, which are becoming more prevalent. In value-based arrangements, the self-referral incentive is dramatically reduced compared to fee-for-service models. However, even in fee-for-service models, these updated rules give greater autonomy to providers.

Value-based arrangements

The variables in qualification for safe harbors include the status of the payees as value-based enterprises, and whether, and to what extent, both the payee organization and the particular physician take on financial risk with respect to payment. Central to the new rules is the protection of payments among participants in a value-based arrangement, defined as arrangements with the purpose of:

Background

The *Ethics in Patient Referrals Act/Stark Law* and *Anti-Kickback Statutes* were adopted during the height of the fee-for-service model and were intended to address the practice of physicians prescribing and referring patients for additional therapies to providers in which the physician had a financial interest, or who paid the physician a referral fee.

In the years since the *Stark Law* was enacted and the CMS' regulations for its enforcement were adopted, the practice of medicine has steadily migrated away from the fee-for service model that motivated the *Stark Law*, evolving towards a value-based model in which patient outcomes, rather than procedures performed and tests administered, are the basis of compensation and reimbursement. However, the fee-for-service model still exists, particularly in procedural subspecialties, where it is generally compensated higher than in nonprocedural care.¹

Ethics in Patient Referrals Act

The *Ethics in Patient Referrals Act*, with some narrow exceptions, prohibits a physician from knowingly referring patients to designated health services payable by Medicare or Medicaid, if a relationship exists between the physician and/or family member and the designated health service.² Designated health services are those that perform inpatient and outpatient clinical services, physical or occupational therapies, prescription services, clinical laboratory testing, radiology services, medical equipment and supplies, parenteral and enteral resources, prosthetic and orthotics, or home-health services. The *Stark Law* also prohibits healthcare providers from charging Medicare or Medicaid for medical services performed on the basis of a prohibited referral. Violations of the *Stark Law* may result in denial of reimbursement claims, restitution of payments made and civil penalties.³

Anti-Kickback Statute

The *Anti-Kickback Statute* covers similar activity, but has a broader scope. It imposes criminal, and in connection with the False Claims Act (31 U.S.C. Sec. 3729-3733), civil sanctions on those who knowingly or willfully offer, solicit, receive or pay any remuneration in exchange for covered medical services and products underwritten by any federal healthcare program.⁴ It is applied to all government programs, whereas the *Stark Law* only applies to Medicare and Medicaid. Therefore, patients under Department of Labor programs would also be included in the *Anti-Kickback Statute*. Additionally, the *Anti-Kickback Statute* is not limited to physicians, as is the *Stark Law*. Any person who illegally refers patients in exchange for compensation is potentially culpable under the *Anti-Kickback Statute*.⁴ While the *Stark Law* only applies to designated health services, the *Anti-Kickback Statute* applies to all services and items if they are paid for by a government program. ❖

- Coordinating care;
- Improving the quality of care;
- Reducing costs for payers (without negatively impacting care); or
- Transitioning the practice from a volume-based model to an outcome-based model for a target patient population. Qualifying value-based enterprises must have a person or body responsible for overseeing the enterprise's clinical and financial activities, and must create a document that evidences the way the member of the enterprise will meet the value-based objective.

Modifications/Safe harbors

The new rules create a number of exemptions and safe harbors to permit what would otherwise be prohibited physician referrals under the *Stark Law*, where the physician and the designated health service provider are part of a value-based enterprise. One major modification permits pharmaceutical manufacturers, distributors and wholesalers, pharmacy benefit managers, laboratories, and medical device manufacturers and suppliers to be considered participants in value-based enterprises.⁷

Care-coordination arrangements

The new rules also create a care-coordination arrangement safe harbor under the *Anti-Kickback Statute* for in-kind remunerations between value-based enterprise participants according to the terms outlined in a value-based arrangement.^{6,7} The safe harbor cannot be applied to administrative duties of the recipient or to benefit patients outside of the target patient population of the value-based arrangement, which must be defined. A qualifying value-based arrangement must also specify an evidence-based outcome that the arrangement will advance. The arrangement also requires the recipient to pay at least 15% of the cost to ensure they are motivated to benefit the target population.^{7,8} If the arrangement does not achieve its outcomes, it must be terminated within 60 days.^{7,8}

Downside financial-risk safe harbors

The amendments also create downside financial-risk safe harbors. This allows for referral remuneration for participants in value-based arrangements who have specified amounts of downside financial risk due to the nature of their arrangements and would share in any loss incurred by the arrangement. This risk is determined by a participant who receives a partial payment or it shares in the payer's losses.

The CMS also outlined a parallel rule for physicians under the purview of the *Stark Law*. A clinical example of such an arrangement that is permitted by the updated rules would be a hospital discharging patients to a skilled nursing facility.

Under the new rules, the hospital could provide a nurse to follow patients discharged from the hospital to the nursing facility and the nursing facility could aid in transitioning care from the hospital to the nursing facility without concerns about violating the *Stark Law*, which helps control costs and maintain a higher degree of clinical care between the two institutions. Previously, this exchange of services would have to be monetized and discretized individually, leading to higher costs for patients.

Patient engagement and support

A new patient engagement and support safe harbor outlines an exception to the *Stark Law* that permits participants to provide patients in the target population with tools or supports that are specific to certain goals and must be recommended by a patient's healthcare provider.⁷ This exception only extends to in-kind items, purposefully not extending to cash or cash equivalents, and is capped at \$500 annually.⁷

Services and management contracts

Finally, the new rules extend an existing Anti-Kickback Statute safe harbor for services and management contracts, for which payments are dependent on outcomes, and requires the arrangement to specify the total size of payments.⁸ The rule removes the requirement of specifying the total size of payments as long as there is transparency in how the payment will be calculated. The sixth rule concerns the CMS-sponsored care delivery and a payment arrangement safe harbor, and removes the scrutiny on these programs by the Office of the Inspector General (OIG), since they are CMS-sponsored. A limitation of this exception is that it does not extend to arrangements or patient populations outside of the CMS ecosystem.

These modifications collectively remove regulatory oversight on healthcare providers and their referral channels, by providing them with increased autonomy for their respective practices.

Examples of value-based arrangements

With these changes, the opportunity exists for healthcare providers to enter into innovative value-based arrangements without a fear of *Stark Law* violations. For example, consider a primary care practice that wants to collaborate with a gastroenterology practice to lower costs and improve healthcare outcomes of its patients. If the gastroenterology practice performs data analytics to analyze risk factors of the primary care's patients, the previous *Stark Law* would prohibit the gastroenterology practice from sharing that data with the primary care practice unless the primary care practice paid the "market price" for the information. Despite the clinical utility of the information, the market price requirement actually discourages its use by increasing the cost to

the primary care provider, patient and payers.

Another inefficiency that the updated *Stark Law* addresses are arrangements between hospitals and physicians within the hospital's electronic health records system, where the hospitals could not previously provide cybersecurity software at a reduced fee to physicians because of a potential *Stark Law* violation. With the updates, those concerns of violations no longer exist, and hospitals do not need to decide between accepting increased risk of security breach and restricting physician access to electronic health records.

Conclusion

The changes to the *Stark Law* and the *Anti-Kickback Statute* are complex and are not completely congruent with each other. Providers should consult with counsel regarding their specific arrangements, as compliance with the new rules requires close analysis. Hopefully, though, these changes will accelerate the implementation of innovative and more coordinated patient care practices by facilitating arrangements between physicians and designated health services.

Key Changes in the *Anti-Kickback Statute* and *Stark Law*

Pharmaceutical manufacturers, distributors and wholesalers, pharmacy benefit managers, laboratories, and medical device manufacturers and suppliers are considered participants in value-based enterprises.

"Care-coordination arrangements" safe harbor for in-kind remunerations between value-based enterprise participants according to the terms outlined in a "value-based arrangement."

The safe harbor cannot be applied to administrative duties of the recipient or to benefit patients outside of the target patient population of the value-based arrangement, which must be defined.

"Downside financial-risk" safe harbor for referral remuneration for participants in value-based arrangements who have specified amounts of downside financial risk due to the nature of their arrangements and would share in any loss incurred by the arrangement.

"Patient engagement and support" safe harbor permits participants to provide patients in the target population with tools or supports that are specific to certain goals and must be recommended by a patient's healthcare provider.

This exception only extends to in-kind items, purposefully not extending to cash or cash equivalents, and is capped at \$500 annually.

Safe harbor modified for services and management contracts, for which payments are dependent on outcomes, and requires the arrangement to specify the total size of payments. The rule removes the requirement of specifying the total size of payments as long as there is transparency in how the payment will be calculated.

"CMS sponsored-care delivery and payment arrangements" safe harbor removes the scrutiny on these programs by the OIG.

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