



# New Stark Law and Anti-Kickback Statute Safe Harbors Promote Value-Based Arrangements

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On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) finalized rules creating [new exceptions to the Federal Physician Self-Referral or “Stark Law”](#) and [safe harbors under the Federal Anti-Kickback Statute \(AKS\)](#). These new rules went into effect in January 2021 and were part of the federal government’s Regulatory Sprint to Coordinated Care. The underlying purpose of these revisions is to promote the transition of the U.S. health care system from a fee-for-service payment model to one that rewards value-based care.

While the new Stark Law and AKS rules share the same purpose, they do not fully align with one another. HHS states that the differences were intentional to allow the AKS to provide “backstop” protection for federal health care programs and beneficiaries against abusive arrangements that involve the exchange of remuneration intended to induce or reward referrals under arrangements that could potentially satisfy the requirements of an exception to the Stark Law. [85 Fed. Reg. 232, 77492, 77508](#).

## I. The New Stark Law Exceptions

The Stark Law is a strict liability statute that prohibits a physician from referring a patient to an entity for certain Medicare-payable services if the physician, or the physician’s immediate family member, has a “financial relationship” with that entity, unless an exception applies. [42 CFR 411.353](#). Likewise, the entity is prohibited from billing Medicare for these certain services that are the result of a prohibited referral.

Under the new Stark Law exceptions related to value-based arrangements, remuneration paid under the following three “value-based arrangements,” as defined at 42 CFR 411.351, is not considered a financial relationship. Thus, arrangements that meet

these exceptions are protected under the Stark Law.

- **“Low Risk Exception”** – [42 CFR § 411.357\(aa\)\(3\)](#). This exception requires that the arrangement must be in writing and describe the:
  - value-based activities to be provided and how they are expected to further value-based purposes,
  - the target patient population,
  - the type of remuneration and how it is determined, and
  - the outcome measures against which the recipient of the remuneration is assessed, if any.

An “outcome measure” is a benchmark that quantifies either improvements in or maintenance of the quality of patient care, or reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

These written documentation requirements have conditions attached to them as well. For example, any outcome measures against which the recipient of the remuneration is assessed must be objective, measurable, and selected based on clinical evidence or credible medical support. The remuneration exchanged must also be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

At least once per year, or at least once during the term of the agreement if the term is less than a year, the parties must monitor whether the value-based activities were actually furnished and assess how continuing those activities are expected to further the value-based purposes of the enterprise. If no such continuation is expected to occur, the parties must terminate the arrangement.

- **“Meaningful Risk Exception”** – [42 CFR § 411.357\(aa\)\(2\)](#). This exception requires that the physician take on “meaningful downside financial risk” for their failure to achieve the value-based purposes of the value-based enterprise (“VBE”) during the entire duration of the arrangement. Meaningful downside

financial risk means that the physician is responsible to repay or forgo at least 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

Amongst other requirements, the arrangement must be in writing and describe the nature and extent of the physician's downside financial risk. Additionally, it must describe the methodology used to determine the amount of the remuneration before the value-based activities are undertaken by the physician for which remuneration is paid. The remuneration must be for or result from value-based activities undertaken for patients in a target patient population. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. The remuneration cannot be conditioned on referrals of patients who are not part of the target patient population or businesses not covered under the value-based arrangement.

Finally, if the remuneration paid to the physician is conditioned on the physician's referrals to a particular entity, the requirement to make such referrals must be in writing and signed by the parties and must not apply if the patient expresses a preference to receive services from a different entity, if the patient's insurer determines where the patient will receive services, or if the referral is not in the patient's best medical interests in the physician's judgment.

- **"Full Financial Risk"** – [42 CFR § 411.357\(aa\)\(1\)](#). This exception requires that the VBE be at "full financial risk" (or be contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the arrangement. Full financial risk means that the VBE is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

This exception also requires that the remuneration be or result from value-based activities undertaken by the recipient

of the remuneration for patients in the target patient population and not be conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

Finally, just as with the meaningful risk exception, if the remuneration paid to the physician is conditioned on the physician's referrals to a particular entity, the requirement to make such referrals must be in writing and signed by the parties and must not apply if the patient expresses a preference to receive services from a different entity, if the patient's insurer determines where the patient will receive services, or if the referral is not in the patient's best medical interests in the physician's judgment.

## II. The New Anti-Kickback Statute Safe Harbors and Other Modifications

Generally, the federal AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward, among other things, referrals for, or purchases of, items or services reimbursable by a federal health care program. [42 USC 1320a-7b](#). The AKS revisions include modifications to four existing safe harbors and the addition of seven new safe harbors. Three of the new safe harbors are focused on VBEs with varying amounts of financial risk. The new AKS safe harbors use the same definitions as the Stark Law's value-based exceptions discussed above for the following terms, except as noted:

- "VBE,"
- "value-based arrangement,"
- "value-based activity" except that the Stark Law definition does not specifically exclude the making of a referral,
- "value-based purpose,"
- "value-based participant" except the Stark Law definition does not specifically exclude a patient, and
- "target patient population."

A VBE can be a formal structure or a looser affiliation but must have at least two VBE participants who engage in value-based activities to achieve one or more value-based purposes, such as improving care for a target patient population.

The new safe harbors divide VBEs into three types based on the amount of financial risk assumed by the VBE participants, with the new safe harbors providing greater flexibility to those VBE participants who take on greater financial risk.

- **“Care Coordination Arrangements”** – [42 CFR § 1001.952\(ee\)](#).

Arrangements meeting this safe harbor do not require the VBE participants to take on any financial risk. They are arrangements designed “to improve quality, health outcomes, and efficiency.” The safe harbor for these VBEs provides that, if certain standards are met, “remuneration” as prohibited by the AKS “does not include the exchange of anything of value between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement.”

This safe harbor does not protect the exchange of monetary payments. It does, however, does permit the provision in-kind remuneration “used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population.” In order to qualify for the safe harbor, the in-kind remuneration must meet a number of requirements, including being part of a value-based arrangement that is “commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.”

- **“Value-based Arrangements with Substantial Downside Financial Risk”** – [42 CFR § 1001.952\(ff\)](#). This safe harbor allows the exchange of both in-kind and monetary remuneration between a VBE and a VBE participant. As the title of this safe harbor suggests, it is only available if the VBE assumes “substantial downside financial risk” — a term that is defined in the regulation to mean varying percentages of potential loss depending on the type of calculation used.

This safe harbor is unavailable to: (i) pharmaceutical manufacturers, distributors, and wholesalers; (ii) pharmacy benefit managers; (iii) labs; (iv) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (v) medical device and medical supply manufacturers; (vi) sellers of durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and (vii) medical device distributors and wholesalers that do not otherwise manufacture devices or medical supplies.

- **“Value-based Arrangements with Full Financial Risk” – [42 CFR § 1001.952\(gg\)](#).** A value-based arrangement with full financial risk is an arrangement in which the VBE is “financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year.” As with value-based arrangements with substantial downside risk, both in-kind and monetary remuneration may be permitted if all of the criteria of this safe harbor are met, but the same list of entities (pharmacy manufacturers, distributors and wholesalers, PBMs, labs, etc.) are prohibited from qualifying for this safe harbor.

HHS’ modifications to the AKS also include the addition of other safe harbors designed to support value-based care, including one for “arrangements for patient engagement and support to improve quality, health outcomes, and efficiency.” This permits VBEs to provide tools and supports, with an aggregate value of up to \$500 per year, to patients in the VBE’s target patient population to promote their participation in and compliance with the VBE’s initiatives. Cash and cash equivalents are not permitted and, as with the value-based arrangements discussed above, certain VBEs are excluded.

HHS also modified a number of the existing AKS safe harbors in order to provide entities with greater flexibility in some of their value-based pursuits, like the “personal services and management contracts” safe harbor.

- **Personal Services and Management Contracts Safe Harbor**

- [42 CFR 1001.952\(d\)](#). This safe harbor now permits certain outcome-based payments for improving patient care or decreasing health costs. This protects a payment from one party to another for achieving quality measures that are:

- selected based on clinical evidence or credible medical support, or
    - have benchmarks that are used to quantify improved or maintained quality of patient care or a material reduction in the cost or growth in expenditure of payors while maintaining or improving quality of care; or both.

Any outcomes-based payment must be a reward for achieving an outcome measure or a recoupment of a reduction in payment for failing to achieve an outcome measure. Outcome measures and benchmarks must be monitored, assessed and revised. Significantly, however, this safe harbor is not available to certain types of entities (e.g., pharmaceutical manufacturers, distributors or wholesalers, pharmacy benefit managers, laboratory companies, medical supply companies, etc.).

### III. Stark Law/AKS Changes and the Future of Value-based Care

Overall, HHS's revisions to the safe harbors offer significant relief to many of the restrictions the AKS has placed on the efforts of health care providers, suppliers, and payors to implement value-based payment initiatives. Most value-based enterprises likely consider these revisions long overdue, and some may also consider them insufficient. Nevertheless, the revisions are substantial, and they demonstrate that federal health agencies recognize they must modify health care referral laws if they want the U.S. health care system to transition from fee-for-service payments to value-based care.

Providers and payors are going to want to review these new changes and determine whether it might be useful to them to

engage in a value-based arrangement with another party. The transition to value-based care is continuing to become more prevalent, and we are happy to assist in structuring these relationships in compliance with the myriad of health care regulatory concerns. Please contact the author of this article with any questions. You can also visit our [Health Law Matters blog](#) for more insight into legal issues impacting the health care industry.

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