Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

Paving the Way for Value-Based Health Care Arrangements: Proposed Rules

April 16, 2020

Last fall, as part of a broader effort to improve health care payment and delivery in the United States, the U.S. Department of Health and Human Services (HHS) issued two proposed rules to promote value-based arrangements. Value-based arrangements are health care payment and delivery models designed to reward health care professionals for the *quality* of health care provided, rather than the *quantity* of services rendered. Some Members of Congress, health care providers, and other stakeholders view the federal Anti-Kickback Statute and the Physician Self-Referral Law (known as the "Stark Law") as impediments to establishing value-based arrangements. To foster the creation of value-based arrangements, the HHS's proposed rules would, among other things, establish new safe harbors and exceptions to these two health care fraud and abuse statutes—*safe harbors* for the Anti-Kickback Statute and *exceptions* to the Stark Law. This Legal Sidebar provides background on the potential interaction between value-based payment arrangements, the Anti-Kickback Statute, and the Stark Law. The Sidebar also explores central components of the proposed rules relating to value-based arrangements and selected key takeaways for the 116th Congress.

Background

Fraud and Abuse Laws Governing Health Care Entities

Several federal statutes address fraud, waste, and abuse in federally funded health care programs, such as Medicare and Medicaid, by restricting financial relationships among physicians, hospitals, health insurance plans, and other entities that furnish health care items and services under these programs. The general idea behind these restrictions is that if health care providers have a financial relationship with another entity, this relationship can inappropriately incentivize providers to steer patients to that entity, and treat patients based on economic gain, rather than clinical appropriateness. Two of the more prominent federal statutes that restrict financial relationships in federal health care programs are the Anti-Kickback Statute and the Stark Law.

The Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)). This statute establishes criminal penalties for any person who knowingly and willfully offers, pays, solicits, or receives "remuneration" (i.e., monetary compensation or non-monetary items of value) in return for a patient referral or other generation of

Congressional Research Service
https://crsreports.congress.gov
LSB10448

business reimbursable under a federal health care program. To illustrate, an arrangement under which a hospital pays a physician $1,000 each time the physician refers a patient to the hospital for Medicare-covered services could violate the Anti-Kickback Statute. To allow health care providers to enter into non-abusive, legitimate business arrangements, the Anti-Kickback Statute authorizes HHS's Office of Inspector General (OIG) to issue regulatory "safe harbors" to the Statute.

The Stark Law (42 U.S.C. § 1395nn). Under the Stark Law, if a physician or physician's immediate family member has a "financial relationship" with an entity, then (1) the physician may not make a referral to the entity for the furnishing of designated health services for which payment may be made under Medicare or Medicaid, and (2) the entity may not submit a claim to these programs or otherwise bill for designated health services furnished pursuant to a prohibited referral. The Stark Law authorizes the Centers for Medicare and Medicaid Services (CMS) to establish regulatory exceptions to the law for financial relationships that "do not pose a risk of patient or program abuse."

Value-Based Health Care Arrangements

In contrast to traditional fee-for-service models, in which health care providers receive payment for each item or service provided to program beneficiaries, value-based payment arrangements are designed to reward health care professionals for the *quality* of health care provided. While value-based payment arrangements take various forms, some of these arrangements may seek to offer financial incentives or non-monetary items of value (such as the donation of telemedicine equipment or software) to health care providers that meet certain quality metrics or cost savings goals. In exchange for these potential benefits, under some value-based arrangements, providers have to assume some degree of financial risk (i.e., shoulder financially responsibility) if they fail to achieve quality or cost savings-related results.

Many health care providers and others assert that the Anti-Kickback Statute and the Stark Law hinder the establishment of value-based arrangements, including those arrangements that require the assumption of risk. The basis for this claim is that if value-based arrangements provide a financial or other incentive to health care professionals in exchange for taking measures designed to promote better quality health care while achieving measurable savings targets, then there can be a prohibited financial relationship between the health care entity paying the incentive and the entity receiving it. For example, a hospital and a physician group may seek to enter into a financial arrangement that compensates physicians based on compliance with the hospital's health screening protocol. The goal of this protocol is to detect more cancer in patients and reduce overall patient care costs. It is possible that the physicians' referrals of patients to the hospital for these screening services and the hospital's submission of claims to Medicare could implicate the Anti-Kickback Statute or Stark Law, absent a safe harbor or exception from these statutes.

Proposed Safe Harbors and Exceptions for Value-Based Care Arrangements

In October 2019, the HHS OIG issued a proposed rule that would create three Anti-Kickback Statute safe harbors for value-based arrangements. That same month, CMS issued a proposed rule that would establish, among other things, three Stark Law exceptions for value-based arrangements that roughly correspond to the three proposed Anti-Kickback Statute safe harbors as depicted in Table 1. The three categories of safe harbors and exceptions are tiered so that the more risk health care providers assume under a value-based arrangement, the fewer conditions would be imposed on the arrangement. The three Anti-Kickback safe harbors and Stark Law exceptions are: (1) Full Financial Risk; (2) Substantial Downside Financial Risk Safe Harbor and Meaningful Downside Financial Risk Exception; and (3) Care Coordination Arrangements Safe Harbor and Value-Based Arrangements Exception.

Key Proposed Safe Harbors and Exceptions for Value-Based Arrangements

	HHS OIG Proposed Safe Harbors to Anti-Kickback Statute	CMS Proposed Exceptions to Stark Law	Description
Highest Risk, Fewest Conditions	Full Financial Risk	Full Financial Risk	Health care providers responsible for cost of all covered items and services for specified patient group
Some Risk, More Conditions	Substantial Downside Financial Risk	Meaningful Downside Financial Risk	Health care providers partially financially responsible for failure to achieve goals
Low/No Risk, Most Conditions	Care Coordination Arrangements	Value-Based Arrangements	Available regardless of assumption of risk by health care providers

Source: CRS.

Full Financial Risk. Both the OIG and CMS proposed rules would permit compensation between participants in a value-based arrangement if the relevant parties assume "full financial risk" for the patients receiving services under the arrangement. As part of these arrangements, health care providers would be responsible for the cost of *all* covered items and services for each patient in this group. An example could include a Medicaid managed care organization that receives a fixed, monthly amount to cover the cost of all Medicaid-covered items and services furnished to a pre-determined patient group. Given that the full financial risk safe harbor and exception involve the assumption of the highest level of risk of financial loss under the proposed rules, health care providers participating in these arrangements would also have to meet fewer conditions compared to the other value-based safe harbors and exceptions.

Substantial Downside Financial Risk Safe Harbor and Meaningful Downside Financial Risk Exception. The substantial downside financial risk safe harbor for the Anti-Kickback Statute and the "meaningful downside financial risk" exception to the Stark Law would cover value-based arrangements in which a health care provider is partially financially responsible for failure to achieve the value-based arrangement's goals. For example, under the Stark Law exception, a physician would be responsible for repaying at least twenty-five percent of the value of the compensation or other remuneration the physician receives if the arrangement fails to meet the value-related outcomes. Compared to the full financial risk exception, these value-based arrangements would have to meet, among other things, enhanced documentation requirements to enhance transparency and accountability in these arrangements.

Care Coordination Safe Harbor and Value-Based Arrangements Exception. This safe harbor and exception would apply to value-based arrangements regardless of risk undertaken by the participants. Value-based arrangements that would meet this Anti-Kickback Statute safe harbor or Stark Law exception would be subject to the most conditions and limitations. For example, the value-based arrangement safe harbor would only apply to "in-kind" contributions (i.e., non-monetary remuneration) and recipients receiving an item of value would have to cover fifteen percent of the donor's cost as part of the arrangement. As the OIG notes in its proposed rule, one example of this type of value-based arrangement could be one between a hospital and a nursing facility in which the hospital provides a nurse to the nursing facility to follow designated in-patients in an effort to ensure adequate patient care following transition from one health care setting to another. Under this example, the nursing facility would have to pay for at least fifteen percent of the hospital's cost of the nurse's services. Additionally, this safe harbor would require parties to end a value-based arrangement within a specified period upon a determination that, for example, the arrangement is unlikely to further the coordination and management of care for applicable patients, or it has led to material deficiencies in quality of care.

Key Takeaways for Congress

The HHS OIG and CMS each received numerous comments about the proposed rules, expressing a variety of viewpoints. While some commenters generally articulated support for the Trump Administration's efforts to promote value-based arrangements, others expressed concerns about inadequate safeguards in the proposed rules to protect against the potential for program abuse and risk to patients.

One issue of debate under the proposed rules is whether certain product providers and suppliers should be excluded from participation in a value-based arrangement. Specifically, under the Anti-Kickback proposed rule, the OIG proposed to exclude pharmaceutical manufacturers, laboratories, and certain product suppliers from inclusion as participants in the value-based arrangement safe harbors. CMS, however, did not exclude particular entities from participation in the proposed Stark Law exceptions, but the Agency requested comments on the matter.

Issues surrounding inclusion of drug manufacturers and other entities as part of value-based arrangements generally center on the products these entities provide. For example, value-based arrangements may involve the provision of technology (for example, providing a smart watch to patients that reminds them to take their prescribed medications) or other products that might help deliver better quality care or improve patient health. In the preamble to the Anti-Kickback Statute proposed rule, the OIG explains that, based on historical enforcement and oversight experience, these types of entities greatly depend on referrals, and the agency voiced concerns that these entities would use value-based-type arrangements as a way to anchor clinicians or patients to the use of a particular product, even when a different product could be more clinically effective. The CMS and OIG will likely address this issue in the forthcoming final rules.

Additionally, in the proposed rules, both the OIG and CMS seek comments on the definition of "target patient population," i.e., the identified patient group that could receive care under the value-based arrangement. Currently, the proposed rules would define this population broadly as a group that must be identified in advance and further the value-based purpose of the arrangement. In the preamble to the Anti-Kickback proposed rule, the OIG indicated that it is considering limiting the target patient population to patients with a chronic condition or a particular disease who could benefit from care coordination. Both the OIG and CMS also sought comment on whether third parties outside the value-based arrangement participants should be involved in selecting the patient group. Changes to the definition of "target patient population" could substantially affect the scope of arrangements eligible for protection under the value-based arrangement safe harbors and exceptions.

Author Information

Jennifer A. Staman
Legislative Attorney

Disclaimer