Holland & Hart

J. Malcolm (Jay) DeVoy

Partner
702.669.4636
Las Vegas, Reno
jmdevoy@hollandhart.com

Final Rules for Stark and Anti-Kickback Reforms Issued by CMS and OIG

Insight — 11/23/2020

On November 20, 2020 the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services Office of the Inspector General (OIG) issued two final rules to modernize and clarify the Physician Self-Referral regulations (the Stark Law, or Stark) and the Anti-Kickback Statute (AKS) safe harbor regulations. These new final rules generally take effect on January 19, 2021.

The prior Stark and AKS regulations were developed in a volume-based health care delivery and payment system. Over time, and with the rise of data that could be used by providers and payers to better anticipate patient needs and payment for them, concern arose that the existing regulations and policies would potentially inhibit the innovation necessary for moving toward a value-based system of care and payment. These new final rules aim to alleviate those concerns and advance the transition to value-based care and encourage the coordination of care among providers, while continuing to provide important safeguards to protect against fraud, abuse, and overutilization.

1. STARK FINAL RULE

The Stark final rule aims to build a successful value-based system by encouraging innovative new models in Medicare and Medicaid and removing regulatory barriers that impede care coordination. The final rule includes: three new value-based exceptions and relevant defined terms; guidance and clarification on several key definitions and requirements; clarification regarding group practice profit shares and productivity bonuses; and new exceptions for non-abusive arrangements for which there is currently no applicable exception. These regulations are effective on January 19, 2021, except for the amendment regarding group practice compensation methodologies, which is effective January 1, 2022.

A. The final rule establishes new exceptions to Stark for value-based arrangements.

Three new exceptions have been added for value-based compensation arrangements. These exceptions differ from the prior Stark exceptions, which require that compensation be set at fair market value, and not determined in a manner that takes into account the volume or value of referrals. Instead of requiring adherence to requirements that arose in a fee-based environment, the definitions and requirements of 42 CFR § 422.357(aa) provide criteria specific to a value-based environment to

guard against program or patient abuse. For example, each new exception includes the requirements that (1) remuneration is not an inducement to reduce or limit medically necessary items or services to any patient; and (2) if a patient expresses a preference for a provider, such preference supersedes any referral conditions. The new requirements and definitions form a foundation of program integrity which, together with the intrinsic disincentives created when entities assume a substantial downside financial risk, result in arrangements that do not create risk of overutilization or patient or program abuse.

The following new terms, which are essential to reference when analyzing whether a particular compensation arrangement qualifies for one of the new value-based exceptions, are defined at 42 CFR § 411.351: (1) value-based activity; (2) value-based arrangement; (3) value-based enterprise (VBE); (4) value-based purpose; (5) VBE participant; and (6) target patient population.

The three new exceptions apply only to value-based arrangements and are found at 42 CFR § 422.357(aa):

1. Value-based arrangements where a VBE has assumed full financial risk from a payor for patient care services for a target patient population, for the entire duration of the arrangement.
2. Value-based arrangements where a physician has a meaningful downside financial risk for failure to achieve the value-based purposes of the VBE during the entire duration of the arrangement. This exception requires a description of the nature and extent of the physician's downside financial risk to be set forth in writing.
3. Any value-based arrangements that meets specific requirements. This exception requires the arrangement to be set forth in writing, commercially reasonable, and signed by the parties. Further, this exception requires parties to monitor whether they have furnished the value-based activities required under the arrangement and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the VBE.

B. The final rule sets forth further guidance and clarifications and new exceptions.

The final rule also amends several existing definitions and provisions. The terms “commercially reasonable,” “designated health services,” “fair market value,” “isolated financial transaction,” “referral,” and “remuneration,” amongst others, have been clarified. The rules also set forth a method for determining when compensation will be considered to “take into account” the volume or value of referrals. The final rule restructures and clarifies the group practices regulations regarding the application of the “volume or value standard” as well as profit shares and productivity bonuses. This portion of the final rule is not effective until January 1, 2022 to allow group practices with existing arrangements to evaluate and revise their contracts concurrent with the calendar year cycle.

New exceptions for non-abusive arrangements for which there is currently no applicable exception in Stark were also added. For example, there is a

new exception for certain arrangements under which a physician receives limited remuneration ($5,000 or less per calendar year) for items or services actually provided by the physician. Additionally, the final rule amends the existing exception for electronic health records (EHR) items and services and establishes a new exception for donations of cybersecurity technology and related services.

2. AKS FINAL RULE

The AKS final rule implements seven new safe harbors, modifies four existing safe harbors, and codifies one new exception under the beneficiary inducements civil monetary penalty (CMP). This final rule also revises the definition of “remuneration” set forth in the civil monetary penalty law, 42 USC § 1320a-7a. All of the new safe harbors and amendments to existing safe harbors are effective January 19, 2021. AKS is an intent-based, criminal statute that prohibits any form of remuneration, whether monetary or in-kind, in exchange for referrals or other Federal health care program business by any person or entity (not solely a physician or person acting at a physician's direction). Prior guidance from the OIG confirms that where even one purpose of remuneration is to influence or obtain referrals for services paid for by federal health programs (including Medicare, Medicaid, or Tricare), the AKS is implicated. Safe harbor regulations describe voluntary payment and business practices that, if fully followed, will not constitute a violation of the AKS, even though the underlying transactions or relationships may implicate that law. While a party need not comply does not have to comply with a safe harbor in order to not violate the AKS, compliance with a safe harbor provides protection against liability under that law. The CMP consequences for providing beneficiary inducements (Beneficiary Inducements CMP) is a civil, administrative statute that prohibits knowingly offering something of value to a program beneficiary to induce them to select a particular provider, practitioner, or supplier.

The final rule's changes, particularly to the AKS safe harbors, were made in response to concerns that existing safe harbors stifled innovation in entering value-based arrangements with other providers to improve the quality of patient care. In issuing the AKS final rule, OIG stated that its purpose was to aid the transformation of established practices needed to facilitate collaboration between providers and other individuals or entities, and to pay for health and outcomes rather than volume of services rendered.

A. The AKS final rule codifies safe harbors for a range of risk-sharing agreements.

The AKS final rule codifies three new safe harbors for parties in value-based arrangements (as defined within the final rule): (1) care coordination agreements, (2) value-based arrangements with substantial downside financial risk, and (3) value-based arrangements with full financial risk. These new terms and standards bear a relationship with the exceptions found in the Stark final rule, using many of the same terms, including VBEs, to condition and qualify these relationships. Each new safe harbor has subtly distinct requirements and limits to the remuneration they cover,

ranging from in-kind services to monetary payment, which vary based on the level of financial risk inherent in the relationship.

The scale of risk can be summarized for these three new safe harbors found in 42 CFR § 1001.952(ee), (ff), and (gg):

1. Care coordination agreements define coordination and management of care to be the deliberate organization of patient care activities and sharing of information between two or more VBE activities, one or more VBE participants and the VBE, or one or more VBE participants and patients, and which is designed to achieve safer, more effective, or more efficient care to improve the target patient population's health outcomes. 42 CFR § 1001.952(ee)(14)(i). As this definition is focused on conduct and activity rather than financial participation, it applies only to in-kind remuneration and not a monetary exchange. 42 CFR § 1001.952(ee)(1)(i).
2. The definition of “substantial downside financial risk” within a value-based arrangement with substantial downside financial risk can be satisfied by three different standards This standard is satisfied where there is (1) risk equal to at least 30% of any loss based on a comparison of current expenditures against bona fide benchmarks to approximate the total cost of care; (2) risk equal to at least 20% of any loss based on a comparison of current expenditures against bona fide benchmarks to approximate the total cost of care for defined clinical episodes agreed upon by the parties; or (3) a prospective, per patient payment that is designed to produce material savings and paid at least annually for a defined set of services or items furnished to the patient population, anticipated to satisfy the costs for those items and services. 42 CFR § 1001.952(ff)(9)(i)(A)-(C).
3. A value-based arrangement with full financial risk exists where a 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 population for a term of at least 1 year. 42 CFR § 1001.952(gg)(10)(i).

These new safe harbors contemplate different levels of financial risk and tailor their protections to reflect each party's degree of participation. While care coordination agreements require little or no assumption of financial risk and apply only to remunerative in-kind services, value-based arrangements with substantial or full financial risk protect the exchange of both in-kind services and monetary remuneration.

Additionally, the AKS final rule modifies one existing safe harbor to allow for flexibility in paying monetary remuneration in exchange for services performed or outcomes achieved. The final rule modifies the safe harbor for personal services agreements and management agreements under 42 CFR § 1001.952(d) by adding new protection for outcomes-based payments. Similar to the terms of the original underlying safe harbor, these outcome-based payments must be in writing; describe the services subject to outcome-based payments; identify the outcome measures that must be achieved to receive an outcomes-based payment; state the clinical

evidence or credible medical support relied upon to select the outcome measures; and be set in advance. Parties participating in an outcomes-based arrangement must also have policies and procedures in place to address and correct material performance failures or deficiencies in quality of care resulting from the agreement. Notably, outcomes-based payments can be positive or negative: successfully achieving an outcome results in payment, while failure to reach an outcome can result in a reduction in payment or recoupment of previously paid funds.

For the Medicare Shared Savings Program (MSSP) and other payment models that CMS sponsors or may wish to test through the Centers for Medicare and Medicaid Innovation (CMMI), the AKS final rule creates a new safe harbor at 42 CFR § 1001.952(ii). Under this safe harbor for CMS-sponsored model arrangements and patient incentives promulgated by CMMI, parties acting under a CMS-sponsored model arrangement may exchange anything of value between or among themselves, provided that the exchange of value does not induce the parties to the model agreement or other suppliers to furnish medically unnecessary items or services. Additionally, payments under the model arrangement cannot induce its parties or suppliers to reduce or limit medically necessary items or services. The payments made under this safe harbor cannot be made to obtain referrals for business paid by other federal healthcare programs, or for business unrelated to the model arrangement. The parties' relationship must be in writing upon or prior to participating in the CMS-sponsored model arrangement, specify each party's activities, and each party must make its related materials available to the DHHS Secretary to demonstrate compliance with this safe harbor.

B. Electronic health records and cybersecurity receive special attention.

The AKS final rule modified the existing safe harbor for electronic health records items and services found at 42 CFR § 1001.952(y). This revision removed sections regarding interoperability that have since been addressed by the 21st Century Cures Act and subsequent rulemaking (e.g., the Information Blocking Rule), and removed prohibitions on the donation of equivalent technology. The AKS final rule also clarified the cybersecurity technology and services included in an electronic health records arrangement.

As a separate and distinct item or service from electronic health records, cybersecurity receives its own safe harbor under the AKS final rule, found at 42 CFR § 1001.952(jj). This safe harbor allows for the donation of cybersecurity technology pursuant to a written agreement that describes the technology and services provided, and which cannot take into account the value or volume or referrals, or condition such a donation on future referrals or an ongoing business relationship. To future-proof this safe harbor against new and unforeseen types of risks, it takes a broad definition of cybersecurity to include “preventing, detecting, and responding to cyberattacks.” 42 CFR § 1001.952(jj)(5)(i).

C. Patient engagement and protection from beneficiary

inducement penalties.

The AKS final rule also creates a new safe harbor for patient engagement and support programs within 42 CFR § 1001.952(hh). This new safe harbor allows a value-based enterprise to provide a tool, such as an application, Internet-provided service, or other service, that is recommended by the patient's physician in order to encourage patient adherence with treatment or drug use, follow-up, or management of an ongoing disease or condition. These programs cannot be used for marketing to patients and cannot involve the payment of any monetary remuneration; moreover, the in-kind value of the tool or support service cannot exceed $500 on an annual basis, which amount is tied to increase with inflation (although the regulation does not specify if this spending restriction is based on a calendar year or a rolling 12-month basis determine on when the patient began using the tool or service).

Finally, the AKS final rule modifies the Beneficiary Inducement CMP so that certain benefits offered to patients do not violate its terms. These activities removed from the scope of the CMP include: (1) telehealth technologies that can be furnished to in-home dialysis patients; (2) patient engagement and support programs permitted under 42 CFR § 1001.952(hh); and (3) the modified safe harbor for local transportation within 42 CFR § 1001.952(bb). When rendered in compliance with the applicable rules, these services will not form the basis for civil monetary penalties. Relatedly, a new safe harbor found within 42 CFR 1001.952(kk) protects ACO incentive payments made by the ACO to assigned beneficiaries if the payments are made in compliance with applicable law. This last new safe harbor also furthers the goal of creating financial incentives and rewards for baseline levels of health that obviate the need for medical care.

3. CONCLUSION

While the proposed rules issued by CMS and OIG on October 17, 2019 provided an indication of what issues both offices intended to address in their final rules, the final rules were issued with a limited time for affected individuals and entities to comply. Ultimately, the Stark and AKS final rules may open the door to new financial arrangements that parties previously chose not to enter because they did not fall within an applicable exception or safe harbor. Beginning in January of 2021, current and prospective arrangements will have to be analyzed with consideration of these new provisions.

The text to the Stark Final Rule can be found here.

The text to the AKS Final Rule can be found here.

This publication is designed to provide general information on pertinent legal topics. The statements made are provided for educational purposes only. They do not constitute legal or financial advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the author. This publication is not intended to create an attorney-client relationship between you and Holland & Hart LLP.

Substantive changes in the law subsequent to the date of this publication might affect the analysis or commentary. Similarly, the analysis may differ depending on the jurisdiction or circumstances. If you have specific questions as to the application of the law to your activities, you should seek the advice of your legal counsel.

This publication is designed to provide general information on pertinent legal topics. The statements made are provided for educational purposes only. They do not constitute legal or financial advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the author(s). This publication is not intended to create an attorney-client relationship between you and Holland & Hart LLP. Substantive changes in the law subsequent to the date of this publication might affect the analysis or commentary. Similarly, the analysis may differ depending on the jurisdiction or circumstances. If you have specific questions as to the application of the law to your activities, you should seek the advice of your legal counsel.