AAOS
American Association of Orthopaedic Surgeons

Changes to the Physician Self-Referral Law and Anti-Kickback Statute

In December 2020, the Centers for Medicare & Medicaid Services (CMS) released finalized changes to the Physician Self-Referral (Stark) Law and the Department of Health and Human Services' Office of the Inspector General concurrently released changes to the Anti-Kickback Statute. Updates to these decades-old rules will result in a restructuring of the regulatory landscape which has long hamstringed physicians attempting to shift to value-based care. In formalizing a new universe of value-based care definitions for providers to collaborate within, the agencies will mitigate many regulatory or legal disparities between the two rules which create new safe harbors for value-based arrangements and reward greater financial risk with greater regulatory flexibility. AAOS has long-advocated for such changes and applauds the agencies' efforts to reduce burden for physicians.

CMS' Physician Self-Referral Law

The final rule offers new and permanent exceptions to the Physician Self-Referral (Stark) Law intended to simplify and increase participation in value-based arrangements for both Medicare and non-Medicare patients. The value-based arrangements grant greater flexibility based on the level of financial risk which parties to the arrangement assume.

Definitions

Value-based activity: "any of the following activities, provided that activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties to the arrangement are participants."

Value-based arrangement: "an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (1) A value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise."

- The value-based arrangement must be a compensation arrangement, not any other type of financial relationship which is prohibited by the law
- Does not require care coordination and management to be qualified as a value-based arrangement
- "Only an arrangement for activities that are reasonably designed to achieve at least one of the value-based enterprise's value-based purposes may qualify as a value-based arrangement."

Value-based enterprise: "means two or more VBE participants: (1) Collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)."

- Includes only "organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care delivery and payment system

- The enterprise could be either a "distinct legal entity—such as an ACO with a formal governing body, operating agreement, or bylaws, and the ability to receive payment on behalf of its affiliated health care providers"; or it may "consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s)."
- The definition is intended to focus on the functions of the enterprise and not limit the legal structures for qualifying as such
- "Each participant in the enterprise…must be a party to at least one value-based arrangement with at least one other participant in the enterprise."
- Should the enterprise consist of just two value-based enterprise participants, they "must have at least one value-based arrangement with each other in order for the enterprise to qualify as a value-based enterprise."
- "A value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise."
- The value-based enterprise "must have a governing document that describes the enterprise and how its VBE participants intent to achieve its value-based purpose(s)."

Value-based purpose: "means: (1) Coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population."

> ***Example:*** "if the value-based purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement might require routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. The value-based activity—that is, the physician's participation in the post-discharge meetings—would be reasonably designed to achieve the enterprise's value-based purpose."

Value-based enterprise participant: "means a person or entity that engages in at least one value-based activity as part of a value-based enterprise."

- The definition "does not exclude any specific persons, entities, or organizations from qualifying as a VBE participant."

Target patient population: "means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s)."

- Legitimate and verifiable criteria "may include medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed Type 2 diabetes), geographic characteristics (for example, all patients in an identified county or set of zip codes), payor status (for example, all patients with a particular health insurance plan or payor), or other defining characteristics."

Participants must meet the requirements of the above definitions and participate in compensation arrangements which qualify as eligible value-based enterprises to receive the safe harbor of the exceptions to the law.

The law will not finalize a "requirement that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the entity."

Exceptions to the Physician Self-Referral Law

Full Financial Risk: "an exception to the law that applies to a value-based arrangement between VBE participants in a value-based enterprise that has assumed full financial risk 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; that is, the value-based enterprise is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of such patient care items and services"

- For VBE's which apply to Medicare beneficiaries, CMS intends for "this requirement to mean that the value-based enterprise, at a minimum, is responsible for all items and services covered under Parts A and B."
- CMS is extending the time period during which "the exception will be available prior to the value-based enterprise's financial responsibility for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population."
- Instead of requiring the VBE to be financially responsible within the 6 months following the commencement date of the value-based arrangement, the VBE must be financially responsible, or contractually obligated to be financially responsible, within a 12-month timeframe following the start date of the value-based arrangement
- Financial responsibility entails obligation 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 may take the form of capitation payments of global budget payments from a payor who compensates the VBE for providing all patient care items and services for a specified period of time and target patient population, however, CMS is not "prescribing a specific manner for the assumption of full financial risk"
- The VBE must be at full financial risk during the "entire duration of the value-based arrangement for which the parties to the arrangement seek protection."
- The final exception will not safeguard those arrangements that "begin at some point during a period when the value-based enterprise has assumed full financial risk, but that continue into a timeframe when the safeguards intrinsic to full-financial risk payment, such as the disincentive to overutilize or stint on medically necessary care, no longer exist."
- "Remuneration under the value-based arrangement is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population."

- CMS does not interpret the rule to "mandate a one-to-one payment for an item or service (or other value-based activity)…gainsharing payments, shared savings distributions, and similar payments may result from value-based activities undertaken by the recipient of the payment for patients in the target patient population.
- "The requirement that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population"
- Payments for referrals "or any other actions or business unrelated to the target patient population, such as general marketing or sales arrangements" will not be protected under the exception
- In-kind remuneration: CMS states that "the remuneration must be necessary and not simply duplicate technology or other infrastructure that the recipient already has."
- While the remuneration "must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, parties would not be prohibited from using the remuneration for the benefit of patients who are not part of the target patient population."
- Remuneration "under a value-based arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not."
- "The remuneration must 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. The final exception does not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration."

Example: "The exception will not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement requires that the physician perform all his or her orthopedic surgeries at the hospital."

- "If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier the value-based arrangement complies with both of the following conditions: (A) must be set out in writing and signed by the parties; and (B) the requirement to make referrals to a particular provider, practitioner, or supplier may not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interest"

Meaningful Downside Financial Risk to the Physician: "the physician is responsible to pay the entity no less than 10 percent of the value of the remuneration the physician receives under the value-based arrangement."

- The physician "must be at meaningful downside financial risk for the entire duration of the value-based arrangement to curtail any gaming that could occur by adding meaningful downside financial risk to a physician during only a short portion of an arrangement."
- "The methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided."

- However, this is only a deeming provision and "parties are free to confirm satisfaction of the requirement another way."
- To prevent patient harm, "remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act"
- "The remuneration must 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. The final exception does not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration."

Example: "If a physician is entitled to a base payment of $50,000 with the ability to earn an additional $25,000 for performing certain value-based activities, meaningful downside financial risk equals at least 10 percent of the total compensation of $75,000, or $7,500. The $25,000 that is at risk for purposes of this example exceeds the 10 percent requirement. However, unless the receipt of the $25,000 is tied to the achievement of the value-based purpose(s) of the value-based enterprise, the arrangement will not satisfy the requirement"

Value-based Arrangement Exception:

- This exception will be subject to all of the same safeguards included in the Meaningful Downside Risk exception, including to patient choice
- An additional requirement is that "the remuneration under the value-based arrangement is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement."
- The value-based arrangement must be set forth in writing, signed by the parties, and include "a description of the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any."
- Outcome measures "against which the recipient of remuneration will be assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support."
- Outcome measures: "a benchmark that quantifies: (A) Improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care."
- "The outcome measures against which the recipient of the remuneration will be assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support."
- Explicit monitoring requirement: "Parties seeking to utilize the value-based arrangement exception (or the value-based enterprise in which they participate) must monitor the value-based arrangement no less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, to determine whether the parties 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 value-based enterprise."

- The "value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties if the parties terminate the arrangement within 30 consecutive calendar days or modify their arrangement within 90 consecutive calendar days after completion of the monitoring."
- Parties will have 90 consecutive calendar days to "terminate or replace an outcome measure that their monitoring indicates is unattainable."
- There will be a "90-day timeframe for the termination of value-based activities that are not expected to further the value-based purpose(s) of the value-based enterprise."
- CMS is not finalizing a contribution requirement from the recipient of nonmonetary compensation

New Cybersecurity Technology Exception: Allows for the "nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity" if the arrangement is documented in writing, "neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties", and "neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor."

- Cybersecurity: "the process of protecting information by preventing, detecting, and responding to cyberattacks"
- Technology: "any software or other type of information technology"
- The existing electronic health record (EHR) exception has been made permanent and been clarified to state that the "exception is applicable (and always has been applicable) to certain cybersecurity software and services, and to more broadly protect the donation of software and services related to cybersecurity."

New Exception for Limited Remuneration to a Physician: The new annual aggregate remuneration limit to the physician will be $5,000 instead of $3,500, and the exception "permits the physician to provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians." The arrangement must also be "commercially reasonable even if no referrals were made between the parties."

Updates to the Rules for Ancillary Income Distribution in Group Practices: The Stark Law final rule makes a substantive change to how the profits from ancillary services may be split among members of a group practice. Under the updated law, group practices will be required define "overall profits" as the aggregate of all profits from designated health services (DHS) of the entire group, or each component of the group which comprises at least five physicians. The group practice will not be allowed to allocate the profits from DHS by service line. Rather there are multiple methodologies by which the group practice may disburse the portions of the overall DHS profits to each group of five physicians. However, the disbursements may not be directly tied to the volume or value of referrals.

***Example*:** "Assume a group practice comprised of 15 physicians furnishes clinical laboratory services, diagnostic imaging services, and radiation oncology services. Assume further that the group practice has divided its physicians into three components of five physicians (component A, component B, and component C) for purposes of distributing the overall profits from the designated services of the group practice. Under the final regulations, for each component, the group practice must aggregate the profits from all the designated health services furnished by the group and referred by any of the five physicians in the component. The group practice may distribute the overall profits from all the designated health services of component A using one methodology (for example, a per-capita distribution methodology), distribute the overall profits from all the designated health services of component B using a different methodology (for example, a personal productivity methodology in compliance with § 411.352(i)(1)(iii)(B)), and distribute the overall profits from all the designated health services of component C using a third methodology that does not directly relate to the volume or value of the component physicians' referrals (or the methodology used for component A or B). However, a group practice must utilize the same methodology for distributing overall profits for every physician in the component. That is, using the illustration above, the group practice must use the per-capita distribution methodology for each physician in component A, the personal productivity methodology for each physician in component B, and the same methodology (whichever it utilizes) for each physician in component C."

HHS' Anti-Kickback Statute

The final rule offers new and permanent exceptions to the Anti-Kickback Statute intended to simplify and increase participation in value-based arrangements, as well as increase regulatory congruence with the Physician Self-Referral (Stark) Law. The value-based arrangements grant greater flexibility based on the level of financial risk which parties to the arrangement assume.

Definitions

Value-based enterprise: "two or more VBE participants (A) Collaborating to achieve at least one value-based purpose; (B) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (C) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (D) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)."

Value-based arrangement: "an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (A) The value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based enterprise."

Target patient population: "an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) Are set out in writing in advance of the commencement of the value-based arrangement; and (B) further the value-based enterprise's value-based purpose(s)."

Value-based activity: "means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action; and does not include the making of a referral."

Value-based enterprise participant: "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient."
Value-based purpose: "(A) Coordinating and managing the care of a target patient population; (B) improving the quality of care for a target patient population; (C) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (D) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population."
Coordination and management of care: "the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population."
Outcomes measures: "Parties to a value-based arrangement establish one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support. The measure(s) must: (i) Include one or more benchmarks related to improving, or maintaining improvement, in the coordination and management of care for the target patient population; (ii) relate to the remuneration exchanged under the value-based arrangement; and (iii) not be based solely on patient satisfaction or patient convenience."

- The measures must be "monitored, periodically assessed, and prospectively revised, as necessary, so that working towards the measure continues to advance the coordination and management of care of the target patient population."

New Safe Harbors
Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor: "The safe harbor protects in-kind remuneration exchanged between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement that squarely satisfies all of the proposed safe harbor's requirements…The safe harbor includes conditions related to commercial reasonableness, outcomes measures, written documentation, record retention, monitoring, termination, marketing and patient recruitment, and diversion and reselling remuneration."

- "The safe harbor requires that protected remuneration be used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population."
- "Protected arrangements cannot induce VBE participants to furnish medically unnecessary care or reduce or limit medically necessary care; cannot limit medical decision-making or patient freedom of choice; and cannot take into account the volume or value of business outside the value-based arrangement."
- "All recipients must pay 15 percent of the offeror's cost or 15 percent of the fair market value of the remuneration."

Value-Based Arrangements with Substantial Downside Financial Risk Safe Harbor: "For a value-based arrangement to be protected under this safe harbor, a VBE must assume substantial downside financial risk from a payor under one of three methodologies, and a VBE participant must assume a meaningful share of the

VBE's total risk…at least 5 percent. The safe harbor, as finalized, protects both monetary and in-kind remuneration exchanged."

- The other requirements to meet safe harbor status are: "the inclusion of a 6-month phase in period; requirements that certain remuneration be used to engage in value-based activities and directly connect to certain value-based purposes; writing and record retention requirements; protections for patient choice and clinical decision-making; protections against medically unnecessary services; limits on marketing or patient recruitment; and limits on remuneration that takes into account business or patients outside the value-based arrangement."
- This safe harbor may apply to participants in CMS-sponsored models, but is intended for commercial market value-based arrangements

Value-Based Arrangements with Full Financial Risk: For a value-based arrangement to be protected under this safe harbor, the VBE must "be at risk 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."

- The VBE or VBE participant must refrain from "taking into account the volume or value of, or condition the remuneration on: (i) Referrals of patients who are not part of the target patient population; or (ii) Business not covered under the value-based arrangement."

New Safe Harbor for Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency: HHS is finalizing a new safe harbor to protect the "remuneration in the form of patient engagement tools and supports furnished directly by VBE participants to patients in a target patient population."

- The safe harbor protects a broad range of tools, but only in the form of in-kind remuneration
- Entities which "may not furnish or otherwise fund or contribute to protected tools and supports under this safe harbor includes manufacturers, distributors, and wholesalers of pharmaceuticals; pharmacy benefit managers; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices and medical supplies (unless the tool or support is digital health technology); entities or individuals that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services); medical device distributors and wholesalers; and physician-owned medical device companies."

New Safe Harbor for CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives: HHS is finalizing a new safe harbor for payment models being tested or expanded by the Center for Medicare and Medicaid Innovation (CMMI). The safe harbor aims to provide protection for remuneration exchanged in the process of advancing "one or more goals of the CMS-sponsored model arrangement."

- The "remuneration does not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement for which CMS has determined that this safe harbor is available."

New Safe Harbor for Cybersecurity and Technology Services: HHS is finalizing a new safe harbor to protect arrangements "intended to address the growing threat of cyberattacks impacting the health care ecosystem." Not limited to software, the "final safe harbor will protect certain cybersecurity hardware donations" as well.

- As long as the other conditions of the safe harbor are met, "all donors, without any limitation on the type of individual or entity donating cybersecurity technology and services" will be protected.

Updates to Existing Safe Harbors

Modifications to the Electronic Health Records Safe Harbor: The existing safe harbor is being modified to make permanent changes "to update and remove provisions regarding interoperability, remove the sunset provision and prohibition on donation of equivalent technology, and clarify protections for cybersecurity technology and services included in an electronic health records arrangement."

Personal Services and Management Contracts and Outcomes-Based Payments: HHS is finalizing "changes to increase flexibility for part-time or sporadic arrangements and arrangements for which aggregate compensation is not known in advance." The safe harbor for "outcomes-based payments protects payments tied to achieving measurable outcomes that improve patient or population health or appropriately reduce payor costs."

Warranties: HHS is modifying the "revisions to the definition of "warranty" and to provide protection for warranties for one or more items and related services." The safe harbor is available to any type of entity.

Local Transportation: HHS is "finalizing, with modifications, changes to expand mileage limits for rural areas (up to 75 miles) and eliminate mileage limits for transportation to convey patients discharged from the hospital to their place of residence." This applies to rideshares as well.

Legal Disclaimer: The information on this page is meant to serve as an educational summary of federal laws related to the Physician Self-Referral Law and Anti-Kickback Statute. It does not constitute or substitute for legal advice. Interested parties should continue to consult their legal professionals.