

MEMORANDUM

October 15, 2019

Re: HHS Releases Proposed Rules Reforming Stark & Anti-Kickback Regulations

On October 9, 2019, the Department of Health and Human Services released companion proposed rules to reform the physician-self referral prohibitions (“Stark Law”), as well as the Medicare and Medicaid Anti-Kickback Statute (“AKS”). The proposed rules are the result of a CMS request for information (RFI)¹ on potential modifications to the Stark Law, and a separate RFI² from the HHS Office of Inspector General (OIG) on potential changes to the anti-kickback statute.

The proposed rules would create new protections under the AKS and Stark Law for healthcare entities engaging in value-based arrangements, allowing “value-based enterprises” to design and participate in certain “value-based activities.” A value-based arrangement would be required to have a “value-based purpose” related to coordinating and managing care, improving quality of care, reducing the cost, and/or transitioning to health care delivery and payment mechanisms based on the quality of care and control of costs of care. The proposed rules define these terms in greater detail as they apply to the AKS and Stark Law.

The proposed changes add flexibility and some critical clarifications. The newly proposed value-based exceptions and safe harbors are generally broad and flexible; however, OIG is considering excluding certain players from participating in Safe Harbor-approved “Value-Based Enterprises (VBE),” specifically pharmaceutical manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics or supplies, and laboratories.

The rules also add documentation complexity to an already highly technical regulatory scheme. For example, a significant requirement in both rules is creating a document outlining any value-based arrangement to get the safe harbor and exception. The document must include the targeted patient population, value-based outcome, and duration of the deal.

The proposals, if finalized, will remove legal barriers that have impeded care coordination but are likely to primarily benefit larger organizations that have the infrastructure to implement these types of value-based programs.

Click [here](#) for the CMS Stark Law fact sheet, and [here](#) for the proposed rule. Click [here](#) for the OIG AKS fact sheet, and [here](#) for the proposed rule. The rules have yet to be published in the Federal Register, but according to a CMS Fact Sheet, **comments will be due by December 31, 2019.**

Proposed Rule to Update the Stark Law

CMS notes that the Stark Law regulations have “not been significantly updated” since their enactment nearly 30 years ago. Accordingly, CMS’ proposed rule would create three new, permanent exceptions to the physician-self referral “Stark Law” for providers in value-based payment arrangements that differ

¹ Medicare Program; Request for Information Regarding the Physician Self-Referral Law, CMS, 83 Fed. Reg. 29,524 (June 25, 2018); Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, OIG, 83 Fed. Reg. 43,607 (Aug. 27, 2018).
² Request for Information on Modifying HIPAA Rules To Improve Coordinated Care, OCR, 83 Fed. Reg. 64,302 (Dec. 14, 2018).

based on the level of financial risk. The exceptions would apply regardless of whether the arrangements relate to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.

In the Proposed Rule, CMS explains that the new exceptions are dependent on the parties to a proposed arrangement satisfying both the requirements of the Proposed Rule's new definitions applicable to the new exceptions as well as each element of the exceptions themselves. The new definitions include the following:

- **The value-based activity** would mean any of the following activities that are 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.
- **The value-based arrangement** would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among – (1) the value-based enterprise and one or more of its VBE participants or (2) VBE participants in the same value-based enterprise.
- **Value-based enterprise** would mean 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 has an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that has a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).
- **Value-based purpose** would mean (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
- **VBE participant** would mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.
- **Target patient population:** an identified patient population selected based on legitimate and verifiable criteria that are set out in writing in advance of beginning the value-based arrangement and further the enterprise's value-based purpose(s).

As noted above, CMS is considering excluding the following from the definition of VBE participant: pharmaceutical manufacturers, DME manufacturers and distributors, PBMs, wholesalers, and distributors. The agency does say that these groups would still be able to participate and contribute to a value-based enterprise; however, CMS is seeking feedback on which persons and entities should qualify as VBE participants.

CMS is proposing three new exceptions to the self-referral law for compensation arrangements that satisfy specific requirements:

- **The full risk exception:** this exception to the physician self-referral law applies to value-based arrangements 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 population for the entire duration of the value-based arrangement. Financial risk must be prospective.
 - For Medicare beneficiaries, CMS is interpreting this requirement to mean that a value-based enterprise is minimally responsible for items and services covered under Part A and Part B.
- **The meaningful downside financial risk exception:** this exception would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose of the enterprise.
 - In this exception, meaningful downside financial risk would mean the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration received under the value-based arrangement.
 - Remuneration may also not be provided as an inducement to reduce or limit medically necessary items or services to any patients, whether in the target population or not.
- **The value-based arrangements exception:** the exception would permit both monetary and nonmonetary remuneration between the parties of compensation arrangements that qualify as value-based arrangements. This would apply regardless of the level of risk undertaken by the VBE or any of its participants.
 - The remuneration, as with the meaningful downside financial risk exception, must be for value-based activities undertaken for patients in the target population.
 - The methodology for the remuneration must be set in advance and cannot be provided as an inducement to reduce or limit medically necessary items or services.
 - This exception would be applicable to value-based arrangements where neither party has undertaken downside financial risk.

CMS also makes several clarifications regarding the “volume or value standard” concerning physician group practices and the appropriate distribution of profit shares, productivity bonuses, and revenue associated with participation in a value-based enterprise.

CMS also provides a cybersecurity technology donation safe harbor. Currently, a hospital that wants to protect its electronic health records (EHRs) and other data may be worried about providing cybersecurity software at a reduced fee to physicians using the system due to concerns about the Stark Law. The goal is to protect the broader healthcare system by providing cybersecurity software to physician practices that may individually find it financially infeasible to purchase it themselves

The proposed rule also includes a provision directed at protecting beneficiary incentives for the utilization of telehealth for certain in-home dialysis patients.

Finally, CMS seeks feedback on "the role of price transparency in the context of the Stark Law and whether to require cost-of-care information at the point of a referral for an item or service."

Proposed Rule to Update the Anti-Kickback Statute

The anti-kickback proposal from HHS' OIG proposes to create new and modify existing safe harbors to promote innovative arrangements. OIG noted that, for some arrangements, the Anti-Kickback Statute appropriately should serve as "backstop" protection for arrangements that might qualify for protection under the Stark Law. So, the differences between the two rules are likely to limit the agencies' efforts to provide a unified set of regulations.

Under the proposed rule, OIG proposes the following safe harbors:

1. **Cybersecurity Technology:** Like the proposed changes to the Stark Law regulations, the OIG also includes changes to allow for donations of cybersecurity technology and services through a new safe harbor;
2. **CMS-Sponsored Models:** Implement a new safe harbor for certain remunerations provided under specific CMS-sponsored payment models;
3. **Patient Engagement:** Implement a new safe harbor for specific tools and supports provided to patients that are intended to bolster efficiency, health outcomes, and quality;
4. **Value-Based Arrangements:** Implement three new safe harbors for certain remunerations between eligible participants under "care coordination arrangements to improve quality, health outcomes, and efficiency"; "value-based arrangements with substantial downside financial risk"; and "value-based arrangements with full financial risk";
5. **EHR Services:** Modify the existing safe harbor for EHR to include protections for certain EHR-related cybertechnology, update provisions related to interoperability, and remove the current sunset date;
6. **Local Transportation:** Modify the existing safe harbor for local transportation to expand mileage limits for rural areas and beneficiary transportation from inpatient facilities after a discharge;
7. **Outcomes-Based Payments and Part-Time Agreements:** Modify the existing safe harbor for personal services and management contracts to increase flexibility for outcomes-based payments and part-time agreements;
8. **Warranties:** Modify the existing safe harbor for warranties to update the provision's definition of "warranty" and include protections for certain bundled warranties;
9. **ACOs:** Codify a statutory exception to the definition of "remuneration" in relation to accountable care organization beneficiary incentive programs under the Medicare Shared Savings Program; and
10. **Telehealth for In-Home Dialysis:** A proposed amendment to the definition of "remuneration" in the rules interpreting and incorporating a new exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients.