NCPA Summary of OIG Anti-Kickback and CMS Stark Law Proposed Rules

Comments due 12/31/19

The Department of Health and Human Services (HHS) released two proposed rules on October 9, 2019 to modernize and clarify the regulations that interpret the Federal Anti-Kickback Statute (AKS) (AKS Proposed Rule) [1] and Physician Self-Referral Law (Stark Law) (Stark Law Proposed Rule).[2] The AKS and Stark Law Proposed Rules are part of HHS' Regulatory Sprint to remove potential regulatory barriers to care coordination and value-based care created by four key healthcare laws and regulations: (i) Stark law; (ii) AKS; (iii) Health Insurance Portability and Accountability Act (HIPAA); and (iv) rules under 42 CFR Part 2 related to substance use disorder treatment.

While the agencies are working in tandem to align any proposed changes, in some instances the Office of Inspector General's (OIG) proposed modifications to AKS and the Civil Monetary Penalties (CMP) Law may be more restrictive than the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Stark Law. In some instances, AKS will act as a "backstop" to protect against arrangements that meet a Stark Law exception, but are still considered fraudulent or abusive. Further, CMS proposes to remove the provision in several Stark Law exceptions that requires compliance with AKS.

AKS PROPOSED RULE

Background: AKS provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, including Medicare and Medicaid.[3] The CMP law prohibits beneficiary inducements and imposes CMPs against any person who offers or transfers remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program.[4] A physician is a referral source to a pharmacy. If a pharmacy provides any type of remuneration to a physician for his or her services, such as money, gifts, etc. to a physician, then both the pharmacy and the physician need to comply with AKS. **The AKS Proposed Rule** sets forth provisions that would modify existing AKS safe harbors, create new AKS safe harbors, and create new CMP law exceptions.

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[1] *Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements Proposed Rule (OIG-0936- AA10-P)*, Office of Inspector General, Department of Health and Human Services, 42 CFR Parts 1001 and 1003, *available at* https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

[2] *Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations* (*CMS-1720-P)*, Centers for Medicare & Medicaid Services, Department of Health and Human Services, 42 CFR Part 411; RIN 0938-AT64, *available at* https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations.

[3] 42 U.S.C. § 1320a-7b(b).

[4] 42 U.S.C. § 1320a-7a(a)(5).

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New AKS Safe Harbors:

Value-Based Enterprise (VBE) Safe Harbors (numbers 1-3 below). VBEs include all entities that would participate in arrangements that would be eligible for a safe harbor, such as networks of individuals or entities that collaborate to achieve a value-based purpose. A **VBE participant** is defined as "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise." Engaging in a **value-based activity** may include (i) performing an action to achieve certain quality or outcome metric and the providing or receiving of payment for such achievement, or (ii) coordinating care to achieve better outcomes or efficiencies. **Potential VBE participants** could be physician practices, hospitals, payors, post-acute providers, pharmacies, chronic care and disease management companies, and social services organizations. **VBE participants do not include** pharmaceutical manufacturers, manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS); and laboratories.

OIG is considering whether to exclude all pharmacies, or only compounding pharmacies, from the definition of VBE participant, or from specific safe harbors. The agency acknowledges that some **pharmacies have the potential to contribute to the type of beneficial value-based arrangements** this rulemaking is designed to foster (i.e. through medication adherence programs or education services for diabetic patients). However, OIG is concerned that because pharmacies primarily provide items, that **pharmacies' participation in value-based arrangements may not further care coordination.** Based on OIG's enforcement experience, the agency stated that **compounding pharmacies may pose a heightened risk** of fraud and abuse and would not play a direct role in patient care coordination. OIG seeks specific comments on what **beneficial arrangements pharmacies may want to undertake and safeguards that could be implemented**. OIG is also seeking to exclude pharmacy benefit managers (PBMs), wholesalers, and distributors.

1. ***Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency***.[5] Covers care coordination arrangements to improve quality, health outcomes, and efficiency. Also covers certain in-kind remuneration, including services and infrastructure.
2. ***Value-Based Arrangements With Substantial Downside Financial Risk.***[6] Protects in-kind and monetary remuneration. VBE Participants must "meaningfully share" in downside risk**.**
3. ***Value-Based Arrangements With Full Financial Risk*.**[7] Protects in-kind and monetary remuneration. VBE Participants must have taken on full responsibility for all the costs of care for a specific patient population.
4. ***Patient Engagement and Supports*.**[8] Protects certain tools and supports furnished to patients by certain individuals and entities to improve quality, health outcomes and efficiency. Limited to in-kind remuneration and excludes gift cards, cash, and any cash equivalent. OIG solicits comments on the potential impact of its **considered exclusion of pharmacies**, PBMs, wholesalers, and distributors, if included in the final rule.
5. ***CMS-Sponsored Models*.**[9] Protects certain remuneration provided in connection with a CMS-sponsored model, such as those designed by the CMS Innovation Center, to replace the current fraud and abuse waiver process for each new model.

[5] 42 C.F.R. § 1001.952(ee).
[6] 42 C.F.R. § 1001.952(ff).
[7] 42 C.F.R. § 1001.952(gg).
[8] 42 C.F.R. § 1001.952(hh).
[9] 42 C.F.R. § 1001.952(ii).

6. ***Cybersecurity Technology and Services*.**[10] Creates a standalone protection for cybersecurity technology and services donations.

Modifications to Existing AKS Safe Harbors:

***Electronic Health Records Items and Services Safe Harbor*.**[11] An entity may donate software and training services "necessary and used predominantly to create, maintain, transmit, or receive electronic health records" if 12 requirements are satisfied. OIG proposes to update interoperability provisions, add certain cybersecurity technology protections, and remove the sunset date of Dec. 2021.

- **Interoperability**: Currently, donated items and services must be interoperable and donors are prohibited from taking action to limit the interoperability of the donation. Software is "deemed to be interoperable if, on the date it is provided to the recipient, it has been certified by a certifying body . . . "
    - OIG proposes to modify this language to clarify that, on the date the software is provided, it "is" certified. The certification would need to be current as of the date of the donation, instead of the software having been certified in the past but no longer maintaining certification on the date of the donation.
- **Cybersecurity**: Currently, the safe harbor protects electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.
    - OIG proposes to expand the EHR safe harbor to expressly include cybersecurity software and services so that it is clear that an entity donating EHR software and providing training and other related services may also donate related cybersecurity software and services to protect EHR. For clarity, OIG also proposes to incorporate a definition of "cybersecurity" in this safe harbor that mirrors the definition in the stand-alone cybersecurity safe harbor. A party seeking safe harbor protection needs to comply with the requirements of only one safe harbor.
- **Sunset Date**: The EHR safe harbor originally was scheduled to sunset on December 31, 2013. In the 2013 Final EHR Safe Harbor Rule, OIG extended the sunset date of the safe harbor to December 31, 2021, a date that corresponds to the end of the electronic health record Medicaid incentives.
    - OIG is proposing to either eliminate the sunset provision or extend it to another date.
- **15% Recipient Contribution:** The recipient must pay 15% of the donor's cost for the items and services prior to receipt, and the donor cannot finance or loan funds for this payment.
    - OIG proposes to:
        - Eliminate or reduce the 15-percent contribution requirement for small or rural practices. Soliciting comments on how to define small or rural practices.
        - Eliminate or reduce the 15-percent contribution requirement for *all* recipients; or
        - Retain the 15-percent contribution requirement or reduce that contribution requirement for some or all recipients, *and* modify or eliminate the contribution requirement for updates to previously donated EHR software or technology.
    - **Do community pharmacies participate in this 15% contribution?**
- **Example of application to pharmacy setting**: Electronic medication administrative records (eMARs) are not required for drug regimen reviews (DRR); hard copy records are acceptable. Still, a facility may desire to utilize eMAR software for DRRs. The facility and a pharmacy (that receives referrals from the facility) may

[10] 42 C.F.R. § 1001.952(jj).
[11] 42 C.F.R. 1001.952(y).

wish to enter into an arrangement in which the pharmacy pays for the software. If the pharmacy receives referrals from the facility and pays for the software, the pharmacy is providing "something of value" to the facility, implicating AKS.

***Personal Services and Management Contracts Safe Harbor*.**[12] Remuneration does not include any payment made to an independent contractor as long as a number of standards are met.

- OIG proposes to modify the existing safe harbor to substitute the requirement that **aggregate compensation** be set in advance with a requirement that the methodology for determining compensation be set in advance.
- OIG proposes that if an agreement is **part-time**, the schedule of services no longer needs to be set out in the written agreement.
- OIG proposes to protect certain **outcomes-based arrangements**. Does not protect outcomes-based payments that only relate to internal cost savings for the party paying the remuneration.
- Similar to the definition of a VBE participant, **OIG is considering excluding pharmacies** (including compounding pharmacies), PBMs, wholesalers, and distributors. OIG is soliciting comments about these proposed exclusions, as well as examples of beneficial or problematic outcomes-based payment arrangements that might be excluded or included if we finalize some or all of these exclusions.
- **Example of application to pharmacy setting:** When entering into a medical director agreement (MDA) with a referring physician, the arrangement needs to comply with the personal services and management contracts' safe harbor to the anti-kickback statute, and personal services exception to Stark.

***Warranties*.**[13] The proposed modification revises the definition of "warranty" and provides protection for bundled warranties for one or more items and related services.

***Local Transportation*.**[14] The proposed modification (i) expands the distance which resident of rural ares may be transported; and (2) removes mileage limits on transportation of patients discharged from inpatient facilities. OIG clarifies that ride-sharing arrangements are permissible under this safe harbor.

New CMP Law Exceptions

***Accountable Care Organization (ACO) Beneficiary Incentive Programs*.**[15] Codifies the statutory exception to the definition of "remuneration" for ACO Beneficiary Incentive programs for the Medicare Shared Savings Program.

Telehealth for In-Home Dialysis. Amends the definition of "remuneration" to incorporate the statutory exception for telehealth technologies furnished to certain in-home dialysis patients.

[12] 42 C.F.R. § 1001.952(d).
[13] 42 C.F.R. § 1001.952(g).
[14] 42 C.F.R. § 1001.952(bb).
[15] 42 C.F.R. § 1001.952 (kk).

STARK LAW PROPOSED RULE

Background: The Stark law (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. [16] DHS includes prescription drugs and durable medical equipment (DME). A pharmacy falls within the definition of an entity that furnishes DHS. **The Stark Law Proposed Rule** creates new exceptions for value-based care arrangements, which would apply broadly to care provided to all patients, not just Medicare beneficiaries. The proposed rule also clarifies key statutory terms and other compliance requirements.

Proposed Definitions[17]

- **Value-based activity**: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action; and is reasonable designed to achieve at least one value-based purpose of the VBE.
- **Value-based arrangement:** arrangement between: (1) VBE and one or more of its VBE participants; or (2) VBE participants in the same VBE.
- **VBE:** 2 or more VBE participants: (1) collaborating to achive 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; that have an accountable body or person responsible for financial operational oversight of the VBE; and (4) that have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).
- **Value-based purpose:** (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:** an individual or entity that engages in at least one value-based activity as part of a VBE.
    - OIG is considering excluding laboratories and DMEPOS suppliers from the definition of VBE participant or, in the alternative, whether to include in the exceptions at §411.357(aa), if finalized, a requirement that the arrangement is not between a physician (or immediate family member) and a laboratory or DMEPOS supplier. **We note that, regardless of whether we exclude these suppliers (or any other providers or suppliers) from the definition of "VBE participant," they may nevertheless be part of a value-based enterprise.**
    - We are also considering whether to exclude the following providers, suppliers, and other persons from the definition of "VBE participant": pharmaceutical manufacturers; manufacturers and distributors of DMEPOS; PBMs; wholesalers; and distributors. Even if we exclude pharmaceutical manufacturers, manufacturers and distributors of DMEPOS, pharmacy benefit managers, wholesalers, distributors, or other parties from the definition of "VBE participant," **no person,**

[16] 42 U.S.C. 1395nn.
[17] 42 C.F.R. § 411.351

whether or not a provider or supplier in the Medicare program, would be precluded from participating in and contributing to a value-based enterprise.

- We seek comment on which persons and entities should qualify as VBE participants.

New Compensation Exceptions[18]

Value-Based Care Exceptions. CMS proposes three new exceptions for value-based care arrangements that satisfy a series of requirements, depending on the level of financial risk undertaken by the parties to the arrangement. These exceptions would only apply to compensation arrangements.

***Full Financial Risk*.**[19] Applies to value-based arrangements where a VBE assumes full financial risk for the cost of all patient care for a defined population for the duration of the arrangement.

***Meaningful Downside Financial Risk to a Physician*.**[20] Applies to value-based arrangements under which a physician accepts meaningful downside financial risk for failure to achieve the pruposes of the VBE for the duration of the arrangement.

***Value-Based Arrangements*.** Applies broadly to any value-based arrangement where additional requirements are satisfied (starting on page 71 of the proposed rule).

Newly Defined Terms

- **Commercially reasonable.**[21] Many of the statutory and regulatory exceptions require compensation agreements to be commercially reasonable. CMS clarifies that commercial reasonableness is not determined by valuation or profitability. CMS proposes 2 alternative definitions:
  - The arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.
  - The arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.
- **Volume or value standard.**[22] Currently, compensation takes into account the volume or value of referrals or other business generated if the formula used to calculate the compensation includes referrals or other business generated as a variable, and the amount of the compensation correlates with the physician's (or immediate family member's) referrals to or generation of other business for the entity. CMS proposes that the formula would violate this standard if it includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that:
  - **Positively** correlates with the number or value of the physician's referrals to the entity. I.E., the physician (or immediate family member) receives additional compensation as the number of the physician's referrals to the entity increase; or

[18] 42 C.F.R. § 411.357(aa).
[19] 42 C.F.R. § 411.357(aa)(1).
[20] 42 C.F.R. § 411.357(aa)(2).
[21] 42 C.F.R. § 411.351.
[22] 42 C.F.R. 411.354(d)(5) and (6).

  - **Negatively** correlates with the number or value of the physician's referrals to the entity. I.E., the physician (or immediate family member) pays less compensation as the number or value of the physician's referrals to the entity increase.
- **Designated health service (DHS).**[23] The modification states that an inpatient hospital service is only DHS if furnishing the service affects the amount of Medicare's payment to the hospital under the Inpatient Prospective Payment System.
- **Fair market value.**[24] The new definition would apply broadly to the rental of equipment and office space. Applies to the value of an asset or service to hypothetical parties in a hypothetical situation.
- **General market value.**[25] Under the proposed rule, general market value would apply to the value of an asset or service to the actual parties to a transaction that is set to occur within a specific timeframe.

Other Regulatory Modifications

- **New Exception for Limited Remuneration to a Physician.** The proposed modification would protect compensation from an entity to a physician not exceeding an aggregate of $3,500 per calendar year.
- **New Exception for Cybersecurity Technology and Related Services.** The proposal creates an exception to protect arrangements involving the donation of certain cybersecurity technology and related services.
- **Temporary Non-Compliance.** The proposed rule expands the 90-day grace period for certain writing requirements.
- **Clarification for Electronic Health Records Items and Services.** The proposal modifies the physician contribution requirement and permits certain donations of replacement technology.
- **Exception for Assistance to Compensate a Nonphysician Practitioner**[26] **(NPP).** CMS proposes to define "NPP patient care services" as direct patient care services furnished by an NPP that address the medical needs of specific patients of the physician with which the NPP has a compensation arrangement.
- **Price transparency.** CMS asks whether to require physicians to share cost-of-care information at the point of referral.

[23] 42 C.F.R. § 411.351.
[24] 42 C.F.R. § 411.357(a) and (b).
[25] 42 C.F.R. § 411.351.
[26] CMS defines covered NPPs as nurse practitioners, clinical nurse specialists, and physician assistants who practice with or under the supervision of a physician. *PECOS for Physicians and NPPs*, MLN Booklet, Centers for Medicare and Medicaid Services (Feb. 2019), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedEnroll_PECOS_PhysNonPhys_FactSheet_ICN903764.pdf.