



November 6, 2019

**ILLINOIS HEALTH AND HOSPITAL ASSOCIATION  
M E M O R A N D U M**

**SUBJECT: IHA Summary: Stark and Anti-Kickback Proposed Regulations**

On October 9, 2019, the U.S. Department of Health and Human Services (“HHS”) proposed **significant amendments** to the Stark (42 U.S.C. §1395nn), the Anti-Kickback (42 U.S.C. § 1320a-7b(b)) and the Civil Monetary Penalty (“CMP”) (42 U.S.C. §1320a-7a(a)(5)) Laws. These proposed amendments are intended to modernize and clarify these laws, encourage value-based arrangements and care coordination and reduce some of the regulatory burdens on healthcare providers. The proposed amendments reflect efforts of the U.S. Centers for Medicare and Medicaid Services (“CMS”) and the HHS Office of Inspector General (“OIG”) to address the transition to value-based healthcare systems.

**Stark Law**

In the regulatory preamble, CMS acknowledges that the Stark Law and its existing regulations were initially enacted to prevent fraud and abuse under a fee-for-service payment model. Recognizing that the Stark Law may impede the transition to value-based care models that align payment with the quality and cost effectiveness of care, CMS proposes specific Stark Law exceptions for value-based arrangements (“VBAs”). Among other things, a VBA must involve a value-based activity that is reasonably designed to achieve at least one “value based purpose,” defined as:

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 care delivery and payment mechanisms based on volumes to mechanisms based on the quality and cost control of care for a target patient population.

The making of a referral would **not** be a value-based activity.

**New Stark Value Based Arrangements Exceptions:**

- **Full Financial Risk (§ 411.357(aa)(1)):** This exception would apply to VBAs

between value-based entity participants that assume full financial risk. The value-based entity must be financially responsible for the cost of all patient care items and services. CMS explains that full financial risk could include capitation payments or a global budget and the financial risk must be prospective. Further, the proposed exception requires that: (a) the remuneration paid is not to reduce medically necessary care; (b) the remuneration is not conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals, the arrangement satisfies the special rules on compensation; and (c) records are retained for at least six years.

- ***Value-Based Arrangements With Meaningful Downside Financial Risk to the Physician (§ 411.357(aa)(2))***: This exception is available for remuneration resulting from value-based activities that is paid under a VBA where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose for the entire term of the VBA. CMS proposes that: (a) the arrangement must be in writing; (b) the remuneration methodology must be set in advance; (c) the remuneration paid is not to reduce medically necessary care; (d) the remuneration is not conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals the arrangement satisfies the special rules on compensation; and (e) records are retained for at least six years.
- ***Value-Based Arrangements (§ 411.357(aa)(3))***: This exception would protect remuneration for value-based activities of any VBA regardless of the level of financial risk involved. Much like the previous exceptions, CMS proposes that: (a) the arrangement must be in writing — including specific requirements of the writing to outline the arrangement; (b) the performance/quality metrics are used to measure the recipient; (c) the remuneration methodology must be set in advance; (d) the remuneration paid is not to reduce medically necessary care; (e) the remuneration is not conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals, the arrangement satisfies the special rules on compensation; and (f) records are retained for at least six years. CMS also is seeking comment on whether to include a recipient financial contribution requirement under this exception.

**Clarifications to Existing Stark Exceptions:**

- ***Guidance on Critical Definitions*** – Clarification on the following definitions:
  - ***Fair Market Value***: Revisits the fair market value standard and confirms that it is separate and distinct from the volume or value and other business generated standards. Proposes revising the

definition of fair market value to eliminate cross-references to the volume or value standard and reorganizing the definition of fair market value into three different components (i.e., general application, equipment rentals, office space rentals) to achieve more clarity. Provides additional guidance on fair market value, including in-depth discussion regarding distinctions between “general market value” and “market value” in the context of hypothetical physician recruitment scenarios.

- **Commercial Reasonableness:** Proposes the following definition in an attempt to clarify that commercial reasonableness should not turn on whether an arrangement is profitable: ***Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.*** This proposed change corresponds to the more longstanding view under Anti-Kickback analysis that the concept of commercially reasonable should be analogous to a purpose-driven arrangement serving a legitimate need.
- **Volume or Value Standard:** Proposes a bright-line standard regarding two circumstances where compensation will be considered to “take into account” the volume or value of referrals. First, the standard would be violated if the formula used to calculate a physician’s compensation includes the physician’s referrals to an entity as a variable, resulting in an increase or decrease of compensation that positively correlates with the number or value of the physician’s referrals to the entity (i.e., compensation increases as referrals increase or compensation decreases as referrals decrease). Second, the standard would be violated if there is a predetermined, direct correlation between a physician’s prior referrals to an entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which compensation is determined.
- **Other Business Generated:** Proposes a similar bright-line test for the “other business generated” standard as for volume/value.
- **“Taking into Account” Standard:** Reiterates CMS’ prior position on “shadow referrals”, noting that a productivity bonus will not take into account the volume or value of a physician’s referrals solely because corresponding hospital services are billed each time a physician performs a professional service.

- ***Decouple from Anti-Kickback Statute*** -- Deletes the condition that an arrangement not violate the Anti-Kickback Statute from every exception where it appears today.
- ***Changes to the Definition of a "Group Practice"***: Clarifies circumstances under which the profits of a group practice may be shared with its members, including compensation that relates to participation in a value-based arrangement.
- ***Revise Definition of Remuneration***: Removes carve-out of surgical devices, items, or supplies from the definition of "remuneration."
- ***Extending Grace Period for Signature Requirements for Certain Exceptions***: CMS proposes to expand the current 90-day grace period for obtaining the requisite signatures on written arrangements to also include a 90-day grace period for the written document itself. Note that the parties would still be required to comply with all other elements of the applicable exception, including any set in advance requirements.
- ***Payments to Physicians Less than \$3,500***: Creates a new exception for arrangements where an entity pays a physician less than \$3,500 in a calendar year in exchange for items or services. This proposed exception would not have a writing, signature or set-in advance requirement but would require that compensation paid is consistent with fair market value and that the terms of the arrangement are commercially reasonable. CMS said that it developed this exception in response to numerous non-abusive self-disclosures involving nominal amounts of remuneration.
- ***Donations of Certain Cybersecurity Technology and Related Services***: Broadens the definition of "electronic health record" for purposes of the current donation exception as well as add a new exception to protect arrangements with physicians for donations of certain cybersecurity technology and related services.

### **Anti-Kickback Statute (AKS)**

In the preamble to the AKS proposed rule, the OIG acknowledged that the broad reach of the AKS and the CMP law provision prohibiting inducements to beneficiaries might inhibit beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care. The OIG also recognized that, because the consequences of potential noncompliance with these statutes could be dire, providers and suppliers may be discouraged from entering into innovative arrangements that would improve quality and health outcomes, produce system efficiencies, and lower costs.

As a result, the OIG proposed significant changes to the Anti-Kickback Law by adding six new safe harbors among which are three new safe harbors for value-based arrangements, as well as new safe harbors for donations of cybersecurity technology, CMS-sponsored models and services, and for certain tools and supports furnished under patient engagement arrangements. The OIG also proposed to update several existing safe harbors.

**New Proposed AKS Safe Harbors:**

- **Value-based enterprise (VBE) safe harbors** would protect certain remuneration exchanged between or among participants in a value-based arrangement that fosters better coordinated and managed patient care:
  - ***Care coordination arrangements to improve quality, health outcomes, and efficiency*** (§ 1001.952(ee)): Applies to certain in-kind remuneration, including services and infrastructure, exchanged between qualifying VBE participants in value based arrangements;
  - ***Value-based arrangements with substantial downside financial risk*** (§ 1001.952(ff)): Protects certain in-kind and monetary remuneration and offers greater flexibility in recognition of a VBE's assumption of substantial downside financial risk from a payor; and
  - ***Value-based arrangements with full financial risk*** (§ 1001.952(gg)): Covers certain in-kind and monetary remuneration and offers even more flexible conditions, because VBEs that assume full downside financial risk from a payor present fewer traditional fee-for-service fraud and abuse risks.
  - ***Arrangements for patient engagement and support to improve quality, health outcomes and efficiency*** (§1001.952(hh)): Furnished by VBE participants to specified patients and is intended to remove barriers presented by the AKS and the beneficiary inducement CMP to providers offering patients beneficial tools and supports to improve quality, health outcomes and efficiency, by promoting patient engagement with their care and adherence to care protocols.
  - ***CMS-sponsored model arrangements and CMS-sponsored model patient incentives*** (§ 1001.952(ii)): Permits remuneration among parties to arrangements (e.g., distribution of capitated payments, shared savings or losses) under CMS sponsored models and initiatives and to permit remuneration in the form of incentives and supports provided by CMS model participants under a CMS-sponsored model to patients covered by such model. This safe harbor would standardize and simplify AKS compliance for CMS-sponsored model participants and reduce the need for the OIG to issue

distinct fraud and abuse waivers for new CMS sponsored models.

- **Cybersecurity technology and related services** (§ 1001.952(jj)): Protects donations of certain cybersecurity technology and related services to improve cybersecurity posture of the health care industry by removing a real or perceived AKS barrier and to allow parties to address the growing threats of cyberattacks.
- **Modifications to Existing AKS Safe Harbors:**
  - **Electronic health records items and services** (§ 1001.952(y)): Adds protections for certain cybersecurity technology included in an electronic health records arrangement, update provisions regarding interoperability, and remove the sunset date.
  - **Personal services and management contracts** (§ 1001.952(d)): Proposes to: substitute the requirement that *aggregate compensation* over the arrangement's term be set in advance with a requirement that the *compensation methodology* be set in advance, thus adopting a similar approach to the comparable Stark Law exception; eliminate the requirement that a part-time arrangement must specify the schedule, length and exact charge for each interval of service; and extend the safe harbors to certain outcomes-based payments tied to measurable improvements in the quality of patient care or to reductions in payor costs or the growth of payor expenditures (but not when payments relate solely to the principal's internal cost savings).
  - **Warranties** (§ 1001.952(g)): Expands the definition of "warranty," to cover bundled items and services under certain conditions (not just single items) and to exempt beneficiaries from the reporting requirements applicable to buyers. Notably, warranties cannot be conditioned on exclusivity or minimum purchase requirements.
  - **Local transportation** (§ 1001.952(bb)): Expands the distance that residents of rural areas may be transported from 50 miles to 75 miles and removes any mileage limit on transportation of a patient upon discharge from a healthcare facility to the patient's residence. In addition, the preamble clarifies that the safe harbor may apply to transportation provided through ride-sharing services.

#### **ACO Beneficiary Incentive Program**

The proposed rule codifies the statutory exception to the definition of "remuneration" (42 U.S.C. § 1320a-7b(b)(3)(K)) to carve out incentives paid to promote beneficiary use of certain

primary care services under an ACO Beneficiary Incentive Program for the MSSP (§ 1001.952(kk)). While the regulatory language is nearly identical to the statutory language, it clarifies that ACOs may pay incentives only to assigned beneficiaries.

**Civil Monetary Penalty Law**

With respect to proposed changes to the CMP rules, the proposal incorporates a new exception for beneficiary inducements regarding telehealth technologies provided to certain in-home dialysis patients. The OIG also noted that the proposed changes to the local transportation safe harbor and new patient engagement safe harbor would also serve as exceptions under CMP's prohibition of beneficiary inducement.

**Next Step**

This memo provides a summary of the highlights of the proposed regulations, but hospitals should review the text of the proposed regulations thoroughly.

HHS is accepting comments on the proposed regulations until December 31. IHA, in conjunction with the American Hospital Association (“AHA”), will submit comments to help improve these important revisions.