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UNPACKING HHS'S PROPOSED CHANGES TO THE ANTI-KICKBACK STATUTE & STARK LAW

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November 5, 2019

The webinar will begin shortly

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- Questions will be answered after the presentation in the interest of time.
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Background

HHS's Regulatory Sprint to Coordinated Care

- Announced in June 2018
- Stated Goals
  - Accelerate the transformation from a fee-for-service health system to a value-based system
  - Reduce regulatory burdens that pose barriers to value-based care and care coordination
- HHS issued Requests for Information on how to address any undue impact and burden of the following laws:
  - Stark Law in June 2018
  - Anti-Kickback Statute and Beneficiary Inducement Provisions of the Civil Monetary Penalty Law in August 2018
  - HIPAA in December 2018
  - 42 C.F.R. Part 2 in August 2019 (Proposed rule)

HHS's Proposed Rules

- Proposed rules were published in the Federal Register on October 17th
- Primarily focused on reducing barriers to value-based arrangements through new AKS safe harbors, new Stark Law exceptions, and modifications to existing AKS safe harbors
- Additional proposed changes intended to increase regulatory flexibility
- Comment period ends December 31st
- Final rules expected in 2020

Overview

- New safe harbors and exceptions related to value-based arrangements
- Other significant proposed changes to the safe harbors
- New safe harbor and exception for donations of cybersecurity technology and services and proposed changes to the EHR donations safe harbor and exception
- Other significant proposed changes to the Stark Law exceptions and definitions

Value-Based Arrangements

AKS Safe Harbors and Stark Law Exceptions

Value-Based Exceptions and Safe Harbors

- Intended purpose
  - Remove regulatory barriers to:
    - Promote innovation in the delivery of care
    - Create flexibility in the delivery of cost-effective and coordinate care
  - Support a more rapid transition from FFS/volume-based payment models to value-based care and payment models
- Three new exceptions/safe harbors – value-based enterprise (VBE)
  1. Protection for certain in-kind and monetary arrangements where the VBE assumes ***full downside financial risk*** from payor
  2. Protection for certain in-kind and monetary arrangements where the VBE assumes ***substantial downside financial risk*** from payor
  3. Protection for certain in-kind remuneration exchanged between qualifying VBE participants for value-based activities directly connected to care coordination

Value-Based Arrangements – Key Terminology

- **Value-Based Enterprise**
  - Broadly defined to capture any number of network arrangements where the participants have agreed to collaborate for value-based purposes
  - Two or more VBE participants party to a value-based arrangement
  - An accountable body or person responsible for financial and operational oversight of the VBE
  - VBE must adopt a governing document describing the VBE and its value-based purposes
- **Value-Based Purposes**
  1. Coordinating and managing care of a target patient population
  2. Improving quality of care for target patient population
  3. Appropriately reducing costs without reducing quality of care
  4. Transitioning from payment mechanisms based on volume to payment based on quality of care and control of costs

Value-Based Arrangements – Key Terminology (Cont.)

- **Value-Based Enterprise Participant**
  - Examples: hospital, physician practice, payor, or social services organization
  - Excludes: pharmaceutical manufacturers; manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); and laboratories
  - HHS is considering excluding pharmacies, pharmacy benefits managers (PBMs), wholesalers, and distributors
- **Value-Based Arrangement**
  - Each VBE Participant in the VBE must be party to a "value-based arrangement" – defined as:
    - "an arrangement for the provision of at least one value-based activity for a target patient population between or among: (A) the value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based enterprise"

Value-Based Arrangements – Key Terminology (Cont.)

- **Value-Based Activity**
  - 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
- **Target Patient Population**
  - Identified patient population selected by the VBE using "legitimate and verifiable criteria" that is (i) set out in advance in writing, and (ii) furthers the VBE's value-based purpose
  - VBE arrangement and its VBE activities must be tailored to meet the needs of a defined patient population
  - Not limited to federal health care program beneficiaries

Proposed New AKS Safe Harbors for Value-Based Arrangements

- **VBE Arrangements with Full Financial Risk**
  - VBE at full financial risk
  - Designed to afford the most flexibility of the safe harbors
- **VBE Arrangements with Substantial Downside Financial Risk**
  - VBE participants meaningfully share in the financial risk
- **VBE Arrangements with No Financial Risk**
  - More conditions and safeguards since no assumption of downside financial risk
  - General Requirements:
    - Commercially reasonable and set out in writing
    - Specific, evidence-based outcome measures
    - Remuneration exchanged used primarily to engage in value-based activities
    - 15% contribution requirement
    - Monitoring, assessment, and reporting requirements

Proposed New Stark Exceptions for Value-Based Arrangements

- **Proposed Exception for Full Financial Risk**
  - VBE has assumed full financial risk during the entire duration of the value-based arrangement
  - Remuneration cannot be conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement
- **Proposed Exception for Meaningful Downside Financial Risk**
  - Meaningful downside risk means:
    - The Physician is responsible to pay at least 25% of the value of the remuneration the physician receives under the value-based arrangement OR
    - The physician is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the payor for each patient in the target patient population
- **Proposed Exception for Value-Based Arrangements Regardless of the Level of Financial Risk**
  - Additional safeguards required given arrangement where neither party has assumed any financial risk

Other Significant Proposed Changes to the Safe Harbors

Significant Proposed AKS Changes

- Patient Engagement and Support Services
- Personal Services and Management Contracts
- Outcomes-Based Payments
- Warranties
- Local Transportation
- CMS-Sponsored Model Arrangements and Patient Incentives
- ACO Beneficiary Incentive Program

Patient Engagement and Support Services

- New safe harbor that would protect certain patient engagement tools and support services to improve quality, health outcomes, and efficiency furnished by VBE participants
- Intended to remove barriers presented by the AKS and the Beneficiary Inducements CMP
- Limited to items furnished directly by a VBE participant to its target patient population
  - Excludes pharmaceutical manufacturers, DMEPOS, laboratories
  - Considering excluding pharmacies, PBMs, wholesalers, distributors
- Limited to in-kind remuneration directly connected to coordination and management of the patient's care and cap of $500 annually per patient
- Items furnished cannot be cash, gift cards, or other cash equivalents
- Must be recommended by the healthcare provider and be medically necessary

Personal Services and Management Contracts Safe Harbor

- Key modifications to the existing safe harbor for personal services and management contracts
- Intended to align this safe harbor with the personal service arrangements exception to the Stark Law
- Aggregate compensation
  - Loosening the requirement that aggregate compensation itself must be set in advance to require only that the *methodology for determining the compensation* be set in advance
  - Would allow for compensation set on a per-unit or hourly basis
- Periodic, sporadic, or part-time services
  - Eliminate the requirement that the contract must specify the schedule, length, and the exact charge for such intervals

Outcomes-Based Payment Arrangements Safe Harbor

- New section of the personal services and management contracts safe harbor
- Would protect payments to reward achievement of outcome measures that improve quality of patient care, reduce costs, or both
- Excludes payments, directly or indirectly, by a pharmaceutical manufacturer, DMEPOS, or a laboratory
  - Considering excluding payments by pharmacies, PBMs, wholesalers, distributors
  - Alternatively, the OIG may limit this safe harbor to VBE participants
- Evidence-based outcome measures that are measurable and include benchmarks that are reset periodically (e.g., every 1,3, or 5 years)
- Methodology for determining the compensation
  - Compensation *methodology* must be set in advance, commercially reasonable, consistent with FMV, and volume or value and other business generated standards
- Signed, written agreement
- Does not protect payments related solely to internal cost savings (e.g., payments from hospital to physician group but financial risk is only with respect to hospital reimbursement)

Cybersecurity/EHR Technology and Services Donations

AKS Safe Harbors and Stark Law Exceptions

New Safe Harbor and Exception for Cybersecurity Technology and Services Donations

- Response to numerous comments as well as a June 2017 report published by the Health Care Industry Cybersecurity Task Force
- Not necessarily related to value-based care or care coordination; focus is regulatory flexibility
- Concern is that physicians cannot afford to implement, or are not otherwise prioritizing the implementation of, cybersecurity measures to guard against cyberattacks on the health care system
- Patterned (in most respects) after the safe harbor and exception for EHR donations.
- Highlights
  - No restrictions on permissible donors
  - Extends only to technology and services “necessarily and used predominantly” to implement cybersecurity measures
  - Donors can’t “directly” take the volume of value of referrals or other business generated between the parties into account
  - Recipients cannot make the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor
  - No cost-sharing requirement

Cybersecurity Technology and EHR Donations – Areas for Comment

- Should donors be limited, as they are under the current EHR donations safe harbor?
  - Should laboratory companies be specifically prohibited, even if no other limits are placed on donors?
  - Should donors under the EHR donations safe harbor be expanded?
- Should cybersecurity hardware be permitted? If so, under what circumstances?
  - OIG has included an alternative proposal for comment
- What does it really mean to "directly" take into account volume or value of referrals or other business generated between the parties? Should OIG better define this concept?
- Is there any danger that physicians (or patients) could choose with whom they do business based on who offers the best package of cybersecurity technology items and services? If so, what, if anything, can be done to prevent such tactics?
- Should a cost-sharing requirement apply? If so, how could it be administered from a practical perspective and should some recipients be exempted?

Clarification and Guidance on Key Stark Law Terminology and Requirements

Overview of Proposed Stark Law Changes

- New Definition for Commercially Reasonable
- Changes to the Definitions of FMV and Designated Health Services
- Bright-Line Tests for Taking into Account the Volume or Value of Referrals or Other Business Generated
- Clarifications on the Special Rules for Profit Shares and Productivity Bonuses Paid to Physicians in a Group Practice
- AKS Compliance Requirement
- Directed Referrals Requirement
- Titular Ownership or Investment Interest
- Special Rules on Compensation Arrangements
- Several Provider-Friendly Modifications to Existing Exceptions

Commercially Reasonable

- Two alternative definitions for “Commercially Reasonable”
  - that “particular 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
- Clarification that an arrangement may be commercially reasonable even if it does not result in profit for one or more parties

Remuneration

- Proposed changes to an exception to the definition of “Remuneration” of particular interest to laboratories and their physician customers
- Remuneration currently does **not** include “the furnishing [by a laboratory] of items, devices or supplies (not including surgical items, devices or supplies) that are used solely for” specimen collection, transport, processing, or storage, or the ordering of laboratory tests or communication of results
- Mere fact that an item, device, or supply is routinely used as part of a surgical procedure would no longer result in the item, supply, or device not qualifying under the exception
  - Still only for single-use items, devices, or supplies of low value
  - Still does not extend to an item, device, or supply with a primary function of prevention infection or contamination (e.g., gloves)
- Also a proposal to clarify that an item, device, or supply could be used for another purpose, but that the focus is no how it is actually used

Taking into Account the Volume or Value of Referrals or Other Business Generated

- Adding special rules on compensation designed to set forth bright-line, objective tests
- Proposed special rules do not apply to the proposed VBE exceptions
- Special rule for compensation *from an entity to a physician*
  - Physician's compensation cannot *increase* in correlation with the number or value of referrals.
  - Common examples that may fail the special rule: productivity bonuses; physician pools
- Special rule for compensation *from a physician to an entity*
  - Physician's compensation cannot *decrease* in correlation with the number or value of referrals
  - Example that may fail the special rule: physician leases medical office space from a health system, and the rental charges are reduced for each diagnostic test ordered by the physician and furnished in the health system's outpatient departments

Period of Disallowance

- Physician may not make referrals for DHS to an entity and the entity may not bill Medicare for the referred DHS when a financial relationship between the parties fails to satisfy the requirements of any Stark exception
- Under current regulations the period of disallowance begins when a financial relationship fails to satisfy an exception and ends when:
  - If the noncompliance is unrelated to compensation, the date the financial relationship satisfies an exception
  - If the noncompliance is due to excess or insufficient compensation, the date on which all excess compensation is returned or additional required compensation is paid.
- Proposal is delete the period of disallowance rules in their entirety to provide more flexibility
- CMS clarifies that parties can bring a financial relationship back into compliance as long as the financial relationship is still active, but that, once a financial relationship has ended, parties cannot retroactively cure previous noncompliance by recovering or repaying excess or insufficient compensation

Isolated Financial Transaction

- Definition of “Isolated Financial Transaction” amended to exclude “a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated”
- Purpose is make clear that CMS does not allow the isolated transactions exception (which does not require a written agreement) to protect such arrangements
  - Typically would arise when parties discovered services were provided without a written arrangement and thus no other exception applies
  - For example, a hospital paid a physician on one occasion during a six-month period for call coverage on multiple occasions where the parties had no written agreement
- CMS does not believe this exception is available to “retroactively cure noncompliance”

New Exception for Limited Remuneration to a Physician

- New exception intended to permit limited payments to a physician without a written agreement or compensation that is set in advance
- Limited to $3,500 per calendar year (to be adjusted for inflation)
- Additional requirements:
  - payment must be for items or services actually provided by the physician
  - the arrangement must be commercially reasonable
  - the remuneration must be fair market value and not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician
- Can be used to cover lease payments or use of premises, equipment, personnel, items, supplies, or services if certain conditions are met
- Example: Short-term medical director services as a result of unexpected resignation of a hospital's previous medical director

QUESTIONS?

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- Counsels clients on structuring arrangements, contracts and transactions to comply with federal and state fraud and abuse laws
- Counsels PBMs, health plans, pharmacies, and distributors on federal and state regulatory and compliance matters
- Extensive experience drafting, negotiating, and structuring PBM agreements, retail, mail and specialty pharmacy agreements, GPO agreements, and pharmaceutical purchase, distribution, and rebate agreements
- Practice extends to counseling on drug pricing and reimbursement issues and Medicare Advantage and Medicare Part D compliance

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- Substantial health care regulatory background includes advising clients on matters pertaining to the federal anti-kickback statute, the Stark law, and state statutes prohibiting kickbacks and self referrals
- Focuses on representing health care industry clients in state and federal investigations and in regulatory, transactional, and operational matters
- Serves as health care regulatory counsel to a variety of clients, including private equity firms and health care providers, in mergers, acquisitions, and other transactional matters

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- Advises clients on the Anti-Kickback Statute, Stark Law, False Claims Act, Medicare billing and reimbursement regulations, beneficiary inducement prohibitions, and civil monetary penalties
- Experience includes representing clients under investigation by the Department of Justice, designing and implementing effective compliance programs, and providing representation in significant reimbursement and coverage disputes

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