Buchanan Ingersoll & Rooney PC

Fraud and Abuse Regulatory Update

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Agenda

- Background
- Proposed Stark Law Updates
  - Value-Based Exceptions
  - Definitional Modifications and Clarifications
  - Proposal Potpourri
- Proposed AKS and CMP Updates
  - Value-Based Safe Harbors
  - Proposal Potpourri
- Future Predictions

Regulatory Sprint to Coordinated Care

- Ongoing effort by HHS to accelerate the transition from a fee-for-service to a value-based health system
- **Summer 2018** – CMS and OIG published RFIs seeking feedback on modifications to the Stark Law and AKS to reduce regulatory burdens and advance alternate payment models and coordinated care
- **December 2018** – OCR issued RFI seeking input on revisions to HIPAA to improve care coordination and promote the transition to value-based healthcare while preserving patients' privacy

Regulatory Sprint to Coordinated Care (cont.)

- **October 17, 2019** – CMS and OIG separately published proposed rules in the *Federal Register* with potential changes to the Stark Law, AKS and civil monetary penalties law regarding beneficiary inducements
- **December 31, 2019** – Comments were due to CMS and OIG
- **Pending** – OCR's proposed rules with potential HIPAA changes

Proposed Stark Law Updates

Value-Based Exceptions

- Exception: Applies to ***value-based arrangements*** between ***value-based enterprise participants*** in a ***value-based enterprise*** that has assumed a certain level of ***financial risk, under any of three value-based payment models,*** for the cost of patient care items and services covered by the applicable payor for each patient in the ***target patient population*** for a specified period of time.
- Key Definitions
  - Value-Based Enterprise (VBE)
  - VBE Participant
  - Value-Based Purpose
  - Value-Based Activities
  - Value-Based Arrangement
  - Target Patient Population

Value-Based Exceptions – Key Definitions (cont.)

- Value-Based Enterprise (VBE) – Two or more VBE Participants:
  - Collaborating to achieve at least one value-based purpose;
  - 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;
  - that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
  - 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 Exceptions – Key Definitions (cont.)

- VBE Participant – An individual or entity that engages in at least one value-based activity as part of a value-based enterprise.
- Value-Based Purpose:
  - Coordinating and managing the care of a target patient population;
  - improving the quality of care for a target patient population;
  - appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
  - transitioning from healthcare 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.

Value-Based Exceptions – Key Definitions (cont.)

- Value-Based Activities – 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:
  - The provision of an item or service;
  - the taking of an action; or
  - the refraining from taking an action.

The making of a referral is not a value-based activity.

Value-Based Exceptions – Key Definitions (cont.)

- Value-Based Arrangement – An arrangement for the provision of at least one value-based activity for a target patient population between or among:
  - The VBE and one or more of its VBE participants; or
  - VBE participants in the same VBE.
- Target Patient Population – An identified patient population selected by a VBE 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 VBE's value-based purpose(s).

Value-Based Exceptions – Value-Based Payment Models

- **Full Financial Risk** – The exception would cover a VBE that is financially responsible (or contractually obligated to be financially responsible) within the 6 months following the commencement of the value-based arrangement and for the entire duration of the value-based arrangement thereafter, 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. "Prospective Basis" means that the VBE has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor **prior** to providing patient care items and services to patients in the Target Patient Population.
  - The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
  - The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
  - The remuneration 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.
  - If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
  - Records for the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.
- *CMS is currently seeking comment regarding whether a VBE should be considered to be at full financial risk if it is (a) responsible for the cost of only a defined set of patient care services for a target patient population or (b) whether CMS should require a minimum period of time during which the VBE is at full financial risk. However, CMS notes that full financial risk may take the form of capitation payments (predetermined payment per patient per month or other period of time) or global budget payment from a payor that compensates the VBE for providing all patient care items and services for a target patient population or a predetermined period of time.*

Value-Based Exceptions – Value-Based Payment Models

- **Meaningful Downside Financial Risk** – 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(s) of the value-based enterprise and:
  - The physician is responsible to pay the entity no less than 25% (*CMS definition of "meaningful downside financial risk"*) of the value of the remuneration the physician receives under the value-based arrangement; or
  - The physician is financially responsible to the VBE on a prospective basis for the cost of all or a "***defined set of patient care items and services***" covered by the applicable payor for each patient in the target patient population for the **entire** term of the value-based arrangement. *Because this exception does not require "full-risk," CMS proposes that the physician must be at a meaningful downside financial risk for the entire term of the value-base arrangement and CMS is seeking comment regarding the minimum appropriate for a "defined set of patient care and services."*

Value-Based Exceptions – Value-Based Payment Models

- **Meaningful Downside Financial Risk** – Requirements:
  - A description of the nature and extent of the physician's downside financial risk is set forth in writing and extends the entire duration of the value-based arrangement.
  - The methodology used to determine the amount of remuneration is set in advance.
  - The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
  - The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
  - The remuneration 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.
  - If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
  - Records for the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

Value-Based Exceptions – Value-Based Payment Models

- **Value-Based Arrangements, Regardless of Risk Level** – Intended to encourage physicians to enter into value-based arrangements:
  - The arrangement is set forth in writing and signed by the parties, including:
    - The value-based activities to be undertaken;
    - How the value-based activities are expected to further the value-based purpose(s) of the VBE;
    - The target patient population;
    - The type and nature of the remuneration;
    - The methodology used to determine the remuneration; and
    - The performance or quality standards against which the recipient will be measured, if any.
  - Methodology used to determine remuneration must be set in advance.
  - The performance and quality standards, against which the recipient will be measured, if any, must be objective and measurable, and any changes to such standards must be made prospectively and set forth in writing.

Value-Based Exceptions – Value-Based Payment Models

- **Value-Based Arrangements, Regardless of Risk Level** – Intended to encourage physicians to enter into value-based arrangements:
  - The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population,
  - Remuneration is not provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population,
  - Remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based 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, and
  - Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

Value-Based Exceptions – Indirect Compensation

- Indirect Value-Based Arrangements
  - CMS proposes to establish a separate exception for arrangements that qualify as "indirect" value-based arrangements.
  - CMS noted that an indirect compensation arrangement that includes a value-based arrangement may not satisfy the requirements of the indirect compensation exception because the compensation paid to a physician may take into account the volume or value of referrals or other business generated by the physician or the compensation may not meet FMV standards.
  - *Problem: Only the indirect compensation exception can protect an indirect compensation arrangement!*
  - Under the proposed rule, when the value-based arrangement closest to the physician, where the physician is a direct party to the value-based arrangement, the indirect compensation arrangement would qualify as a value-based arrangement for purposes of applying the proposed value-based exceptions. Under this proposal, parties would determine if an indirect compensation arrangement exists and, if it does, determine whether the compensation arrangement to which the physician is a direct party qualifies as a value-based arrangement.

Definitional Modifications and Clarifications

- Key definitional changes to:
  - "Volume or value of referrals"
  - "Fair market value"
  - "Commercially reasonable"
- Represent broader sea of changes than to AKS and CMP
- Changes generally welcome for healthcare stakeholders with certain notable exceptions (*e.g.*, additional requirements for academic medical centers)

Volume or Value of Referrals

- Under the proposed rule, compensation takes into account the volume or value of referrals only if:
  - The formula used to calculate the compensation will result in an increase or decrease of the compensation that positively correlates with the number or value of referrals; or
  - There is a predetermined, direct, and meaningful "if X, then Y" correlation between the volume or value of referrals and the prospective rate of compensation to be paid over the duration of the agreement.
- Consider in light of *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015) and *United States ex rel. Bookwalter v. UPMC 938 F.3d 397* (3d Cir. 2019).

Volume or Value of Referrals – Takeaways

- **Creates new "bright line" test**
- Reduces precedential value of recent case law
- Limits concerns regarding industry standard wRVU-based compensation models

Commercial Reasonableness

- Must further "a legitimate business purpose of the parties and [be] on similar terms and conditions as like arrangements"
- A financial arrangement can be commercially reasonable even if it does not result in profit for one or more of the parties
- Note that the preamble to the proposed rule (and not the proposed rule itself) also states that a "commercially reasonable" arrangement could be one that "makes commercial sense and is entered into by a reasonable entity of similar type of size and a reasonable physician of similar scope and specialty"

Commercial Reasonableness – Takeaways

- **Clarification of historical approach**
- Commercial reasonableness and fair market value remain separate concepts
- Profitability does not dictate commercial reasonableness
- Watch final rule for interplay of proposed rule definition and definition that appears in preamble

Fair Market Value

- The value in an arm's-length transaction, *with like parties and under like circumstances, of like assets or services*, consistent with the general market value of the subject transaction
  - Rental of equipment – the value in an arm's length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use) consistent with the general market value of the subject transaction
  - Rental of office space – the value in an arm's length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction
- "General market value" is "[t]he price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement"

Fair Market Value – Takeaways

- **A fresh look at familiar concepts**
- More expansive view of fair market value
- Salary surveys not the end of analysis
- Increased need for broader market data
- Consider potential impact on internal review processes and in lower cost areas

Proposal Potpourri: Group Practice, Limited Remuneration to Physicians & Temporary Noncompliance

- Group Practice Compensation From Downstream Distributions – Special Rules for Profit Shares and Productivity Bonuses
  - Certain downstream distribution arrangements are currently protected under waivers *inside* the Shared Savings Program and certain Innovation Center models.
  - A group practice could distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician's participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration would be deemed not to directly take into account the volume or value of the physician's referrals.
  - Revised §411.352(i) would permit a 100- physician group practice, for example, to distribute the profits from designated health services derived from two physicians' participation in an alternative payment model directly to those physicians. Physician #1 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the model, and Physician #2 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the model. Neither distribution would jeopardize the group's ability to qualify as a "group practice" under §411.352.

Proposal Potpourri: Group Practice, Limited Remuneration to Physicians & Temporary Noncompliance

- Limited Remuneration to a Physician – Remuneration from an entity to a physician for the provision of items ***or*** services provided by the physician to the entity that does not exceed an aggregate of $3,500 per calendar year (as adjusted for inflation), if the following conditions are satisfied:
  - Compensation does not take into account value or volume of referrals;
  - Compensation does not exceed FMV;
  - Commercially reasonable; and
  - Compensation for the lease of office space or equipment does not violate the per-click and percentage-based compensation formulas under the regulations.
- *CMS is interested in comments regarding whether it is necessary to limit the applicability of the exception to services that are personally performed by the physician and items provided by the physician in order to further safeguard against program or patient abuse.*

Proposal Potpourri: Group Practice, Limited Remuneration to Physicians & Temporary Noncompliance

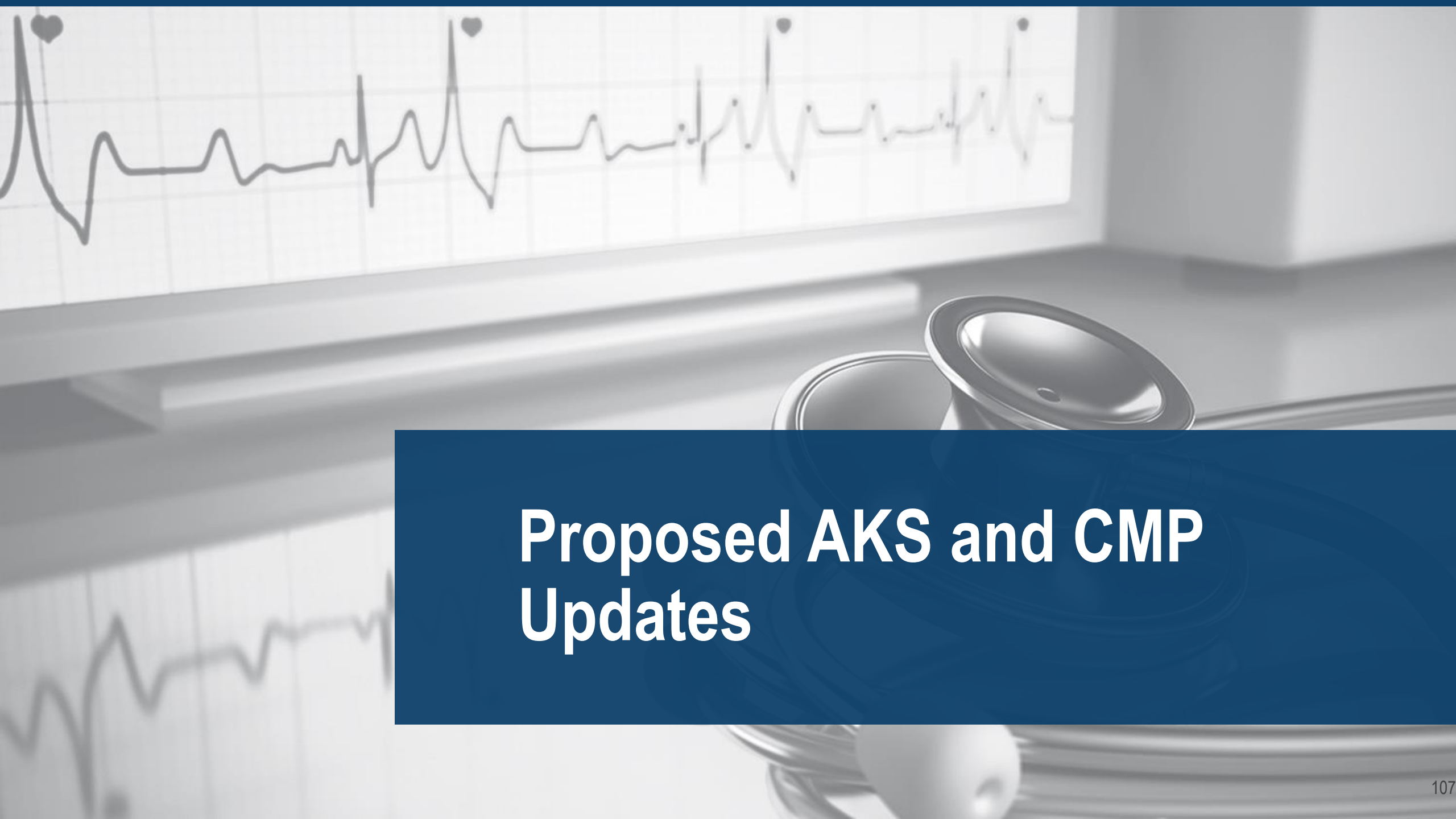
- Temporary Noncompliance with writing or signature requirements of compensation arrangement exceptions
  - Proposing to delete §411.353(g) in its entirety.
  - New Proposal -- the writing requirement or the signature requirement would be deemed to be satisfied if: (1) the compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception.

Proposal Potpourri: Office Space & Equipment, Recruitment & Services Unrelated to DHS

- Exclusive use rule clarified to reflect CMS policy that the lessor of office space or equipment (or a related person or entity) is the only party that is excluded from using the space or equipment while it is being used by the lessee
- Recruitment exception modified to require only a physician signature (and not the signature of the physician's practice) when the practice does not receive any *financial* benefit from a recruiting arrangement
- "Services unrelated to DHS" exception revamped to clarify that remuneration from a hospital to a physician does not relate to DHS if it is for items or services not related to patient care (e.g., services not typically provided by physicians or a hospital's rental of a physician's home for visiting faculty)

Proposal Potpourri – EHR and Cybersecurity

- "Bonus" modifications and clarifications based on response to RFI
- Update of interoperability requirements within EHR exception
- Clarification that donations of cybersecurity software and services may be permitted under the EHR exception
- Permission for certain donations of replacement technology
- Reduction of burden for small/rural physician organizations or all physician recipients (i.e., alternatives to 15% donation requirement)



Proposed AKS and CMP Updates

Value-Based Safe Harbors

- OIG proposes to add safe harbor protections *for certain coordinated care and associated value-based arrangements* between or among clinicians, providers, suppliers and others that squarely meet all safe harbor conditions.
- OIG uses the term "value-based" in a non-technical way to signal value produced through improved care coordination, improved health outcomes, lower costs or reduced growth for costs for patients and payors, and improved efficiencies in the delivery of care.
- The safe harbors are designed to provide greater flexibilities to parties as they assume more downside financial risk for the cost and quality of care.
- OIG believes that focusing on downside financial risk is appropriate because the assumption of downside financial risk may shift the incentives that serve to influence those making the referring and ordering decisions.

Value-Based Safe Harbors (cont.)

- Definition-Driven
  - Many of the value-based definitions proposed by CMS for Stark are aligned with those proposed by OIG, with the following exceptions:
    - VBE Participant
      - Stating "program integrity concerns," OIG excludes pharmaceutical manufacturers; a manufacturers, distributor, or supplier of DME, prosthetics, orthotics, or suppliers; or a clinical laboratory.
      - OIG Preamble also proposed excluding pharmacies, including compounding pharmacies, pharmacy benefits managers, wholesalers, and distributors, and medical device manufacturers of health technology.
  - Coordination and Management of Care – Several of the Safe Harbors require that the remuneration have a direct connection with the coordination and management of care for the Target Patient Population.
    - OIG defines as the deliberate organization of patient care activities and sharing of information between two or more VBE Participants or VBE Participants and patients, tailored to improving the health outcomes of the Target Patient Population, in order to achieve safer and more effective care for the Target Patient Population.
    - No proposed definition by CMS.

Value-Based Safe Harbors (cont.)

- Value-Based Arrangements
  - Full Financial Risk
  - "Substantial" downside financial risk to the VBE
  - Covers care coordination arrangements to improve quality, health outcomes and efficiency.
  - Extends to personal services and management contracts and outcome-based payment arrangements, with accompanying changes to personal services and management contracts safe harbor.

Value-Based Safe Harbors (cont.)

- Full Financial Risk Arrangements -- A VBE is considered at "full financial risk" for the cost of care of a target patient population if the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor. Under the proposed regulations, "prospective" means that the anticipated cost of all items and services covered by the applicable payor for the target patient population has been determined and paid in advance, plus:
  - A writing;
  - The term of the value-based arrangement must be for a period at least 1 year to ensure that the VBE participant is committed to coordinating care for the target patient population of the VBE that has taken on full financial risk;
  - The VBE participant cannot claim additional or separate payment in any form directly or indirectly from a payor for items or services covered under the value-based arrangement.
  - Remuneration exchanged must: (i) be used primarily to engage in the value-based activities set forth in the parties' signed writing; (ii) is directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population; and (iii) not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient.

Value-Based Safe Harbors (cont.)

- Full Financial Risk Arrangements – Safe Harbor requirements (cont.)
  - The VBE and VBE participant must not take into account volume or value of, or condition remuneration exchanged on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
  - The VBE must provide or arrange for an operational utilization review program and a quality assurance program that protect against underutilization and specify patient goals, including measureable outcomes, where appropriate.
  - The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.
  - The VBE or its VBE participants maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions and make such records available to the Secretary upon request.

Value-Based Safe Harbors (cont.)

- "Substantial" downside financial risk arrangements – VBE considered at substantial downside risk if the VBE is subject to risk pursuant to one of the following methods:
  - Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures
  - A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures
  - A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or
  - A partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected FFS payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangement.

Value-Based Safe Harbors (cont.)

- "Substantial" downside financial risk – OIG is proposing to include the following conditions similar to certain conditions proposed for the care coordination arrangements safe harbor:
    - A writing;
    - The VBE or VBE participant offering the remuneration must not take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement;
    - The value-based arrangement does not: (1) place any limitation on VBE participants' ability to make decisions in the best interest of their patients, or (2) direct or restrict referrals to a particular provider, practitioner, or supplier if:
        - A patient expresses a preference for a different practitioner, provider, or supplier;
        - The patient's payor determines the provider, practitioner, or supplier; or
        - Such direction or restriction is contrary to applicable law or regulations under title XVIII and XIX of the SSA;
    - The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities; and
    - The VBE or its VBE participants maintain documentation sufficient to demonstrate compliance with the safe harbor's conditions and make such records available to the Secretary upon request.

Value-Based Safe Harbors (cont.)

- Additional Value-Based Safe Harbors
  - Care Coordination Arrangements
  - Patient Engagement and Support
  - Replacement of OIG current model-by-model fraud and abuse waivers

Proposal Potpourri: Local Transportation Safe Harbor

- Mileage limits expanded from 50 to 75 miles for rural residents
- No mileage restrictions for transportation between a patient's home and the patient's discharging facility
- Comments sought regarding further expansion of mileage limits and covered transportation (e.g., transportation to food banks, support groups and exercise facilities)

Proposal Potpourri: CMS-Sponsored Models

- New safe harbor to permit remuneration between and among parties to arrangements sponsored by the CMS Innovation Center or under the Medicare Shared Savings Program (MSSP)
- Goal of uniform conditions across all models and initiatives sponsored by CMS
- Provides additional protection beyond waivers

Proposal Potpourri: EHR, Cybersecurity & Telehealth

- EHR and cybersecurity-related proposals correlate with the proposed Stark Law changes, with certain notable exceptions (e.g., no specific amendment to the requirement that the recipient of EHR pay 15% of the donor's cost, though comments solicited)
- CMP exception proposed to allow renal dialysis centers to provide telehealth services to patients receiving home dialysis without risk of penalty

Future Predictions: Now What?

Questions? Thank you!

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