WEBINAR

Regulatory Sprint to Coordinated Care Proposed Regulations

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Speakers

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Introduction

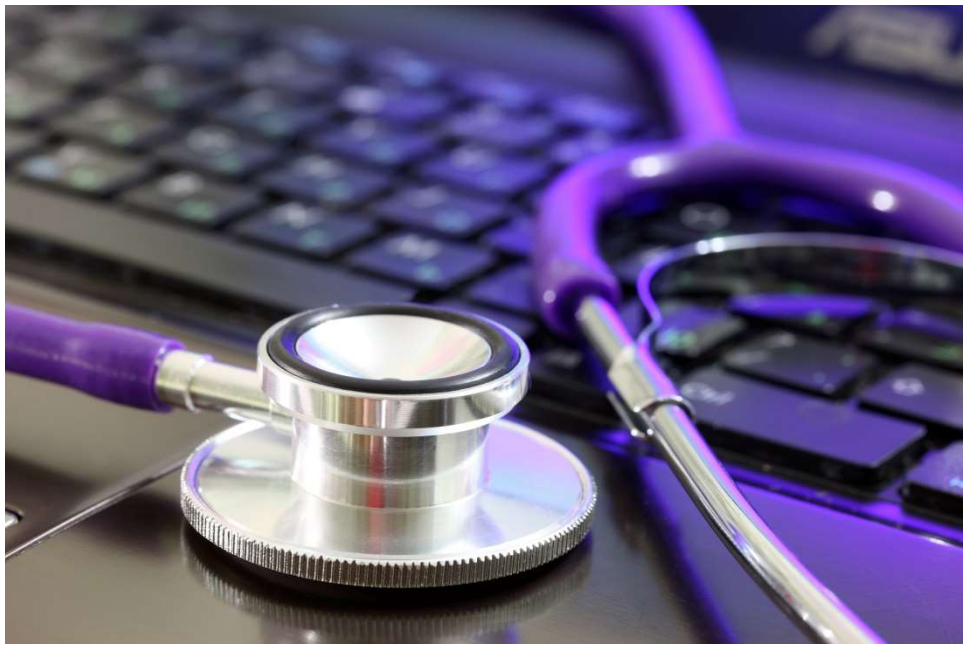
Agenda

- Introduction
- Value-Based Arrangements Exceptions/Safe Harbors
- EHR/Cybersecurity Exceptions/Safe Harbors
- Physician Self-Referral Law (Stark)
  - New Exceptions
  - Clarifications
- Anti-Kickback Statute (AKS)
  - New Safe Harbors
  - Clarifications
- Civil Monetary Penalty (CMP) for Beneficiary Inducements
- Takeaways

Proposed Rules

- No Immediate Effect
- No Guarantee of Adoption
- Subject to Notice-and-Comment Rulemaking
- Opportunity to Comment
  - until December 31
- Many areas where comments are requested
- Overlap, but also differences in the Stark and AKS rules

Value-Based Arrangements Exceptions/Safe Harbors



Value-Based Arrangements

- Purpose of Proposed Regulations
  - Remove regulatory barriers to health care innovation
  - Create flexibility for coordinated and cost-effective care
  - Create incentives to move away from volume-based care to outcome-based care
- Three New Exceptions
  - Applies to Medicare and Non-Medicare Beneficiaries
  - Other potential exceptions may still apply
  - Creates new definitions for use with the exception
- OIG and CMS rules are similar with some distinctions

Value-Based Arrangements:
Common Definitions

Value-Based Activity	• **Provision of item or service; taking of action; refraining from action *does not include making a referral**
Value-Based Arrangement	• Arrangement for provision of at least one value based activity for the target population between or among the Value-Based Enterprise (VBE) and VBE participants
Value-Based Enterprise	• Two or more VBE participants • Accountable body or person responsible for financial and operational oversight • Governing document
Value-Based Purpose	• Coordinating and managing care • Improving quality of care • Reducing costs without reducing quality • Transitioning from volume to value
Target Patient Population	• Identified patient population selected by VBE using “legitimate and verifiable” criteria set out in advance in writing

Value-Based Care Arrangements:
Value-Based Participants

- An individual or entity that engages in at least one value-based activity as part of a VBE
- **OIG Proposed Rule**: Expressly excludes pharmaceutical manufacturers; DMEPOS manufacturers, distributors and suppliers; and laboratories
- CMS seeking comment as to whether to likewise exclude pharma manufacturers; DMEPOS suppliers; laboratories
  - Add PBMs, HHAs?

Value-Based Arrangements:
Full Financial Risk

(AKS – 42 CFR § 1001.952(gg); Stark – 42 CFR § 411.357(aa)(1))

- Greatest Flexibility – Fewer traditional FFS fraud and abuse risks
- General Requirements
  - VBE at full ***financial*** risk (or contractually obligated to assume full risk within 6 months)
  - Remuneration is for, or results from, value-based activities
  - No inducement to reduce or limit medically necessary services
  - No "swapping" – cannot be conditioned on referrals of patients who are not part of target population or business not covered by VBA

Value-Based Arrangements:
Full Financial Risk (continued)

- **Distinctions in OIG/CMS Proposals**
  - OIG
    - Signed writing
    - Accept full financial risk from payor for at least 1 year
    - Cannot claim separate payment for any items or services covered
    - No funding or payment from non-VBE participants (e.g., labs, DMEPOS)
    - No marketing or patient recruitment activities
  - CMS
    - No writing requirement
    - Must accept full financial risk for entire term of agreement
    - Records must be maintained for at least 6 years

Value-Based Arrangements:
Meaningful Downside Financial Risk

(AKS – 42 CFR § 1001.952(ff); Stark – 42 CFR § 411.357(aa)(2))

- Maintains some flexibility in recognition of assumption of downside risk

Key Distinction	
OIG	**CMS**
VBE must be at "substantial financial risk" (within 6 months) • Shared savings w/repayment obligation (at least 40%) • Episodic or bundled payment w/ repayment obligation (at least 20%) • Certain Population-based payments/partial capitation payments	**No requirement for VBE to be at risk**
VBE participant must "meaningfully share" in financial risk • 8% of total VBE risk to payor; • Partial or full capitation (not IPPS); or • Meet Stark exception for physician with meaningful downside risk	**Physician is at "meaningful downside financial risk" if VB purpose not met** • Responsible to pay entity no less than 25% of value of remuneration received; or • Financially responsible to entity on prospective basis for defined set of items and services

Value-Based Arrangements:
Meaningful Downside Financial Risk (continued)

- General Requirements
  - Does not protect ownership/investment interests
  - Must be in writing
    - OIG: Need all material terms
    - CMS: Description of nature and extent of physician's downside risk
  - No inducement to reduce or limit medically necessary services
  - Must protect patient choice and physician's ability to make decisions in best interest of patients
  - No "swapping" – cannot be condition on referrals of patients who are not part of target population or business not covered by VBA

Value-Based Arrangements:
Meaningful Downside Financial Risk (continued)

- **Distinctions in OIG/CMS Proposals**
  - OIG
    - VBE has assumed (or is contractually obligation to assume within 6 months) substantial downside risk from payor
    - Remuneration is:
      - Used "primarily" to engage in value based activities for which VBE is at substantial downside financial risk
      - Directly connected to one or more of VBE's purposes, ***including care coordination and management of care for target population***
    - No marketing or patient recruitment activities
  - CMS
    - Remuneration is for and results from value-based activities for patients in target population
    - Remuneration is "set in advance"
    - Records must be maintained for at least 6 years

Value-Based Arrangements:
Care Coordination Arrangements

(AKS – 42 CFR § 1001.952(ee); Stark – 42 CFR § 411.357(aa)(3))

- Most restrictive since no assumption of risk
- **CMS**: Applies to both monetary and non-monetary remuneration
- **OIG**: Applies only to non-monetary remuneration

- General Requirements
  - Must be set forth in writing and signed by parties and specify key terms
  - No inducement to reduce or limit medically necessary services
  - Must protect patient choice and physician's ability to make decisions in best interest of patients
  - No "swapping" – cannot be condition on referrals of patients who are not part of target population or business not covered by VBA

Value-Based Arrangements:
Care Coordination Arrangements (continued)

- **Distinctions in OIG/CMS Proposals**
  - OIG
    - Must specify one or more specific, evidence-based outcome measures
    - Recipient must pay at least 15% of costs (one-time or reasonable intervals)
    - Remuneration is:
      - Used "primarily" to engage in value based activities that are directly related to ***care coordination and management of care for target population***
    - No marketing or patient recruitment activities
    - Requirement to monitor and assess performance no less frequently than annually; and terminate within 60 days if determined value-based arrangement is unlikely to further coordination, results in major quality deficiencies, or unlikely to meet outcome measures
  - CMS
    - Performance or quality standards against which recipient is measured are optional
    - Remuneration is for and results from value-based activities for patients in target population
    - Remuneration is "set in advance"
    - Records must be maintained for at least 6 years

Value-Based Arrangements:
Indirect Compensation Arrangements

- Stark only
- Under current rules, only exception available for indirect compensation arrangement is indirect compensation exception (42 CFR § 411.357(p))
- Proposed rule would allow certain indirect compensation arrangements to rely on value-based arrangement exceptions, 42 CFR § 411.357(aa)

Patient Engagement

- New, Proposed Safe Harbor
  - 42 CFR § 1001.952(hh)
- Also serves as exception from definition of remuneration for purposes of CMP
- Protects arrangements to assist with patient engagement in their care to improve quality, health outcomes, and efficiency
- Between VBE participants and patient
- For medically necessary care and other non-medical, but health-related items and services that patients might need to adhere to treatment regimens.

Patient Engagement (continued)

- Limited to in-kind remuneration
  - "in-kind, preventative items, goods or services such as health related technology, patient health-related monitoring tools and services and supports or services designed to identify and address a patient's social determinants of health that have a direct connection to the coordination and management of care of the target patient population."
- Excludes gift cards, cash, and any cash equivalent
- Limited to $500 annually (unless financial need)

Patient Engagement (continued)

- Must advance one of the following goals:
  - Adherence to a **treatment regimen** determined by the patient's licensed health care provider.
  - Adherence to a **drug regimen** determined by the patient's licensed health care provider.
  - Adherence to a **follow-up care plan** established by the patient's licensed health care provider.
  - **Management of a disease** or condition as directed by the patient's licensed health care provider.
  - Improvement in **measurable evidence-based health outcomes** for the patient or for the target patient population
  - Ensuring **patient safety**.

CMS-Sponsored Models

- New, Proposed Safe Harbor
  - 42 CFR § 1001.952(ii)
- Provides separate safe harbor to protect CMS-sponsored models, such as those designed by the CMS Innovation Center.
- Intended to replace current model-by-model fraud and abuse waiver process

EHR and Cybersecurity Exceptions/Safe Harbors

AKS:
EHR Donation Safe Harbor

- Revisions to Safe Harbor
  - 42 CFR § 1001.952(y)
- Removes sunset provision
- Extends protection to certain cybersecurity technology
- Updates the interoperability provisions consistent with Office of National Coordinator for Health Information Technology

Stark:
EHR Exception

- 42 CFR § 411.357(w)
- Proposed changes intended to be consistent with OIG
- Interoperability
  - The "Deeming Provision"
  - Information blocking and data lock-in
- Cybersecurity
  - Clarified here and new, broader exception proposed as well
- Removes sunset provision
- 15 Percent Recipient Contribution
- Replacement Technology

AKS:
Cybersecurity Safe Harbor

- New, Proposed Safe Harbor
  - 42 CFR § 1001.952(jj)
- OIG acknowledges need for protection of patient information
- Provides standalone protection for donations of cybersecurity technology and services

Stark:
Cybersecurity Technology Exception

- 42 CFR § 411.357(bb)
- Protect nonmonetary remuneration in the form of certain cybersecurity technology and related services
- Donation must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity
- Not proposing a recipient contribution
- Need written documentation

Physician Self-Referral Law Fundamental Terminology and Requirements

Three Basic Questions

- Does the arrangement make sense as a means to accomplish the parties' goals?
  - Commercial reasonableness
- How did the parties calculate the remuneration?
  - Volume or value
- Did the calculation result in compensation that is fair market value for the asset, item, service, or rental property?
  - Fair market value
- Proposed definitions apply only to Stark law

Commercially Reasonable

- Key question to ask is whether the arrangement makes sense as a means to accomplish the parties' goals
- Made from perspective of the particular parties
- NOT a determination of value
- Compensation arrangements that do not result in profit for one or more of the parties can still be commercially reasonable

Commercially Reasonable Proposed Definitions

- 42 CFR § 411.351
- The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements
- Alternate – 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
- Clarify in regulations that an arrangement that is not profitable can still be commercially reasonable

Volume or Value and Other Business Generated Standards

- 42 CFR § 411.354(d)(5) and (6)
- Value in having an objective test
- Defines exactly when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties
- Establishes a special rule that would be interpreted like a definition

Volume or Value and Other Business Generated Standards (continued)

- Compensation need not be determined based on a mathematical formula
- But, there must be a predetermined, direct positive or negative correlation between the volume or value of the physician's referrals (or other business generated for the entity) and the rate of compensation paid to or by the physician (or an immediate family member of the physician) in order for the compensation to violate the volume or value standard or the other business generated standard
- If X, then Y

Volume or Value Position Reaffirmed

- Phase II Position Confirmed
- Employed physician – productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (DHS) are billed each time the employed physician personally performs a service
- Compensation arrangements – an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula – even when the entity bills for DHS that correspond to such personally performed services – and the compensation will not take into account the volume or value of the physician's referrals

Patient Choice and Directed Referrals

- Special rule at 42 CFR § 411.354(d)(4) permits directed referrals if specified conditions are met to preserve patient choice, insurer's determinations, and protect medical judgment as to best interest of patient

- Proposes to add this as an element to certain arrangements to reiterate how important these protections are

Fair Market Value

- 42 CFR § 411.351
- Value in an arm's length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction
  - Rental of Equipment and Rental of Office Space also modified
- Defines "general market value"

Group Practice Modifications

- 42 CFR § 411.352
- Addressed barriers to qualifying as a group practice that relate to the main purposes of the proposed rule
  - Clarifies the volume or value standard
  - Revises the Profit Share and Productivity Bonus requirements
    - Overall profits means the profits derived from all DHS of any component of at least 5 physicians
    - Profits from all DHS must be aggregated and distributed, with profit shares not determined in any manner that directly takes into account (directly related to) the volume or value of the physician's referrals
    - Cannot distribute profits from DHS on a service-by-service basis
  - Adds the concept of Value-Based Arrangements and the distribution of profits related to DHS directly attributable to physician participation in value-based arrangements

Recalibrating Scope and Application of Regulations

- Removing AKS and Federal and State Laws or Regulations
  - No longer believe it is necessary
  - Congress did not require
  - Does not impact liability under AKS

Special Rules on Compensation

- 42 CFR § 411.354(e)
- Does not have authority to waive violations, but has authority to determine alternative methods for satisfying requirements of an exception
- Reconsidered position on noncompliance with signature and writing requirements
  - Short periods of noncompliance at outset of arrangement before terms established in writing
  - Must meet all other requirements of an applicable exception and can memorialize in writing and obtain signatures within 90 days
- Arrangements can be set in advance without a writing
- Confirms electronic signatures are valid

Definitions:
Designated Health Services

- Proposed rule clarifies that hospital inpatient services do ***not*** constitute DHS if the services do not affect payment under the Medicare IPPS

- CMS declined to extend the clarification to hospital outpatient services
  - Noted that outpatient services typically have only one ordering physician

- Comments sought on the potential applicability of the clarification to non-IPPS hospitals

Definitions:
Physician

- Proposed rule eliminates an ambiguity in the current regulation by simply cross-referencing to the general Medicare definition of physician at 42 U.S.C.§1395x(r)
  - Doctor of medicine or osteopathy
  - Doctor of dental surgery or dental medicine
  - Doctor of podiatric medicine (for limited purposes)
  - Doctor of optometry (for limited purposes
  - Chiropractors (for limited purposes)

- Physician Assistants and Nurse Practitioners are not "physicians"

Definitions:
Referral

- Proposed rule explicitly states that a "referral" cannot be an "item or service" under the Stark statute or regulations
  - Clarifies that exceptions that permit FMV payments for "items and services," such as the one for personal services, cannot be used to protect payments for a physician's referrals
  - Reiterates that the exception for fair market value payments cannot be used to protect recruitment arrangements

Definitions:
Remuneration

- Currently "remuneration" excludes:
  - Furnishing of items, devices, or supplies, (not including surgical items, devices or supplies) used solely for:
    - Collecting, transporting, processing or storing testing specimens for the entity furnishing the items, devices or supplies
    - Ordering tests or communicating the results of test or procedures for the entity furnishing the items, devices or supplies
- Proposed rule
  - Removes the exclusion for surgical items, noting that focus should be on whether the "solely" criteria is met
  - Clarifies that the inquiry should be based on how the items are actually used, not on how they might theoretically be used
  - Clarifies that items used for infection or contamination control, e.g., sterile gloves, would not meet the "solely" criteria

Definitions:
Isolated Financial Transactions

- Proposed rule creates a new free-standing definition of isolated financial transactions which:
  - includes a one-time sale of property or a practice, or similar one-time transaction;
  - does not include a single payment for multiple or repeated services (such as a payment for services previously provided, but not yet compensated).
- Proposed Rule retains the general definition of "transaction" as an instance or process of two or more persons or entities doing business

Period of Disallowance

- CMS notes that it considers the current rule to be "overly prescriptive and impractical" and proposes to delete it without replacement language

- CMS commentary
  - No definite rules
    - A case-by-case facts and circumstances analysis
  - General principles
    - Period of disallowance begins when the relationship fails to meet all requirements of an exception and ends either when it comes into compliance or when the relationship concludes
    - Intent in deleting the rule is to no longer prescribe the particular manner of ending the period of noncompliance

Period of Disallowance (continued)

- CMS general guidance
  - Erroneous over or underpayment of contractual compensation due to administrative error does not create a period of disallowance if detected and "trued up" before the agreement expires
  - Where the errors are not found during the term of the arrangement, the entity should look to potentially applicable safety valves, such as the proposed special rule for writing and signature requirements
  - If no safety valves are available, the entity may need to recoup excess compensation in order to end the period of disallowance

Limited Remuneration to a Physician

- 42 CFR § 411.357(z)
- Creates exception for non-abusive business practices
- Applies to furnishing of items and services by physician
- Remuneration does not exceed $3,500 annually
- May not
  - be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
  - or exceed fair market value for the items or services provided by the physician; and
  - the compensation arrangement must be commercially reasonable.

Ownership or Investment Interests

- Titular Ownership or Investment Interest
  - Extend concept of rules governing ownership or investment interests at 42 CFR § 411.354(b)
  - If physician does not have right to distribution of profits or proceeds of sale, no financial incentive to make referrals

- Employee Stock Ownership Program
  - An interest in an entity arising through participation in an ESOP merits the same protection as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity

Rental of Office Space or Equipment

- Exclusive use clarified (42 CFR § 411.357(a) and (b))
  - Do not want lessor to have sham lease where space or equipment is "rented" to a lessee but lessor continues to use space or equipment when lessor is paying to rent it
  - Multiple lessees can use same rented office space or equipment at the same time as long as lessor is excluded
- Fair market value exception (42 CFR 411.357(l))
  - Reconsidered policy and proposed to make exception available to protect arrangements for the rental or lease of office space
  - Prohibits percentage-based and per-unit of service compensation for office space
  - Does not require 1 year term

Remuneration Unrelated to Provision of DHS

- 42 CFR § 411.357(g)
- Modification to broaden application of the exception
- Delete current provisions and propose language that incorporates the concept of patient care services as the determining factor when remuneration for an item or services is related to the provision of DHS
  - Remuneration from hospital to physician does not involve DHS if the remuneration is for items or services not related to patient care services
  - Services can be provided legally by a person who is not a licensed medical professional and the service is of the type typically provided by such person

Payments by a Physician

- 42 CFR § 411.357(i)
- Reconsidered position regarding availability of the regulatory exception for certain compensation arrangements
  - Not able to protect compensation arrangements specifically addressed by one of the statutory exceptions
  - May be used to protect payments by a physician that is not office space – such as storage space or residential real estate

Recruitment

- Physician
  - 42 CFR § 411.357(e)
  - If physician practice is not receiving any financial benefit from the recruitment agreement, it is not necessary to obtain a signature from the group
- Nonphysician Practitioner (NPP)
  - 42 CFR § 411.357(x)
  - Patient care services to NPP patient care services
  - Conform referral definition for 42 CFR § 411.357(x) – NPP referral
  - Changes limitation on NPP who "practiced" in area within 1 year to "furnished NPP patient care services"

Anti-kickback Statute

OIG Objectives in Proposed AKS Changes

- Permit beneficial innovations in health care delivery
- Avoid regulations that limit innovation to certain arrangements
- Provide safe harbor protection that is useful for a wide range of provider types and sizes
- Allow flexibility
- Create clear, objective, and flexible rules
- Create appropriate safeguards to protect beneficiaries and Medicare

Personal Services and Management Contracts

- Proposed modification and expansion
  - 42 CFR § 1001.952(d)

- Provide protection to certain outcomes-based payment arrangements
  - Measurably improving care, or
  - Materially reducing costs
  - Excludes pharmaceutical company, manufacturer, distributor, DMEPOS supplier, or laboratory

Personal Services and Management Contracts (continued)

- Eliminates requirement that aggregate payment be set out in advance
- Instead, requires payment methodology be set out in advance
- Part-time arrangements no longer required to have schedule set out in written agreement
- Bottom line is more arrangements will qualify for safe harbor protection

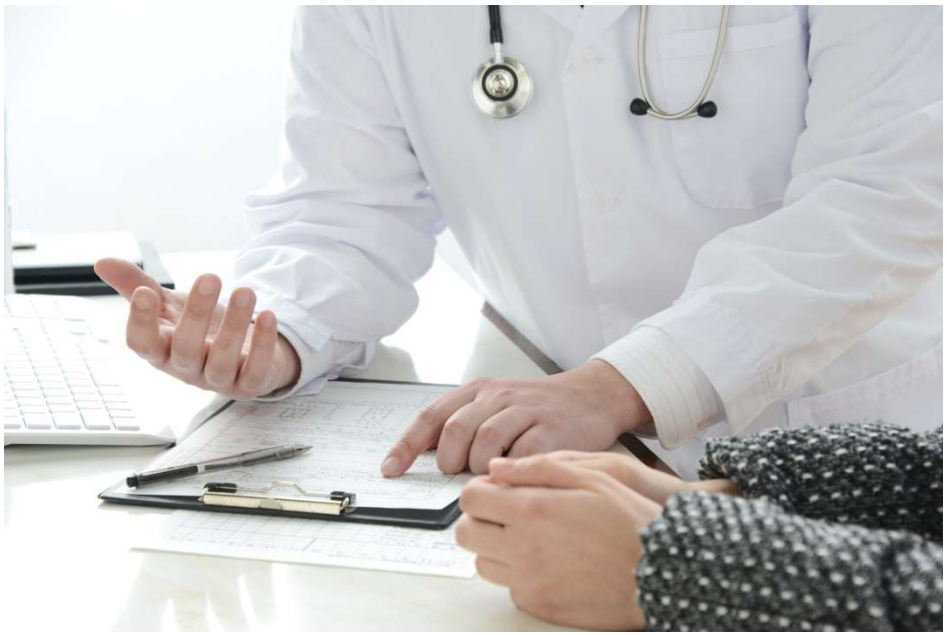
Warranty

- Revisions to Safe Harbor
  - 42 CFR § 1001.952(g)
- Permits protection for one or more items and related services
- Excludes beneficiaries from reporting requirements for buyers
- Defines warranty (rather than relying on the reference to 15 U.S.C. § 2301(6))
- No protection for service-only arrangements
- Adds criteria for protection of bundled warranties

Local Transportation

- Revisions to Safe Harbor
  - 42 CFR § 1001.952(bb)
- Expand distance allowed for residents in rural areas
- Removes any distance limitation for inpatients upon discharge
- Clarifies that ride-sharing arrangements are permissible

Civil Monetary Penalty for Beneficiary Inducements



ACO Beneficiary Incentive Program

- New AKS Safe Harbor
  - 42 CFR § 1001.952(kk)
- Also serves as exception from definition of remuneration for purposes of CMP
- Implements provision of Bipartisan Budget Act of 2018 without modification
- Protects incentive payment made by ACO to assigned beneficiary who receives payment as part of an ACO Beneficiary Incentive Program

Telehealth Technologies for In-Home Dialysis

- New Exception
  - 42 CFR § 1003.110(10)
- Implements statutory change included in Bipartisan Budget Act of 2018
- Permits certain end-stage renal disease (ESRD) patients to receive monthly clinical assessments via telehealth
- Allows telehealth technologies to be provided on a monthly basis to ESRD patients receiving in-home dialysis

Final Thoughts

Takeaways

- Potential opportunities for new and different arrangements
- Will need to reassess and potentially revise existing arrangements
- No immediate effect
- No guarantees

Regulatory Sprint Resource Center

https://www.bakerdonelson.com/regulatory-sprint-to-coordinated-care

We appreciate your participation!