The Sprint Regulations

Idaho Bar Association: Health Law Section

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HHS Regulatory Sprint To Coordinated Care

Sprint launched in 2018 – Reduce Regulatory barriers and accelerate transformation of the healthcare system into one that better pays for value and promotes care coordination

CMS issued Request for Information regarding Stark

- 375 Public Comments

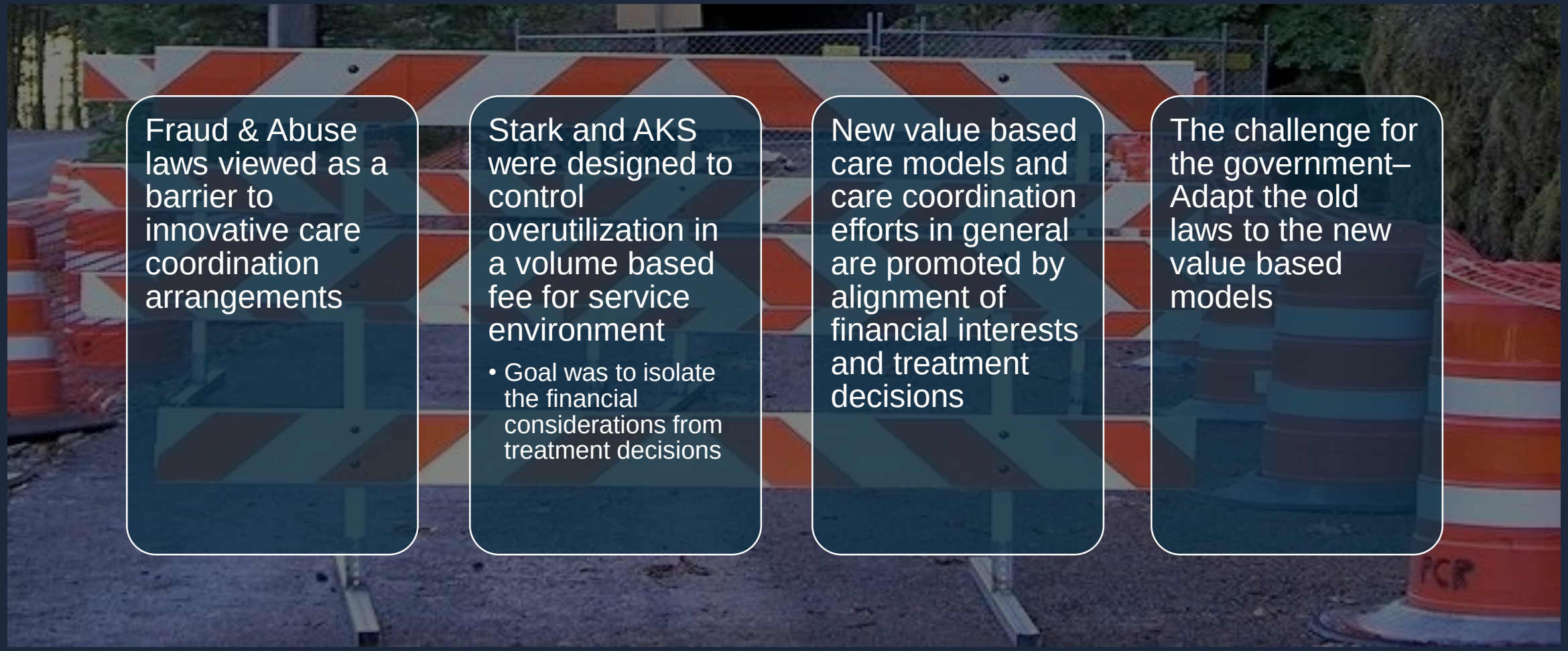
OIG issued Request for Information regarding AKS and Civil Money Penalty Law

- 359 Public Comments

October 17, 2019, CMS and OIG issue Sprint Regs

- Comments due December 31, 2019

Removing the Barriers?



Fraud & Abuse laws viewed as a barrier to innovative care coordination arrangements

Stark and AKS were designed to control overutilization in a volume based fee for service environment

- Goal was to isolate the financial considerations from treatment decisions

New value based care models and care coordination efforts in general are promoted by alignment of financial interests and treatment decisions

The challenge for the government– Adapt the old laws to the new value based models

Sprint Proposals: Value Based

- Proposed Sprint regulations focus on “Value Based Enterprises”
  - New Stark exceptions
  - New AKS safe harbors

Sprint Proposals: Value Based

- Basics: 2 or more VBE participants that
  - Collaborate to achieve a “value-based purpose”
    - Includes coordinating and managing care, improving quality, appropriately reducing costs or growth in expenditures of payors without reducing quality, or transitioning from health care delivery and payment based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care
  - By participation in value based activities in a valued based arrangement
  - Relating to a target patient population
  - Using an accountable body or person responsible for oversight, and who have
  - Governing documents that describe the VBE and how the VBE participants intend to achieve its value based purpose(s)

Value Based Exceptions/Safe Harbors

- Proposed AKS Safe Harbors
  - Full Financial Risk
  - Substantial downside financial risk
  - Care coordination arrangements (limited to in kind remuneration)
- Proposed Stark Exceptions
  - Full Financial Risk
  - Meaningful downside financial risk to physician
  - Value based arrangements
- The less risk the parties assume the more regulatory safeguards

Value Based Proposals

- A number of questions about how to apply the definitions
  - Value base purpose?
  - Value based activity?
  - Need more examples in the Commentary
- Risk requirements significant
  - Note distinctions between Stark Exceptions and AKS Safe Harbors
- In general, easier to qualify for Stark value based exceptions than AKS Safe Harbors
  - Comfortable being uncomfortable . . .
- Comments due 12/31– Rules may well evolve
- Final regulations in 2020 or 2021??

Patient Engagement & Personal Services Safe Harbor

Patient Engagement Safe Harbor (NEW)

- Provision of tools and support services to patients to improve quality, health outcomes and efficiency
- Limited to in kind items or services that have a direct connection to management of care
- Must be offered by VBE participant
- Limited to $500 in the aggregate per year (absent financial need)

Personal Services and Management Contracts Safe Harbor (Modify Existing)

- Revise to eliminate the need to set aggregate compensation in advance
- Eliminate requirement in part time arrangements to provide specifics at the on set of the arrangement
- New provision to protect outcomes based payments –
  - Does not include internal cost savings

EMR Donation and Cybersecurity

CMS and OIG proposed to eliminate the sunset provision for the EMR Donation Stark Exception and AKS Safe Harbor

Revise exception/safe harbor to align with 21st Century Cures Act

- Definition of interoperable
- Revise data lock in provision to prohibit data blocking

Permit donation of replacement EMR technology

Solicit comments on eliminating (or reducing) the requirement that the physician pay 15% of donor's cost

Donation of Cybersecurity software and support specifically addressed

- No physician contribution required

Stark Proposals: The Big 3

- CMS proposes to revise definitions of
  - Fair Market Value
  - Volume or Value
  - Commercial Reasonableness
- Commercial Reasonableness
  - First attempt to define
  - States specifically that an arrangement can be commercially reasonable even if it does not result in a profit for one or more of the parties

Fair Market Value

- New definition– separates the volume or value standard from FMV
- Value in an arm's length transaction with like parties under like circumstances
- Consistent with the General Market Value of the subject transaction
  - General market value is equivalent to the price that would result from bona fide bargaining between the parties on the date of the transaction is entered into
- Special FMV definitions for rental of equipment and rental of property

Volume or Value

- Striving for a bright line test

Compensation from an entity furnishing designated health services to a physician takes into account the volume or value of referrals only if—

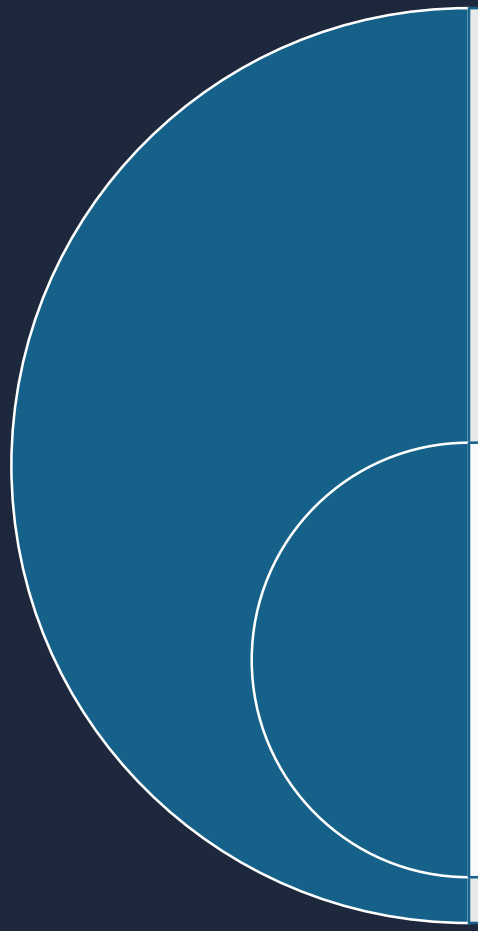
The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or

There is a predetermined, direct correlation between the physician's *prior* referrals to the entity and the *prospective* rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

If prior referrals were X, then compensation for the duration of the current arrangement is Y.

A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

Volume or Value



Similar formula approach for volume or value of referrals or volume or value of other business generated

- Note other business generated means the other business generated by the physician for the entity

Commentary specifically rejects one of the findings of the 4th Circuit *Toumey* :

- payments based on personally performed services do not run afoul the volume or value of referrals prohibition simply because the performance of the service will also generate a hospital facility charge

Fixing Mistakes

The Commentary includes an important clarification on the ability of parties to an arrangement to cure an oversight or error during the term of the arrangement

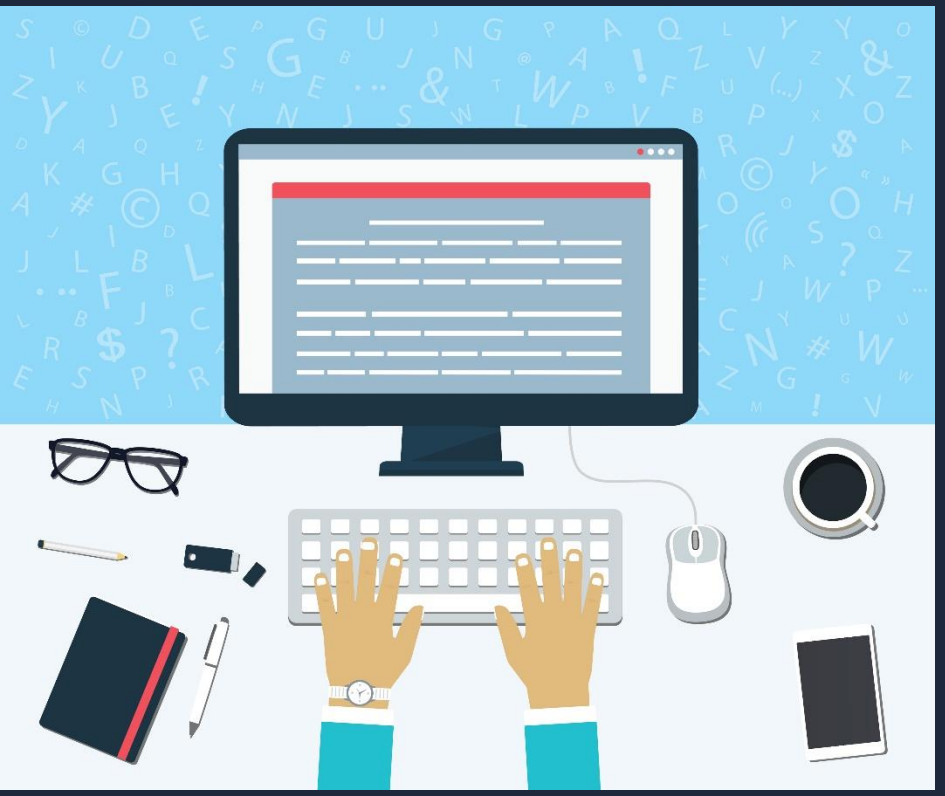
CMS presented the hypothetical of an inadvertent underpayment – contract states physician is to be paid $150 per hour but due to a oversight he is paid $140 per hour

CMS stated it “was never our intent” to have these types of errors trigger the Stark prohibitions

Parties can cure during the term

HOWEVER, if the arrangement ends the parties cannot “unring” the bell

Writing Requirement, DHS & Payments by Physician



- CMS proposes to give parties a 90 day grace period to satisfy the writing requirement
  - Very Similar to the alternative means of compliance with signature requirement
- Definition of DHS proposed to be narrowed to exclude services for a Medicare inpatient if the item or service requested does not affect the amount of the hospital payment
- Payments by Physician Exception
  - Historically CMS has narrowly construed– not available if any other exception applies
  - Proposal is that exception available unless a statutory exception applies

Isolated Transactions, Period of Disallowance

- Isolated Transaction Exception – proposed modification to exclude “a single payment for multiple or repeated services”
  - Agency wants to narrow the exception –not permit its use to retroactively cure noncompliance
- Removal of Period of Disallowance Rules, which currently state that an arrangement ends when all excess compensation is refunded
  - Proposal – parties determine when a prohibited financial relationship ends on a case by case basis

Proposed Exception Z

- CMS proposes to create a new exception for limited remuneration to physicians
  - No more than $3500 per calendar year in the aggregate
  - Must be FMV, not based on Volume or Value and Commercially Reasonable
  - HOWEVER– do not need a writing or signatures and compensation does not have to be set in advance
- Exception Z may be used to protect an arrangement that fails to qualify for another exception for a portion of the contemplated term
  - For example, arrangement that fails to satisfy the FMV arrangement exception because it was not reduced to writing during first few months or the parties' signatures were not secured within 90 days
    - Use Exception Z for first few months then put documentation in place so that arrangement qualifies under another exception


QUESTIONS
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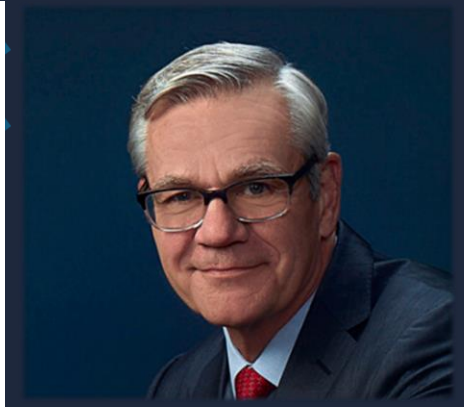

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Healthcare

By

Stark

AKS

AKS

AKS

Healthcare

By

volume or value *commercially reasonable*

bona fide

bona fide

bona fide

"[m]erely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the entity."

United States ex rel. Drakeford v. Tuomey Healthcare System, Inc. *U.S. ex rel Bookwalter v. UPMC*

solely

bona fide

statutory

Healthcare

By

Preamble: Only compensation arrangements may qualify as value-based

arrangements. The definition of value-based arrangement is also broad enough to cover commercial and private insurer arrangements.

Preamble: Organized networks of health care providers, suppliers, and other components of the health care system have flexibility to adopt any legal structure that meets these requirements, including a distinct legal entity such as an ACO. However, a VBE could be a contractual arrangement as well, if all definitional elements are met. The accountable body/person may be a party to a value-based arrangement or if the VBE is a legal entity, it may be the governing board, a committee, or an officer of the legal entity.

Preamble: A VBE participant could include physician practices, hospitals, payors, post-acute providers, pharmacies, chronic care and disease management companies, social service organizations, etc. Entity means any non-natural person, not just DHS entities subject to Stark. For purposes of the AKS safe harbors, the definition of VBE participant expressly excludes pharmaceutical manufacturers, DMEPOS manufacturers, distributors or suppliers, and laboratories. CMS and the OIG are also considering whether to exclude "health technology companies" from the scope of the exception, though they did not define the term.

Preamble: Making a referral is not a value-based activity.

Preamble: This phrase is not defined for the Stark exceptions, but CMS is considering whether to adopt a definition requiring deliberate organization of patient care activities and sharing of information between VBE participants to improve health outcomes and to achieve safer and more effective care, similar to the corresponding AKS safe harbor. For the proposed AKS safe harbors, the OIG has proposed defining "coordinating and managing care" to mean "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."

Preamble: CMS is considering whether to require the purpose to improve quality or maintain improved quality rather than simply not reduce quality in addition to reducing costs/growth in expenditures. This approach would limit the purpose to situations where the VBE has already achieved improvement in the quality of care.

Preamble: CMS acknowledges this purpose is subjective. One example is establishing infrastructure to facilitate patient-centered coordinated care.

Preamble: Medical, health, geographic, and payor status characteristics are all examples of acceptable criteria, while criteria that effectively "cherry-pick" or "lemon-drop" patients would not be acceptable. The proposed definition is not limited to federal healthcare program patients. CMS and the OIG are also considering limiting the definition of "target patient population" to patients with a chronic disease or a shared disease state that would benefit from care coordination.

Preamble: The OIG will not consider measures related to patient satisfaction or convenience to be valid outcome measures. The OIG is also considering how to define "evidence-based," and whether outcome measures must be periodically rebased (i.e., reset the benchmark used to determine whether the outcome measure was achieved).

Preamble: The OIG is considering for the final rule whether in-kind remuneration can have a "spillover" effect and benefit patients outside the target patient population, or whether it may only benefit the target patients. If the latter standard is adopted, safe harbor protection would be unavailable

for common arrangements that involve donation of health tech used across all facets of a provider's business.

Preamble: This requirement is intended to mirror a requirement in the EHR safe harbor. The OIG is considering for the final rule how to determine value for purposes of calculating the 15 percent payment. The OIG is also considering whether to adjust the contribution amount within a range of five to 35 percent, or perhaps waive this requirement for parties in rural or low-access areas.

Preamble: The OIG is not proposing a definition for a material deficiency in the quality of care.

compensation methodology

directly

indirectly