

# Anti-Kickback Request for Information

# + Agenda

- + Introductions
- + Context for the RFI
- + Overview of AKS and Beneficiary Inducement Statute
- + Differentiating AKS from Stark
- + Impact on value-based models
- + Crafting your RFI response

# + About Us

McDermott+Consulting	McDermott Will & Emery
<ul style="list-style-type: none"><li>• Provides health policy, advocacy and data analytics services to health industry clients</li><li>• Team of 10 professionals with different backgrounds, including CMS, Capitol Hill, medicine, legal, and statistics</li><li>• Affiliated with law firm offering seamless, one-stop shopping for clients</li></ul>	<ul style="list-style-type: none"><li>• Integrated, multidisciplinary legal practice with 20 locations around the globe</li><li>• 120+ dedicated healthcare attorneys</li><li>• One of the largest and most prestigious health practices in the world</li></ul>

# + Context for the RFI

- + HHS Secretary Azar has identified four priority areas:
  - Health Reform
  - Drug Pricing Reform
  - Opioids and Mental Health
  - Value-Based Transformation and Innovation
    - Parallel tracks of model development/modification and regulatory relief
  
- + Dep. Secretary Eric Hargan Announces #RS2CC
  - Stark Law RFI
  - AKS RFI
  - HIPAA RFI
  - 42 CFR 2 RFI

## + Value Movement Update

- + New Medicare model development has been very limited
  - Rumblings of Direct Provider Contracting model
  - MAQI model
  - BPCI Advanced
- + Significant modifications to MSSP
  - Overhauling the program rules results in fewer program participants
  - Less potential for shared savings, overall, few bonus opportunities

## + Is there Opportunity in Deregulation?

- + Administration and Congress look to regulatory barriers to coordinated care – or deregulation as an incentive for risk-bearing model participation

# + Anti-Kickback Statute (“AKS”)

- + The AKS prohibits knowingly and willfully:
  - Soliciting, receiving, offering, or paying
  - Anything of value (“remuneration”) (direct or indirect, in cash or in kind)
  - In return for or to induce 1) referrals; 2) purchasing, leasing, ordering; or 3) arranging for or recommending purchasing, leasing, or ordering
  - Items or services paid for, in whole or in part, by a federal health care program
- + “One purpose” test: if any one purpose is improper, other legitimate purposes may not carry the day
- + Enacted in 1972

# + AKS: Enforcement Penalties

## AKS enforcement exists in three forms

Criminal	<p>AKS is a criminal statute</p> <ul style="list-style-type: none"><li>• Felony subject to up to \$25,000 fine and five years in prison</li></ul>
Civil	<p>Civil prosecution under False Claims Act:</p> <ul style="list-style-type: none"><li>• Up to 3 times damages and \$22,000 penalty per claim</li><li>• Government pursues claims that “result from” the kickback as damages</li><li>• Corporate Integrity Agreement (“CIA”) with OIG</li></ul>
Administrative	<ul style="list-style-type: none"><li>• Civil money penalties of up to 3 times amount of kickback and \$75,000 per kickback</li><li>• Exclusion from participation in Federal health care programs</li></ul>



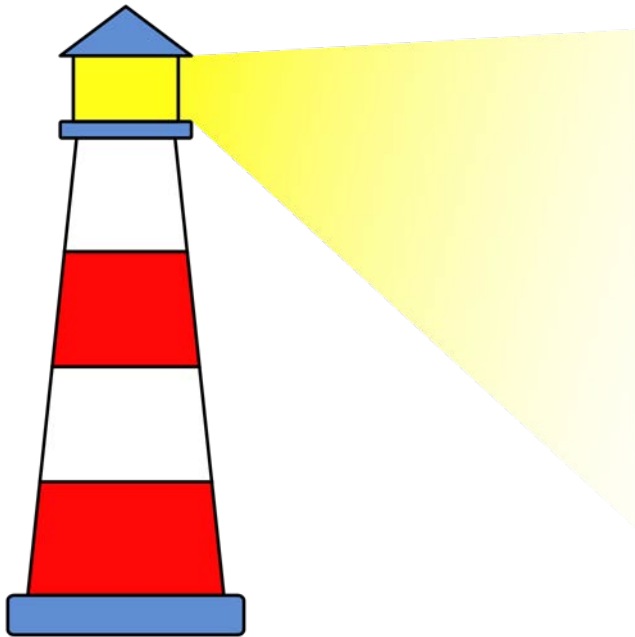
# + AKS: OIG as the Enforcement Organization

## + HHS Office of Inspector General (“OIG”)

- Creates regulatory safe harbors
- Issues Advisory Opinions for specific arrangements
- Issues industry guidance, such as bulletins, alerts, compliance program guidance
- Advises DOJ on criminal and civil cases
- Brings administrative civil monetary penalties (“CMP”) and exclusion cases
- Negotiates corporate integrity agreements



## + AKS: Statutory and Regulatory “Safe Harbors”



- + Protect certain arrangements even if intent is to induce referrals
- + Must meet all elements
- + Voluntary
- + Narrowly drafted on purpose
- + Many of OIG’s safe harbors were created in the 1990s and have not changed

## + AKS: Outside the Safe Harbors

- + Non-safe harbored arrangements analyzed based on specific facts and circumstances
- + No bright lines because:
  - State-of-mind is important
  - Bad intent can negate good intent
  - Corporate intent is collective
  - Bad intent can be contagious
  - Intent is not always knowable without hindsight
- + Some judicial decisions interpreting the AKS exist; most are rather vague and limited to evaluating a motion to dismiss

# + Comparing AKS to Stark

	THE ANTI-KICKBACK STATUTE	THE STARK LAW
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business	<ul style="list-style-type: none"> <li>- Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies</li> <li>- Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral</li> </ul>
Referrals	Referrals from anyone	Referrals from a physician
Items/Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	<ul style="list-style-type: none"> <li>- No intent standard for overpayment (strict liability)</li> <li>- Intent required for civil monetary penalties for knowing violations</li> </ul>
Exceptions	Voluntary safe harbors	Mandatory exceptions
Federal Health Care Programs	All	Medicare

## + Beneficiary Inducement Provisions of the CMP Law

- + Any remuneration to a Medicare or Medicaid beneficiary
- + that the person knows, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services
- + Penalty: Monetary penalty of up to about \$15,000 per claim and up to three times the amount claimed
- + Enacted in 1981

## + Beneficiary Inducement Provisions of the CMP Law

- + OIG rarely enforces directly
- + Creates compliance issues in structuring patient incentive and engagement programs
- + Remuneration implicating the Beneficiary Inducement Statute could also potentially be pursued under the AKS
- + Example: Free smartphone pre-loaded with an app developed by a device manufacturer is given to a Medicare beneficiary

## + Beneficiary Inducement Provisions of the CMP Law

- + OIG guidance permits “nominal” gifts if less than \$15 in each instance and less than \$75 in the aggregate on an annual basis, except
  - No cash or cash equivalents (Visa gift card vs. Starbucks gift card)
- + Several new exceptions were created in the ACA and OIG implemented into regulations in 2017
- + Exceptions are complicated and still require careful factual analysis to fit within exception

## + Example: Promotes Access to Care Exception

- + The ACA created an exception for remuneration that posed low risk of harm to beneficiaries or the Medicare/Medicaid programs and promotes access to care
- + OIG created a narrow regulation that only protects remuneration that *improves the ability to access Medicare/Medicaid covered services*
  - Not protect remuneration that awards or encourages obtaining care, such as adherence to a physician-created treatment plan
  - Not protect remuneration that encourages “healthy living” or “wellness” unless they involve activity tracking or other measures that facilitate interactions with physicians for care planning purposes



# + How AKS and BIS Impact Payment Reform

- + Virtually any financial arrangement among healthcare actors or with beneficiaries can implicate these statutes
  - Employment and service contracts
  - Marketing
  - Selling products/providing discounts/waiving copays
  - Giving free prescription pads to doctors
  - Giving free screenings to beneficiaries at a health fair
  - Product support/reimbursement support
  - Sharing value-based or bundled payments among different care providers

## + How AKS and BIS Impact Payment Reform

- + Compliance with one law does not necessarily result in compliance with the other
  - OIG specifically stated that compliance with BIS exception does not mean AKS compliance is satisfied
    - Example: Promotes access to care
- + Payment reform will necessarily result in incentives to steer patients to particular providers, suppliers, or manufacturers

# + Request for Information

- + Promoting care coordination and value-based care
  - How to define “value”
- + Beneficiary incentives and cost-sharing obligations
  - Adherence to care and medication plans
  - Implementing new AKS safe harbor from the 2018 budget bill for payments by an ACO to a beneficiary
- + Current fraud and abuse waivers
- + Providing cybersecurity technology assistance
- + Telehealth services to end-stage renal disease patients
- + Disclosure emerges as a theme for potential safeguards

## + Reform Challenges

- + Groundwork for Stark Law reform is farther along
  - Been focus of industry and government for a number of years
  - Greater consensus among industry as to Stark solutions
  - CMS has recent track record of taking actions to reduce Stark burden
  - Unclear if consensus exists within the government on AKS and BIS
- + AKS and BIS are intent-based statutes with few bright lines
- + OIG has been reluctant in the past to create bright lines or broad safe harbors for AKS and BIS

# + How To Approach Reform

- + Key concepts from Stark Law RFI apply
  - Fair market value safe harbor
  - Limiting “referral” to care that is separately reimbursed (and not included within a bundled payment methodology)
  - Value-based payment/coordinated care safe harbor
- + Advocate for broader safe harbors and exceptions
  - Personal services safe harbor extremely narrow
  - Promotes access to care exception is too limited
- + Advocate for interpretive guidance on longstanding issues
  - Marketing/product support
  - Employment safe harbor
  - Improper inducement vs good customer service/competition

# + Questions?



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