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Agenda

- Fraud and Abuse Laws: An Overview
- Stark, Kickback, and False Claims Act and Value-Based Care
  - Misalignment: Fee-for-Service Rules for Innovative Forms of Payment and Care
  - Modifications to Consider
- Themes and Trends in Proposals for Modifying the Fraud and Abuse Framework
- Examining Latest Proposals
  - What is included
  - What is left out
- Complying with the Current Framework
- What Comes Next?
- Q & A

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Fraud and Abuse Laws

- Federal
  - Anti-Kickback Statute (42 USC §1320a-7b(b))
  - Physician Self-Referral (Stark) Law (42 USC § 1395nn)
  - Civil Monetary Penalties (CMP) Law (42 USC § 1320a-7a)
  - Civil False Claims Act (31 USC § § 3729-3733)
  - Criminal False Claims Act (18 USC § 287)
  - Exclusion Authorities (42 USC § 1320a-7, § 1320c-5)
  - Criminal Health Care Fraud Statute (18 USC § § 1347, 1349)
- State

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False Claims Act

- Designed to prevent unwarranted government expenditures (1863)
- Forbids ***knowingly***:
  - Presenting or causing to be presented a false claim for reimbursement by a Federal health care program;
  - Making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim;
  - Repaying less than what is owed to the government (reverse false claims);
  - Avoiding or decreasing an obligation to pay the government; and/or
  - Conspiring to defraud the federal government through one of the above actions.
- *Qui tam* provisions (15-25% of gov't recovery to relator)
- Penalties:
  - Recoupment
  - CMPs; treble (3x) damages
  - Criminal penalties (fines, jail time)
- Changes: Fraud Enforcement and Recovery Act (FERA), Affordable Care Act (ACA)
- State False Claims Acts

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Civil Monetary Penalties Law

- Prohibits false and fraudulent conduct related to federal health care programs or beneficiaries, including submission of claims that are:
  - False or fraudulent
  - Provided by someone who has been excluded from participation in federal health care programs
  - Prohibited by the beneficiary inducement law
- Beneficiary inducement provision prohibits the offering or transferring of remuneration and/or inducements to Medicare, Medicaid, and/or CHIP beneficiaries that are likely to influence the beneficiaries to choose goods or services from a particular supplier or provider paid for in whole or in part by such programs
- Penalties:
  - $10,000-$100,000 per claim (depending on violation; adjust for inflation)
  - Treble (3x) damages
  - Exclusion

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Anti-Kickback Statute

- Designed to "[p]rotect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions" ~ Office of the Inspector General, 1999
- Prohibits the knowing and willful solicitation, offer, payment or acceptance of any remuneration to induce:
  - Referral of an individual for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program; or
  - Purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.
- Regulatory safe harbors (42 CFR **§** 1001.952) and statutory exceptions
- Penalties
  - Criminal: fines, jail time, mandatory exclusion
  - Civil: CMPs, exclusion, treble (3x) damages
  - FCA liability (ACA change)

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Physician Self-Referral (Stark) Law

- Designed to prevent corruption of medical decision-making, overutilization, increased program costs, and unfair competition.
  - Premised on government's belief that a conflict of interest is inherent in any arrangement where a doctor refers patients to an entity in which s/he or family has a financial stake.
- Prohibits a physician from referring a beneficiary for "designated health services" covered by Medicare or Medicaid to providers with which the physician (or his/her immediate family) has a financial relationship.
- Regulatory exceptions (42 CFR § § 411.350-389) and statutory exceptions
- Penalties:
  - FCA liability (bootstrapping)
  - CMPs
  - Exclusion for knowing violations

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Current Stark & AKS Framework

- Relevant safe harbors
- Relevant exceptions
- MSSP Waivers
- OIG Advisory Opinions
- CMS Advisory Opinions

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Revisiting the Fraud and Abuse Framework

- Existing framework is designed for a fee-for-service system that rewards volume
- Value-based system (ACA, MACRA, MIPS)
- Transition to a value-based system encourages:
  - Greater integration among providers and settings (including data sharing)
  - Care delivery and payment coordination across providers, settings, and other industry stakeholders
  - Incentivizing value-driven care
  - Improved patient outcomes, increased patient engagement
- Regulatory Sprint to Coordinated Care (2018)
- Still need to protect against fraud and abuse

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Key Issues: False Claims Act

- Fee-for-service payment environment
  - Per claim basis for payment
  - Per claim basis for penalties
- Innovative financial models
  - Capitation (Medicare Advantage)
  - Value-based payment
- Payment determination
  - Risk adjustment and diagnoses (MA)
  - Services (FFS)
- What is a "claim" outside of FFS?

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FCA & MA: Relevant Issues

- ACA Changes to MA (2010)
- *UnitedHealthcare Ins. Co v. Azar* (2018)
- Proposed changes to payment methodology (2020)
- Increasing focus on plans by DOJ
- What's next?
  - Advocacy and education
  - Thought leadership

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Key Issues: Stark & Anti-Kickback

- Stark Law
  - Complicated, technical exceptions
  - Strict liability
  - Bootstrapping to FCA
- Anti-Kickback Statute
  - Intent (one-purpose rule)
- Definitions: volume or value of referrals, fair market value, remuneration
- Limitations of existing exceptions (ex: EHR donation)
- Defining “value-based” arrangements, participants, risk sharing

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Potential Modifications

Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Shared infrastructure; team-based care	Technological advancements not contemplated when electronic health record (EHR) exception/safe harbor originally created necessitate additional flexibility in defining covered technology.	Expand the existing regulatory safe harbor/exception for donation and support of EHR software to include technology related to information sharing as well as industry-supported data collection, analytics, and other technology services.	Existing provisions of EHR exception (Stark) and safe harbor (AKS) that protect against inappropriate financial relationships still exist.

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Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Incentive payments	Value-based payments encourage outcomes-based care as opposed to FFS payments that solely incentivize volume (physicians) or DRG payments (hospitals) that incentivize discharge with little to no accountability for care post-discharge (hospitals;) incentives to control cost are built into value-based arrangements and mitigate the possibility of incentives to increase volume or use higher-level care settings.	Define "volume or value of referrals" to allow for an outcomes-based healthcare payment environment.	Definition of volume or value can include quality of care requirements to ensure that variable payment rates based on volume or value vary solely or primarily on outcomes.
		Issue regulations or guidance on applying "volume or value of referrals" standard within the changing healthcare payment environment.	Alignment between Stark and AKS guidance will ensure consistency across governing agency interpretations.
		Revise definition of fair market value (FMV) in Stark and define FMV in AKS to account for value-based payment models and provide flexibility to allow collaboration among various stakeholders. Issue regulations or guidance on establishing and documenting FMV in value-based payment settings and integrated care models.	Definition of FMV and standards for documenting can include safeguards relating to quality, payment caps, and similar criteria to ensure accurate assessment in a value-based environment without compromising program integrity. Can create standard valuation protocol, require the use of multiple appraisers, and/or require the use of an approved appraisal firm. Underlying protections against inappropriate financial relationships remain the same.

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Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Direct enforcement towards intentional fraud as opposed to technical errors and minor violations (e.g., fine fits the crime).	Changing delivery and payment system and growing list of exceptions subvert the ability to apply the "bright line" test Stark originally created.	Eliminate strict liability for Stark and replace with either an intent-based framework or develop a sliding scale of penalties for violations to align more closely the penalties with the severity of activity	Stark still prohibits inappropriate financial arrangements. Adding an intent requirement ensures that technical errors are not treated with the same severity as intentional fraud, and ensures that good-faith arrangements designed to reduce costs and improve care are not hampered by fear of liability.
	Value-based payments encourage outcomes-based care, as opposed to fee-for-service payments where harm to patients may occur resulting from the underlying incentive to over-utilize services. Incentives to provide only those services that benefit the patient are built into value-based arrangements and mitigate the possibility of incentives to increase volume or use higher-level care settings.	Expand statutory intent provision to include a standard for liability (e.g., patient harm, impact on federal healthcare costs coupled with informed patient consent) and eliminate use of the judicially created "one-purpose test."	The intent requirement can be narrowly tailored to better ensure that any remuneration that harms patients or increases costs to the government falls outside the scope of permissible arrangements. AKS would still prohibit inappropriate remuneration and arrangements that incentivize overutilization.

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Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Payment and Delivery Reform	Policy objectives underpinning exception authority have shifted away from lower utilization to achieve lower costs and moved toward improved outcomes and increased efficiency to lower costs.	Grant CMS enhanced regulatory flexibility to create exceptions that are consistent with shared policy objectives of better efficiency, quality, value, and information sharing and adapt Stark to the current healthcare environment. Expand CMS authority to issue exceptions to ensure that exceptions protect innovative, effective alternative payment models.	Aligns CMS authority to create Stark exceptions with OIG authority to create AKS safe harbors; ensures consistency across fraud and abuse framework. Enables CMS and OIG to create workable exceptions but does not require them to do so.
		Direct HHS OIG to create safe harbors that are consistent with shared policy objectives of better efficiency, quality, value, and information sharing and adapt the AKS to the current healthcare environment.	

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Recent Hill and Agency Activity

- CMS Gainsharing Report to Congress (2015)
- Amendments to Stark regulations (Nov ‘15)
- Stark Roundtable (Senate Finance/House W&M, Dec ‘15); White Paper (Jun ‘16)
- Senate Finance Committee hearing on Stark (Jul ‘16); House W&M (Jul ‘18)
- OIG issues new Anti-Kickback Statute safe harbors (Dec ‘16)
- HHS Health Care Industry Cybersecurity Task Force recommendations (Jun ‘17)
- OIG Solicitation (Jan ’18, Jan ‘20)
- Changes to fraud and abuse laws via Bipartisan Budget Act (Feb ‘18)
- CMS Request for Information (RFI) on Stark (Jul ‘18)
- OIG RFI on Anti-Kickback (Sep ‘18)
- PAVE Act (‘19)
- Physician fee schedule changes to Stark Law (2015-2019)
- OIG Advisory Opinions (2014-2019)
- Various legislative proposals (2014-present)
- **OIG and CMS NPRMS (Oct ‘19)**

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Legislative Proposals: Themes

What they address:

- Need for an AKS safe harbor and Stark exception related to alternative payment models
- Scope varies:
  - MACRA-specific provisions
  - Broad, general language around "value"
- Varying definitions of VBP
  - Specific activities
  - Specific requirements for risk allocation, stakeholder types
  - Broad definition
- Range of stakeholders and activities protected

What they do not address:

- Civil Monetary Penalties Law
- Liability threshold
  - Strict liability in Stark
    - Boot-strapping FCA to Stark
  - One-purpose rule in AKS
- Other key definitions that are unclear in a VBP setting
- Expanding or enhancing CMS/OIG authority to draft exceptions and safe harbors
- Concerns unique to other stakeholders
- EHR exception/safe harbor extension or expansion

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Regulatory Proposals: Oct. 2019

- CMS and OIG released simultaneously
  - Not identical NPRMs
- Create tiered system for value-based arrangement (VBA) safe harbors/exceptions
  - Full financial risk
  - Substantial downside financial risk
  - No downside risk (i.e., care coordination arrangements) (AKS)
  - "Other value-based arrangements" (Stark)
- Definitions:
  - Value-based purpose
  - Target patient population
  - Value-based enterprise
    - Ineligible participants
      - Pharmaceutical manufacturers, DMPEOS companies, laboratories (AKS)
      - MAYBE pharmacies and PBMs (AKS)
      - MAYBE all of the above (Stark)

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Regulatory Proposals: Oct. 2019 (cont'd)

- Additional AKS Safe Harbors:
  - Patient engagement and support
    - In-kind benefits ($500 aggregate/patient annually)
  - CMS-sponsored programs
    - CMS models, ACO beneficiary incentive payments
- Stark "exceptions" clarified:
  - Indirect compensation arrangements
  - CMS-sponsored models
- EHR safe harbor and exception expanded (cybersecurity) and sunset removed
- Other Changes
- Comments received: 984

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2019 NPRMS

What they address:

- Need for safe harbors and exceptions addressing value-based care and payment
- Model variation based on risk allocation
  - Tiered structure
- Need for safe harbors and exceptions addressing CMS waivers and other programs
- Technical fixes for Stark (e.g., signature requirements)
- Clarifying some definitions for Stark
- EHR Safe Harbor/Exception

What they do not address:

- Legislative tasks:
  - AKS Liability (one-purpose rule)
  - FCA bootstrapping to Stark/strict liability
- CMS/OIG authority
- Other key definitions unclear in a VBA framework (Stark and AKS)
- Reducing complexity, decreasing risk for stakeholders
- Other EHR-related concerns

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Complying with the Framework

- Assess existing and potential collaborative arrangements in light of 2019 NPRMs
- Know your compliance officer and reach out with questions, problems, and concerns
- Take action where appropriate!
- Consider connecting with counsel if you are developing new arrangements or are concerned with an existing arrangement
  - Self-disclosure protocols
  - Advisory opinion process
- Expert valuation, waivers
- Assess degree of comfort with risk

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What's Next?

- Communicate with providers and/or other healthcare partners
- Engage with other stakeholders (to extent you collaborate already)
  - Particularly to advocate for industry stakeholders
- Look for movement in legislation and agency-level materials
  - Relevant committees and agencies
  - Rule-making posture
- Opportunities to engage:
  - Submit comments
  - Participate as witness
  - Advocate, educate
- **Consider providing specific examples**

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Selected Resources

- Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models
- Why Stark, Why Now? Senate Finance Committee White Paper
- Medicare Advantage and the False Claims Act Paper
- OIG Compliance Toolkit (Advisory Opinions, Guidance, Self-Disclosure)
- CMS Compliance Toolkit
- Brookings Institution Seminar on Stark and Anti-Kickback Reform (Jan 2019)
- OIG RFI and CMS RFI; OIG NPRM and CMS NPRM

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