

**Fraud and Abuse Regulation, Compliance, and Value Based Purchasing**

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## Agenda

- Fraud and Abuse Laws: An Overview
- Stark and Kickback in a Value-Based Environment
  - Key Areas of Misalignment
  - Potential Modifications
- Environmental Scan: Themes and Trends in Proposals for Modifying the Fraud and Abuse Framework
- Complying with the Current Framework
- What Comes Next?
- Resource List
- Q & A

# 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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## Georgia hospital enters \$5M settlement with feds to resolve false claims case

Ayla Ellison (Twitter | Google+) - Friday, February 8th, 2019 Print | Email

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Union General Hospital in Blairsville, Ga., agreed to pay \$5 million to resolve allegations that it violated the False Claims Act and Stark Law, according to the Department of Justice.

The U.S. Attorney's Office for the Northern District of Georgia launched a civil healthcare fraud investigation into Union General Hospital in 2016 after receiving information regarding criminal misconduct regarding controlled substances.

FOR IMMEDIATE RELEASE

### Electronic Health Records Vendor Settles with DOJ

Greenway Health LLC (Greenway), a Tampa, Fla. company, has agreed to pay \$57.25 million to resolve allegations in a compliance investigation that Greenway caused its users to submit false claims for Medicare services and providing unlawful remuneration to physicians, the Justice Department announced today.

## Orlando nursing center, surgeon pay \$1.5 million to settle lawsuit

Lawsuit filed by former employee alleged fraudulent Medicare practices

By Larissa Hamblin - Digital Intern  
Posted: 12:11 PM, January 29, 2019

## Memphis home dialysis clinic to pay \$3M in anti-kickback settlement

By Kate Crawford

FOR IMMEDIATE RELEASE

## Pathology Laboratory Agrees to Pay \$63.5 Million for Providing Illegal Inducements to Referring Physicians

Pathology laboratory company Inform Diagnostics has agreed to pay \$63.5 million to settle allegations that it violated the False Claims Act by engaging in improper financial relationships with referring physicians, the Justice Department announced today. Inform Diagnostics, formerly known as Miraca Life Sciences Inc., is headquartered in Irving, Texas, and

## Kalispell Regional Settles Whistleblower Suit for \$24M

Unsealed terms reveal scope of government investigation alleging 63 physicians received illegal kickbacks

BY TRISTAN SCOTT // SEP 28, 2018



**Government Recovered \$2.6B from Healthcare Fraud in 2017**

Wednesday, January 30, 2019

## Satellite Healthcare agrees to pay \$3.2 million to settle anti-kickback charges

January 31, 2019

Published: January 29, 2019 8:57 PM CT

## 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 in return for:
  - Referring 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: \$100,000 fine, up to 10 years incarceration, mandatory exclusion
  - Civil: FCA liability, CMPs, exclusion, treble (3x) damages

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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 federal health care program beneficiary for “designated health services” to providers in which the physician (or his/her family) has a financial interest.
- Regulatory exceptions (42 CFR § § 411.350-389) and statutory exceptions
- Penalties:
  - Overpayment/refund obligation
  - FCA liability
  - CMPs, exclusion for knowing violations

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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)
  - Treble (3x) damages
  - Exclusion

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## Civil False Claims Act

- Designed to prevent unwarranted government expenditures
- 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;
  - Knowingly and improperly 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
- Penalties:
  - Recoupment
  - Civil penalties: \$11,181 - \$22,363 per claim (2018 adjustment); treble (3x) damages
  - Possible others (FCA settlement, CIA, CMPs)
- Changes: Fraud Enforcement and Recovery Act (FERA), Affordable Care Act (ACA)

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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)
- Transition to a value-based system encourages:
  - Greater integration among providers and settings
  - Coordination across providers, settings, and other industry stakeholders – care delivery and payment
  - Incentivizing value-driven care
- Still need to protect against fraud and abuse

## Key Issues

- 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” and “alternative payment model”
- Consider: Medicare Shared Savings Program waivers

## Examples

- Hospital A wants to uniformly reward non-employed physicians who follow established care pathways and meet quality metrics (ex: reduce hospital acquired infections (HAIs))
- Hospital B wants to offer supportive services at no charge to patients who have received devastating news or a complex diagnosis

## Examples, con't

- Part D payer wants to enter into a value-based contract with the pharmaceutical manufacturer under which payment would be directly linked to proof that use of the prescribed medication contributed to avoided illness (ex: reductions in emergency room visits or inpatient hospitalizations). Manufacturer will pay for a part of the cost of the data collection necessary to provide the proof required under the contract.
- Hospital and Physician Group form an ACO through the MSSP. Hospital wishes to extend its collaborative efforts with Physician Group and proposes to create an ACO for patients > age 65 with 2+ chronic diseases. This ACO would function identically to the existing arrangement under the MSSP, where any savings realized through care coordination and management of the specified population would be shared between Hospital and Physician Group.

## Potential Modifications

Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Shared payments; incentive payments	Value-based payments encourage outcomes-based care as opposed to FFS payments that solely incentivize volume (physicians) or diagnosis-related group (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.	Create Stark exception and AKS safe harbor that effectively extend waivers to any activities or initiatives that involve integration of care, items, services, and payment across stakeholders that meet certain established value-based healthcare criteria and that are designed to improve patient outcomes and reduce the overall cost of providing care, regardless of whether those stakeholders participate in a Medicare-sponsored project	Stark still prohibits compensation arrangements where remuneration is based on volume or value and AKS still prohibits inappropriate inducement of health care business. Waivers issued only for approved activities or initiatives. Any arrangement that does not meet specified criteria will not be approved and will fall outside the scope of a waiver.

Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Shared infrastructure; team-based care	Provider timetables and resource availability for electronic health record (EHR) technology acquisition differ widely; extending exception is warranted to ensure robust and widespread EHR implementation. Technological advancements not contemplated when exception originally created necessitate additional flexibility in defining covered technology.	Create Stark exception and AKS safe harbor expanding and making permanent the existing (temporary) regulatory exception for donation and support of EHR software, related technologies, and training. Expand exception to include technology related to information sharing and cyber-security 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.

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.

Innovation	System Transformation Impact	Proposed Changes	Remaining Protections & Other Considerations
Directs 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 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.

## Recent Environmental Scan

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

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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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## Complying with the Framework

- Know your compliance officer and reach out with questions, problems, and concerns
- Take action where appropriate!
- Consider connecting with counsel (in-house or outside) if you think you have a problem
  - Self-disclosure protocols
- Expert valuation, waivers
- Assess degree of comfort with risk

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## What's Next?

- Communicate with your providers and/or other healthcare partners
- Engage with other stakeholders (to extent you collaborate already)
- Keep an eye out for movement in legislation and agency-level materials
  - Committees and agencies
- Legislative environment
  - Submit comments
  - Participate as witness
  - MUCH room to 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](#)
- [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](#)

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## Questions?

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