

HEALTH CARE REFORM: Stark and Anti-Kickback Laws in a New Key?

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AHLA Fraud and Compliance Forum
October 6, 2009

Presentation Roadmap

- **Introduction: The Big Picture**
 - Bills on the Hill
 - Changing landscape
 - Two-minute primer on Stark/AKS/CMP
- **Health reform elements that could intersect with Stark/AKS/CMP**
 - Directly: proposed changes to Stark/AKS
 - Indirectly: payment and delivery reforms
- **Implications for industry and government**
 - Compliance
 - Regulation and enforcement



The elephant in the room: Healthcare delivery and payment—and the nature of fraud and abuse—may change fundamentally

Questions to Think About

1. How will new financial relationships and delivery models work under existing law?
2. Will changes to law, regulation, or policy be needed to foster reforms? If so, what should those changes look like?
3. What new issues need to be addressed?
4. What types of fraud and abuse might we see and how should those risks be addressed?

It's not too early to begin thinking this through...

Three Primary Bills

- **Senate Finance Committee** Amended Chairman's Mark ("CM")
(<http://finance.senate.gov/sitepages/legislation.htm>)
- **S. 1679**: Senate Committee on Health, Education, Labor, & Pensions ("HELP")
(<http://help.senate.gov/>)
- **H.R. 3200**: House Energy & Commerce, Ways & Means, Education & Labor Committees
(http://energycommerce.house.gov/Press_111/20090714/aahca.pdf)

General Caveats

- We possess no crystal balls
- Health care reform may happen by legislation, regulation, public policy, and/or evolving private sector practices
- Many important provisions are outside the scope of today's presentation – we are focusing on a specific band of the pending legislation dealing with Stark, AKS and CMP

Vicki's Important Caveat

- The OIG does not take positions for or against particular legislation, and I will not be doing so today.

Objectives of Health Care Reform

- Expand Access to Care/Coverage
- Reduce Cost
- Improve Quality of Care

A Changing Landscape

- Providers would relate to each other and to government in new ways
 - Rewarding value instead of volume
 - Value-based purchasing, gainsharing, bundled payments
 - Coordinating care among and across providers
 - New structures and integration
 - Sunshine and transparency
 - Comparative effectiveness, public disclosures, data-driven approaches
 - Innovation through variation and experimentation
- Stark/AKS were not originally set up to promote these outcomes


Two-Minute Legal Primer

- **The “Stark” Law** (Sec. 1877 of SSA)
- **The Anti-Kickback Statute (“AKS”)** (Sec. 1128B(b) of SSA)
- **CMP prohibiting payments to reduce or limit hospital services (“CMP”)** (Sec. 1128A(b)(1)-(2) of the SSA)

Genesis of Stark/AKS/CMP

- Current laws largely address:
 - FFS system where overutilization is a key concern
 - PPS/episodic reimbursement where underutilization is a key concern
- Preserve integrity of medical decision making by removing financial temptation

A Shifting Focus

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- Integration and shared financial incentives
 - Sound familiar? Back to 1990s...
 - PPOs, PHOs, HMOs: withholds and risk sharing
 - Delivery system integration with insurers
 - Physician incentive payments (RIPs)
 - System employment of physicians

What's Different Now – Hopefully

- Data on payment, quality, and outcomes
 - Electronic health information; claims data
- Systems to collect and use data
- Real time tracking?
 - Avoiding “incurred but not reported” expenses
- Potential for a national, comprehensive policy approach

Big Picture Takeaways

- Possibility for fundamental restructuring of payment and delivery models
- Enhanced focus on quality, efficiency, shared financial risks and rewards
- Fraud and abuse lawyers and government enforcers will face new challenges
- Many changes are likely with or without legislation

Direct Legislative Arrangements: *Proposed Stark Changes*

- **Limitation on Physician Ownership of Hospitals**
 - CM p.208; HR3200 § 1156 (with differences)
- **Stark Self-Disclosure Protocol**
 - CM p.226; H.R. 3556 (McDermott)
- **Imaging Self-Referral Sunshine**
 - CM p.218 (amends IOAS exception)
- **Reporting Requirements (DFRR and more!)**
 - HR3200 § § 1451, 1156
- **New Electronic Health Records (EHR) Exception**
 - HELP § § 232-233

Limitation on Physician Ownership of Hospitals

- **CM p.208**
 - All hospitals, not just specialty hospitals
 - Must have a provider agreement as of 11/1/2009
 - New criteria
 - No growth (with limited exceptions)
 - No conflicts of interest
 - Disclosure/transparency/patient safety requirements
 - Bona fide investment requirements (similar to AKS safe harbor)
- **HR 3200 § 1156** (amends whole hospital and rural provider exceptions)
 - Provider agreement as of 1/1/2009
 - Other differences

Stark Self-Disclosure Protocol

- **CM p.226**
 - CMS to establish a protocol within 180 days
 - Similar to OIG SDP
 - For Stark violations (+ AKS less than \$50,000)
 - “Incentives” to participate
 - Settlement “spectrum” problem
- **HR 3556 (McDermott bill)**
 - Secretary authorized to “reduce the amount due and owing for all violations under [Stark law] to an amount less than that specified in subsection (g)”
 - Factors include: nature and extent of illegal practice, timeliness of self-disclosure, cooperation
 - Allows full book for enforcement, and compromise for self-disclosure

Imaging Self-Referral Sunshine



- **CM p.218**
 - Amends the in-office ancillary services exception (1877(b)(2))
 - Physicians must:
 - inform a patient at the time of an in-office ancillary referral that the patient can obtain the services elsewhere
 - Provide a list of alternative local suppliers

Reporting Requirements (DFRR and more!)

- **HR 3200 § 1451 (physician sunshine provisions)**
 - Hospitals & other A/B billers (excl. managed care orgs) must report direct, indirect physician/family ownership
 - Publicly available
 - DFRR (per §5006 of DRA): Secretary must report full results within 6 months of collection of surveys
 - When will the DFRR come out of OMB?
- **HR 3200 § 1156**
 - Amends 1877(f) reporting requirements (would largely codify existing regulations)
 - Hospitals must report physician ownership interests, and referring physician owners must disclose to patients
 - Public disclosure
 - Expanded CMPs for failing to report/disclose

New EHR Exception

- **HELP §§ 232-233**
 - Covered HIT includes hardware, software, license, right, IP, equipment, upgrades, connectivity
 - Designed or provided primarily for exchange of health information or to better coordinate care or improve quality, efficiency, or research
 - Non-monetary remuneration (including support services) made by a “specified entity” if:
 - Use of HIT not limited to individuals receiving services at the entity
 - Technology can be used in conjunction with other technology
 - No referral conditions
 - No disabling of interoperability
 - “Rule of construction”: nothing prevents entity from forming consortia to offer/purchase/donate HIT

Direct Legislative Arrangements: *Proposed AKS Changes*

- **Definition of “willfully”**
 - CM p.226
 - Addresses Hanlester
 - “...acted voluntarily and purposefully to do what the law forbids and the person need not have actual knowledge of the law or specific intent to violate the law”
- **New EHR safe harbor**
 - HELP § § 231 and 233
 - Similar to Stark proposal (above)
 - Also, an exception to the CMP for reducing/limiting hospital services
 - Inducements to reduce or limit services “shall not include the practical or other advantages resulting from health information technology”

Direct Legislative Arrangements: *Two Related Proposals*

- **Mandatory repayment of overpayments**
 - CM p.226
 - 60 days after date overpayment made or cost report due
 - Repay overpayments identified through internal audit
 - HR 3200 § 1641
 - 60 days after knowing of the overpayment (“knowing” imports FCA standard)
 - “any finally determined funds that person receives or retains under [Medicare/Medicaid/CHIP] to which the person, after applicable reconciliation, is not entitled”
- **Aligning CMPL with FCA amendments**
 - HR 3200 § 1645
 - Parallel universe under OIG CMPs
 - Reverse false claims
 - Conspiracy CMP

Indirect Legislative Arrangements

Payment and Quality Reforms

- **Payment and Provider Integration**
 - Accountable Care Organizations (ACOs)
 - Bundled Payments
 - Medical Homes
- **Pay for Performance/Shared Savings**
 - Value Based Purchasing
 - Gainsharing
- **Innovation**
- **Sunshine, Transparency, and Integrity**
 - Payment sunshine
 - Mandatory compliance programs

Payment and Provider Integration:

Accountable Care Organizations

- **CM p.110; HR 3200 §1301, § 224** (in the public option)
- **Groups of providers/suppliers** accountable for the overall care of group of Medicare beneficiaries
 - Reduce growth of expenditures, improve health outcomes
 - Encourage infrastructure investment and redesigned care processes
- **Various combinations of:** group practices, practice networks, partnerships or joint ventures with hospitals, hospitals employing physicians, others

Payment and Provider Integration:
Accountable Care Organizations

- Payment contingent on clinical outcomes and processes, patient satisfaction, utilization and costs
 - Performance payments
 - Partial capitation (HR 3200)
- HR3200 permits the Secretary to waive Stark/AKS/CMP “in order to implement the pilot”

Payment and Provider Integration
Bundled Payments

- **Medicaid Bundled Payment Demo and Global Payment Demo**
 - CM p.75 – acute and post-acute care (PAC) bundles
- **National Medicare Pilot Program on Payment Bundling** (CM p. 117)
 - Bundling across continuum for episode of care
 - Bundled payments or FFS with withholds/incentives
- **HR 3200 §1152**
 - Sec’y to develop plan to reform PAC services pmt, including PAC bundle, possible integration w/IPPS pmt
 - Sec’y is to consider nature of relationships required between hospitals and physicians, application of gainsharing, Stark, anti-kickback, & anti-trust laws
 - Conversion of acute care episode (ACE) demo to pilot and expansion to include PAC services

Payment and Provider Integration

Medical Homes

- **HR 3200 § 1302** – Medicare medical homes pilot
 - Reimburse qualified patient-centered medical homes for services to high need beneficiaries
 - Direct and ongoing access to primary care
 - Coordinated care by a team across settings
 - Provide for all health needs
 - Risk adjusted payments
 - Evidence based guidelines
 - Independent and community based models
 - per month/per beneficiary payments
- **Medicaid health homes** (CM p.92)

Pay for Performance/Shared Savings Programs

- **Hospital Value Based Purchasing**
 - CM p. 96
 - Move from pay for reporting to P4P
 - Reduce IPPS payments to fund incentive pool (no additional funds, so winners and losers)
- **Physician Value Based Purchasing**
 - CM p.100
 - Payments to reflect use of evidence based practices
 - Bonus/penalty payments based on use of resources
 - Measurements/feedback to docs to influence behavior
 - Winners and losers



Elephant in the room: Value based purchasing reallocates existing dollars between providers, but does not include any fresh dollars

Pay for Performance/Shared Savings Programs

- **Extension of Gainsharing Demo** under Sec. 5007
 - CM p. 124
 - HR 3200 § 1903
- **Home Based Chronic Care Management Program Pilot**
 - CM p. 124
 - Shared savings among interdisciplinary team caring for patients with chronic conditions
 - Non-hospital gainsharing

Innovation



- CMS Innovation Center
 - CM p.113
 - Test and evaluate patient centered delivery and payment models, including new compensation systems, medical homes, integrated models
 - Increase quality, reduce costs
- Ross Amendment to HR 3200 (passed): section 1906 would create “Center for Medicare and Medicaid Payment Innovation”

Sunshine, Transparency, and Integrity

- **Physician Payments Sunshine**
 - **CM p.210**
 - Drug and device manufacturers report:
 - Payments to docs, including ownership interests
 - Payments to hospitals with residency programs
 - Exceptions:
 - Payments less than \$10/\$100 aggregate
 - Samples for patient use
 - Patient educational material
 - Discounts and rebates
 - Items used for charity care
 - Public posting
 - CMPs for failure to report

Sunshine, Transparency, and Integrity

- Physician Payments Sunshine (con't)
 - **HR 3200 § 1451**
 - Includes manufacturers and distributors
 - Covered recipients include physicians, groups, prescribers, pharmacies, insurers, PBMs, hospitals, medical schools, CME sponsors, patient advocacy groups, health care professional organizations, biomedical researchers, GPOs
 - Exceptions include, among others:
 - \$5 payments
 - Covered devices on short-term loan to permit evaluation of the covered device
 - Discounts and cash rebates

Sunshine, Transparency, and Integrity

- Mandatory Compliance Programs
 - **HR 3200 § 1635**
 - Condition of participation
 - Core elements track OIG guidance
 - Must have procedures to return identified overpayments
 - **CM p.225** (less detail)
 - **Nursing homes transparency provisions** also require compliance programs (CM p.212; HR 3200 § 1412)

Now What? Fraud and Abuse Laws after Healthcare Reform

- Tensions between reform delivery and payment systems and fraud and abuse laws
 - Anti-Kickback Law
 - Stark Law
 - CMPs

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Fraud & Abuse Laws after HC Reform

- Regulatory and Enforcement Policy
 - Medical decisions should be based upon clinical considerations and patient's best interest
 - Prevent or limit influence of financial considerations on medical decision process
- Anti-temptation laws: no financial temptation to refer or stint

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Fraud & Abuse Laws after HC Reform

Practical Outcome of Current Laws: “All or Nothing” Integration Approach

- Complete Integration
 - Integrated hc system
 - Employment
 - AMCs
 - Single “entity”
- Silos
 - Separate physician practices
 - Separate hospitals and facility providers
 - Reliance on contracts, joint ventures

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Fraud & Abuse Laws after HC Reform

Examples of “All or Nothing” Approach

- Stark: broad rule—*any* financial relationship triggers ban on referrals, unless meets an exception
 - Hospital /facility and physician silos unless:
 - Employment (411.357(c))
 - AMC 411.355(e))
 - Whole hospital (will it survive reform?) or rural provider (411.411.356(c))
 - Group practice ancillaries (411/355(b))
 - Services by organization to enrollees (Medicare HMOs, prepaid plans)(411.355(c))
 - Risk sharing arrangements (411.357(n))

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Fraud & Abuse Laws after HC Reform

Examples of “All or Nothing” Approach

Stark Law, con’t

- Exceptions for personal services, fmv arrangement, indirect relationships can hinder payments reflecting quality outcomes, resource use
 - No reflecting volume or value of referrals or other business generated
 - Compensation set in advance
 - What is fmv in this context?
 - What is commercially reasonable (fmv and indirect exceptions)
 - No involving activity that violates federal law—CMP issue?

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Fraud & Abuse Laws after HC Reform

Examples of “All or Nothing” Approach

- Anti-Kickback Law: prohibits giving or receiving remuneration intended to induce referral or ordering of service
 - Safe harbors, guidance reflect different incentives under capitated and risk-based systems
 - But personal service arrangement safe harbors, guidance hinge on limiting compensation relating to volume or value of referrals
 - *Greber* and related case law: if one purposes is to induce referral...

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Fraud & Abuse Laws after HC Reform

Examples of “All or Nothing” Approach

- CMPs
 - Measure to prevent stinting under DRG system
 - No exception for hospital payment to limit unnecessary care
 - Cleaner enforcement application
 - Flexibility limited in reflecting resource conservation, best practices concepts under hc reform

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Elephant in the room:
Laws that allow delivery system flexibility and innovation
allow for less enforcement certainty and bright lines

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Fraud & Abuse Laws after HC Reform

- New integration and payment models under HC reform: ACOs, bundled payments, P4P and shared savings
 - Will implicate AKS, Stark, CMP
- Where is the potential fraud and abuse:
 - Overutilization
 - Underutilization
 - Swapping
 - Avoiding sicker patients
 - Gaming outcomes and data

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Fraud & Abuse Laws after HC Reform

Areas Where F&A Laws Already Accommodate Integration, Performance Based Systems

- Managed care
 - Capitated and risk based payment systems
 - AKS and Stark recognize different economic incentives
 - But difficult to manage across a field of diverse payment arrangements for patients with similar conditions or needs

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Fraud & Abuse Laws after HC Reform

Areas of Some Accommodation

- Gainsharing/Shared Savings
 - Hospitals or entity sharing savings with physicians
 - Advisory opinions on gainsharing
 - OIG discretion on case by case basis
 - Approval of programs with substantial structure, quality controls, accountability, safeguards
 - But the path is much less clear under Stark...
 - No specific exception
 - Personal service, fmv, indirect compensation: volume and value limitation; fmv; commercial reasonableness, no promoting violation of federal law
 - The price of guessing wrong: potential Stark penalties

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Fraud & Abuse Laws after HC Reform

- P4P
 - AKS: Advisory Opinion 08-16
 - P4P bonuses from hospital to physicians under private insurer quality and efficiency program
 - Approved:
 - Quality measures, accountability, safeguards
 - Issues:
 - Stark: no express exception for P4P; reliance on other exceptions with an imperfect fit

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Fraud & Abuse Laws after HC Reform

New Areas for Accommodation & Change

- Accountable Health Organizations
 - Employment, AMC and some integrated health systems
 - PPO-style models may require change
 - Stark: Personal services, fmv arrangement and indirect compensation concerns under current rules
 - Possible application of prepaid plan exception or risk-sharing exception
 - AKS: more flexibility
 - Intent based statute; enforcement discretion
 - Advisory opinions and guidance process well developed
 - CMP: Hospital payment only—PPO model may work, but limits on hospital action

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Fraud & Abuse Laws after HC Reform

New Areas for Accommodation & Change

- Bundled Payment Arrangements
 - Focus on episode of care or specific condition (chronic disease management)
 - Multiple types of providers, multiple combinations contemplated
 - Multiple payor sources and types?

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Fraud & Abuse Laws after HC Reform

New Areas for Accommodation & Change

- Bundled Payment Arrangements
 - Single entity approach works: employment, AMC
 - PPO and IHS captive group models issues
 - Similar issues of fit with Stark exceptions, application of AKS and CMP

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Elephant in the room:

ACOs and bundled payments may take a lot of forms and shapes. Fraud & abuse rules will need to accommodate complex and varied of arrangements—and that may be hard

Future Shock: New Systems, New Fraud and Abuse Laws?

- Are the same fraud and abuse laws needed in a healthcare reform world—or different laws?
- Can delivery model be structured to reduce need for referral prohibitions?
 - Payment reform: drive out excess profits that prompt some kickback schemes
 - Payment based on patient need and outcomes
 - Data driven measurement of medical necessity
 - Quality measures
 - Efficient use of resources
- ***Perhaps, but until then...***

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And now some thoughts on meshing fraud and abuse laws with healthcare reform initiatives

Solely from the private bar, completely without government endorsement or agreement

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Future Shock: New Systems, New Fraud and Abuse Laws

- “A Public Policy Discussion: Taking the Measure of the Stark Law”
 - AHLA Public Interest Committee
 - <http://www.healthlawyers.org/Resources/PI/Policy/Pages/StarkConvener.aspx>
- Impact of Stark Law
 - Impact on self referral
 - Unintended consequences
 - Enforcement issues

Private bar perspective; not endorsed or supported by HHS or any government agency

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Future Shock: New Systems, New Fraud and Abuse Laws

- Stark Laws
 - Changes to address new healthcare delivery and payment systems
 - Self disclosure, with CMS discretion on penalties
 - Overall enforcement discretion
 - Broaden rulemaking authority
 - Broader exceptions
 - Managed care exception
 - New exceptions for ACOs, bundled payments, P4P and Shared Savings
 - Simple works better

Private bar perspective; not endorsed or supported by HHS or any government agency

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Future Shock: New Systems, New Fraud and Abuse Laws

- Anti-Kickback Laws
 - Formal guidance
 - Advisory opinions
 - New safe harbors
- CMPs
 - Incorporation of medical necessity concept
 - Need to broaden to address scope of organizations with bundled payment, risk sharing incentives?

Private bar perspective; not endorsed or supported by HHS or any government agency

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It's not just about healthcare reform...

- Even in the absence of comprehensive healthcare reform, there will new payment and delivery models....and regulation of them

The Current Enforcement Landscape

- **HEAT Initiative**
- **Data mining**
- **Quality of care**
- **Partnerships in enforcement**

The Goldilocks Conundrum

- As a purchaser of health care services, encourage incentives to-
 - Reduce cost
 - Improve quality
 - Promote innovation
- As enforcer of current law, concern that incentives lead to-
 - Distortion of medical decision making
 - Stinting on necessary care
 - Anti-competitive practices
- Like Goldilocks, we need to strike a balance “that is just right”



**May all your elephants have the good sense to leave
the room quietly and peacefully...**