Integrated Delivery System Reforms
Jay Christiansen
Topics

• Accountable health care
  – Rollout of payment reforms and demonstration projects from 2010 to 2015
  – Implications for physicians and hospitals
  – Regulatory impediments

• Physician ownership of hospitals
Accountable Care Organizations

What Is an ACO?

• Accountable care system = an entity capable of implementing organized processes for improving quality which is accountable for quality and costs (Shortell and Casalino, 2008)\(^1\)

• Accountable care organization = providers established in a formal legal structure capable of receiving shared savings, including a sufficient number of primary care physicians to serve as the predominant ambulatory care providers for a significant pool of covered lives (Fisher, et al., 2009)\(^2\)

• Accountable care organization = a group of physicians and hospitals that assume responsibility for annual Medicare spending for a defined patient population (MedPAC, 2008)\(^3\)
Accountable Care Organizations

• What is an ACO?
  – Accountable Care Organization = groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to in this section as an “ACO”) (Section 3022 of the Patient Protection and Affordable Care Act)
Accountable Care Organizations

- **ACOs: key attributes**
  - Coordination of patient care
  - Communication linkages between providers and across different sites of service (inpatient and ambulatory)
  - Provider-driven governance and decision-making (including physicians)
  - Receipt and disbursement of reimbursement from bundled, episodic or other non FFS methodology
  - Remain accountable (i.e., be at economic risk) for costs of care and patient outcomes
    - Differentiating between performance risk vs. insurance risk
Accountable Care

- 2010
  - Patient Centered Outcomes Research Institute is created as a nonprofit entity
    - Will compare the clinical effectiveness of various medical treatments
    - Overseen by board of public and private sector representatives
    - Likely to influence public and private sector policies
    - Anticipate support for clinical integration/coordination
    - Also will establish committee to develop and improve the science of comparative effectiveness research
  - Community transformation grants
    - Grant program for 5 years to strengthen prevention activities to reduce chronic disease and health care disparities
    - Grants to government entities, state or local nonprofit entities and tribes
Accountable Care

2010

- Extension of gainsharing demonstration projects
  - Demonstration project extended until 2014
  - Demonstrate benefits of physician/hospital collaboration
- Medicaid global payment demonstration project
  - Operate from 2010 to 2012 in 5 states
  - For participants, payment on global capitation basis rather than fee-for-service
Accountable Care

2011

National strategy for health improvement

- By 1-1-11, Secretary of HHS to establish national strategy to improve the delivery of health care services, patient outcomes and population health
- Identify priorities that
  - Have greatest potential to improve outcomes, efficiency and “patient-centeredness”
  - Have the greatest potential for rapid improvement in quality and efficiency
  - Address gaps in quality, efficiency, effectiveness and outcomes
  - Improve payment policies to emphasize quality and efficiency
  - Enhance the use of data
  - Address cost of care of high cost chronic conditions
  - Improve research and disseminate best practices to improve safety, reduce medical errors, preventable readmissions and acquired infections
- Seek to align federal and private payors
Accountable Care

• 2011
  – Center for Medicare and Medicaid Innovation
    • To test payment and delivery models, including:
      – Payment reform in primary care, including medical homes
      – Comprehensive risk-based compensation
      – Promote care coordination away from FFS reimbursement
      – Community-based health teams
      – Allow states to test all-payer reform
      – Improve post-acute care
      – Collaboration of high quality and low cost institutions to disseminate best practices
      – Comprehensive payments to Healthcare Innovation Zones—groups of providers including a teaching hospital
    • $10 billion in funding from 2011-2019
Accountable Care

• 2011
  – Secretary to submit report on value based purchasing for SNFs and Home Health
  – Community-based collaborative care networks
    • Secretary may award grants to support
    • Defined as consortium of providers with a joint governance structure that provides comprehensive coordinated care and integrated care for low income populations
Accountable Care

• 2012
  – Medicare shared savings program
    • Allows providers organized as ACOs to voluntarily meet quality thresholds and share in Medicare’s cost savings
    • ACO must
      – agree to be accountable for overall care of designated beneficiaries
      – Have adequate participation of primary care providers
      – Define process to promote evidence-based medicine
      – Report on cost and quality
    • Groups of providers can be an ACO if shared governance:
      – Can be a group practice
      – Can be network of professionals
      – Joint ventures
      – Integrated health systems
Accountable Care

• 2012
  – ACO’s must:
    • Be accountable for quality, cost and overall care
    • Three year agreement
    • Formal legal structure to receive and disburse funds
    • Have sufficient primary care
    • Have sufficient other ACO professionals
    • Have clinical and administrative systems
    • Define processes to promote evidence-based medicine and report
    • Meet patient-centeredness criteria specified by the secretary
Accountable Care

• 2012
  – Hospital value-based purchasing
    • Incentive payments in connection with discharges from hospitals that meet quality standards
    • Efficiency standards added in 2014
    • Funded by reduction in inpatient payments to all hospitals (but all returned to qualifying hospitals)
    • Public information on performance
  – Hospital readmission reduction program
    • Provides for payment reductions for hospitals with an “excess readmissions ratio”
Accountable Care

• 2012
  – Independence at home demonstration project
    • High need Medicare beneficiaries to get primary care services at home
    • Participating providers to share in savings from preventable admissions or readmissions, improved outcomes, improved efficiencies, reduction in cost and patient satisfaction
  – Pediatric accountable care organization demonstration project
    • For 2012-2016 allows pediatric providers to organize as ACO similar to general care ACO's
  – Demonstration to evaluate integrated care for hospitalization
    • Participating states may pay bundled payments for episodes of care for Medicaid patients
Accountable Care

• 2013
  – Pilot program on payment bundling
    • For 5 years, program to develop and evaluate bundled payments for inpatient hospital services, physician services and post-acute services for episodes of care
    • For period beginning 3 days before admission and extending 30 days post-discharge
    • One or more of 8 conditions selected by the Secretary

• 2014
  – Quality reporting for long-term care hospitals, inpatient rehab hospitals and hospice
    • Establishes process to submit quality data
    • Payment reductions for failure to submit data
Accountable Care

- 2015
  - Payment adjustment for hospital acquired conditions
    - 1% reduction in payment if in bottom quartile of hospitals with the most acquired conditions
  - Improvements to physician quality reporting system
    - In 2015, 1.5% reduction in payment if not submit quality data
    - In 2016, 2% reduction
Take-Aways

• Mistakes are bad
• Quality is good (and can reduce cost)
• Quality and cost reduction require coordination of care by hospitals, physicians and other providers
  – Pushing of physician and hospital worlds together; physician impact on hospital payment and cost structure
• Coordination of care best accomplished by alignment of incentives
Take-Aways

• Coordination of care and alignment of incentives will be required to achieve acceptable economic outcomes under:
  – Global payments
  – Capitation
  – Value-based purchasing

• Health insurers, market forces and economic necessity: key stakeholders need to bend the cost-curve
Alignment Needs and Relationship Structures

**Future Needs**
- Integrated and professionally managed organizations
  - Common language
  - Shared culture
  - Clear goals and strategies
  - Physician leadership
  - Useful data
  - Shared risk -- Aligned finances and incentives
- Aligned people
- Time and energy to develop effective organizations

**Current State?**
- Competition
- Joint ventures
- Contract arrangements
  - Gain share programs
  - PSA’s
  - “Under arrangement” models
- Employment
  - Direct hospital employment
  - Physician group subsidiary of hospital/health system
Today’s Legal Environment

- Stark: No physician referrals of DHS where financial relationship, unless an exception applies
  - Prohibition on payment
  - Exceptions: Personal services arrangement; fair market value compensation; indirect compensation arrangements; employment
    - “Shared Savings” proposed rule (July 2008)
    - Hospital-physician P4P and “gain share”

- Anti-kickback Statute: Prohibits offer or payment of “remuneration” (anything of value) to influence referrals of Federal Health Care Program patients
  - Criminal statute; intent required
  - Permissive exclusion for violations
  - Safe harbors
    - Advisory Opinion 08-16 (P4P program)
Today’s Legal Environment

- Civil Monetary Penalties Statute: Prohibits hospital or critical access hospital from knowingly making payment, directly or indirectly, to physician as an inducement to reduce or limit services to Medicare beneficiary, and prohibits physicians from accepting same
  - Fines and permissive exclusion for violations
    - Advisory Opinion 08-16 –(P4P program)
Limited Guidance

- Example: P4P
- Advisory Opinion 08-16
  - Commercial pay for performance program
  - Bonus compensation (4% of Base) for performance on quality/efficiency standards
  - Quality targets — Specifications Manual for National Hospital Quality Measures
  - Measurement of all patients — not just commercial
  - Quality enhancement professional service agreement — up to 50% of bonus
  - Per capita distribution
  - OIG discretion on CMP and Anti-kickback Statute
  - Both could be implicated, but no OIG sanctions
Limited Guidance

- Example: employment relationships
  - Waterloo and Tuomey
  - Employment and other exceptions
    - Fair market value
    - Not determined in a manner that takes into account, directly or indirectly, the volume/value of referrals by the referring physician
    - “Commercially reasonable” – if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician . . . of similar scope and specialty, even if there were no potential DHS referrals. 69 Fed. Reg., 16093 (2004)
Compliance — Today & Tomorrow

• Regulatory time lag and evolving hospital-physician relationships
  – Laws on books vs. facts on the ground
  – Advisory opinions
    • Time and cost intense, very conservative and of limited interest
• Future (post-reform) regulatory environment somewhat more forgiving
  – HHS Secretary ability to waive anti-fraud provisions for demonstration projects
• Referrals, treatment decisions and physician compensation: is paying more to do less a legitimate strategy?
  – The practical impact on productivity-based compensation systems
  – The practical effect on a hospital’s bottom-line
Antitrust

• Antitrust: the challenge of collective provider behavior
• The FTC and clinical integration
  – What clinical integration means for antitrust compliance
  – Tri-State Health Partners FTC Advisory Opinion (April, 2009)
• The overlap between clinical integration and successful ACO development: the principle that “quality drives cost”
• Important clinical integration principles
  – Managing but not rationing care
  – Evidence-based medicine as key driver minimizing unwanted variances in care
  – Provider connectivity and oversight
Tax Exemption Issues

- Increased physician role in system governance?
- Retaining sufficient control to protect exempt organization’s mission
- Charitable objectives continue to trump other concerns
- Board education a likely priority regarding ACO development and progress
- IRS Private Use Issues, Revenue Procedure 97-13
State Regulation

- Corporate practice of medicine doctrine
  - Fee-splitting considerations
- Regulation of the business of insurance
- Transparency laws
- Liability variables
- Certificate of need requirements (where applicable)
- Any willing provider statutes (where applicable)
Structural Issues

- Established integrated delivery systems
  - Can culture be transplanted?
- Virtual IDS development
  - Integration by contract
- Employed physicians and independent physicians – accommodating different community characteristics
- The role of non-physician practitioners and non-hospital facilities
- Should ACOs be nonprofit or can ACOs serve as an investment opportunity?
- How big is an ACO’s regional scope?
Structural Issues

- Board and committee structure
- Provider selectivity and retention
- Infrastructure development
  - IT
  - Data collection and reporting
  - Performance oversight
  - HR
  - Managed care contracting
- Legal and practical exclusivity issues
- Capitalization (initial and ongoing)
Practical Insights

- ACOs are not your father’s (or mother’s) physician-hospital organization
- ACOs should not replicate defensive tactics of earlier PHOs and IPAs
- Need forward-looking approach to managing patient health, while being paid to do so
- Hospitals likely to do much of the heavy lifting
Practical Insights

• Timeline relatively clear
• “Best practice” models are based on organizations with decades of history, experience and strong cultures
• Likely future challenges and conflicts
  – Balancing of business needs with regulatory compliance guidance
  – Drive to crafting relationships using “safest” relationship structure
  – Ongoing business challenges
    • Compensation structures and amounts
    • Actual or perceived operating losses
    • Financial management and reporting practices
    • Physician “governance” and decision-making
  – Importance of arrangement “optics” to compliance in time of increasing transparency
Closing Comments

• Clearly a work in progress
• How do you play the game if you don’t know the rules?
  – Watch for regulations, etc.
  – Form your team?
  – Hope for a rainout or postponement?
• Will private payors follow?
• Will regulatory impediments be removed?
Physician Owned Hospitals

• Amendment of the Stark Law
• Need an exception to Stark Law prohibition on referrals to entities in which physician has a financial interest
  – Ownership or compensation interest
• New law amends the “whole hospital” exception
• Key points
  – Doesn’t make ownership illegal; it’s the referral of government beneficiaries that it prohibited
  – Doesn’t apply to ASC’s because they are not “designated services”
Physician Owned Hospitals

- Effectively eliminates new hospitals owned by physicians
- To be grandfathered, must have Medicare provider agreement by 12-31-2010 (and then have physician ownership)
- Restrictions on increase in number of licensed beds, OR’s and procedure rooms
- Annual reports regarding physician ownership
- Notice to patients of physician ownership before admission
- No increase in percentage of physician ownership from that as of date of enactment
- Disclosure to patient and acknowledgement from patient if no doc on site
References


QUESTIONS?

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Tax-Exemption/Community Benefit and Transparency

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Agenda

- Tax exemption for hospitals/community benefit standard

- Other transparency provisions
  - Physician ownership of radiology facilities
  - Drug and device manufacturer payment reporting
  - Pharmacy benefit managers
  - Nursing home disclosure requirements
Hospital Exemption-Background

Community benefit standard (Rev. Rul. 69-545)

- ED open to all
- Community board
- Use surplus revenue for facilities improvement, patient care, and medical training, education, and research;
- Provide care for all persons in the community able to pay, including those covered by Medicare and Medicaid; and
- Open medical staff
- Note: no requirement to provide free care
“Tax-exempt hospitals don’t have many measures of accountability for their special status…. Sometimes that’s resulted in providing very little charitable patient care or other community benefits, failing to publicize charitable care to patients, charging indigent, uninsured patients more than insured patients, and using very aggressive collection practices. The Government Accountability Office and others… have said for a long time that there is often no discernible difference between the operations of taxable and tax-exempt hospitals.”

– Senator Charles Grassley
Exemption- Overview

- New requirements for hospitals to maintain tax-exempt status
- Failure to comply may result in penalty taxes or loss of exemption
- Treasury Secretary must review each hospital’s community benefit activities every three years
- Applies to organizations operating facilities licensed as hospitals or with provision of hospital care as principal function
- Tests must be met for each facility, not just each corporation
Hospital Exemption: Community Needs Assessment

• Hospital must:
  
  – Conduct a community health needs analysis at least once every three years
  
  – Get input from persons representing broad interests of community, including those with public health expertise
  
  – Adopt implementation strategy
Hospital Exemption: Financial Assistance

- Adopt a written financial assistance policies, with eligibility criteria and method to determine patient billing and collections

- Widely publicize policy within the community

- Adopt policy to provide care for emergency medical conditions without discrimination or consideration of patient eligibility for financial assistance
  - Arguably broader than EMTALA requirement to stabilize emergency medical condition
Hospital Exemption: Financial Assistance

- Use “reasonable efforts” to determine eligibility for financial assistance before initiating extraordinary collection actions.

- Limit amounts charged for emergency and medically necessary care to eligible patients to not more than the amounts generally billed to individuals with insurance and do not bill using gross charges.
  - Not yet clear what this means.
  - Different standard than under Minnesota AG agreement.
Hospital Exemption: Reports

- Hospital must describe how it is addressing the needs identified in each community health needs assessment and describe any such needs that are not being addressed along with reasons they are not being addressed.

- Hospital must make audited financial statements publicly available.

- Follows general trend of transparency with 990.
Government Reports

- Secretary of Treasury must send annual reports to Congress on:
  - Levels of charity care
  - Bad debt expenses
  - Unreimbursed costs for services provided under government programs
  - Costs for community benefit activities

- Report trends after five years
Hospital Exemption: Penalties

- Excise tax of $50,000 applies for any taxable year when requirements not met
- Excise tax effective for failures occurring after date of enactment
- Community needs assessment applies to taxable years beginning two years after date of enactment
- Remaining provisions apply to taxable years beginning after date of enactment
OTHER TRANSPARENCY PROVISIONS
Transparency

• Common theme in health reform

• Consistent with general transparency trends
  – Medicare: Nursing Home Compare, Hospital Compare
  – AdvaMed/PhRMA codes
  – IRS Form 990
  – Internet
Physician Ownership of Radiology Providers

- If physician relying on Stark exception for in office ancillary services to provide MRI, CT, PET or other designated imaging services:
  - Must inform patient at time of referral that patient may get services elsewhere, and
  - Provide names of other suppliers who furnish services in area where patient resides

- Effective for services ordered on or after January 1, 2010
Manufacturer Reporting

- Number of states, including Minnesota, require reporting of gifts or other payments to physicians

- Broad statutes enacted recently in Massachusetts and Vermont

- Physician Payments Sunshine Act pending in Congress for several years
Manufacturer Reporting-Key Terms

- **Applicable manufacturer:** manufacturer of drug, device, biological and medical supply paid for by Medicare or Medicaid

- **Covered recipient:** physician or teaching hospital
Manufacturer Reporting – Reporting Requirements

- Applicable manufacturer must report to Secretary of HHS

- Payment or transfer of value to a covered recipient or

- to an entity or individual at the request of a covered recipient
  - No dodging reporting by directing consulting fees to related foundation
Manufacturer Reporting – Reporting Requirements

- Payment reporting
- Name, address and NPI of covered recipient
- Amount, date, type of payment
- Nature of payment
  - Consulting fees, honoraria, gifts, entertainment, food, travel, research, charitable contribution, royalty, ownership interests
- Excludes samples, items under $10, educational materials, warranties, loaned devices, discounts
Manufacturer Reporting – Reporting Requirements

Ownership interest reporting

- Applicable manufacturer and applicable group purchasing organizations report to Secretary:
  - Ownership and investment interests held by physician or immediate family member
  - Dollar amount invested by physician
  - Value and terms of ownership interest
  - Does not apply to publicly traded stock
Manufacturer Reporting-Information Availability

- Secretary must create searchable Internet website

- Information regarding product research or development for new technology and drugs not reported publicly until earlier of date or approval or clearance for marketing or 4 years after date of payment
Manufacturer Reporting - Penalties

- Manufacturer/GPO that fails to report information in timely manner subject to CMP of $1,000-$10,000 per payment, up to $150,000/year

- Knowing failure to submit information carries CMPs of $10,000-$100,000 per payment, up to $1 million/year
Manufacturer Reporting – Final Notes

- Preempts state laws requiring reporting of same information

- No preemption of laws requiring additional information

- Effective date: reports must first be made March 31, 2013 for payments during 2012
Drug Sample Reporting

- Manufacturers and distributors of prescription drugs must report to Secretary:
  - Drug samples provided by mail or other means
  - Names, addresses, professional designation and signature of practitioner making request

- First report must be made by April 1, 2012
Pharmacy Benefit Manager Reporting

• Health benefits plan or PBM managing prescription drug coverage for certain plans must report to Secretary:
  – Percentage of prescriptions provided through retail v. mail order pharmacies
  – Generic dispensing rate by pharmacy type
  – Aggregate amount and type of rebates, discounts, price concessions
  – Aggregate difference between what plan pays PBM and amount PBM pays pharmacies

• Information not public

• No effective date
Nursing Home Transparency

- Nursing facilities and SNFs must disclose information concerning:
  - Owners, governing body, officers, managing persons, landlords, certain service providers

- Until regulations adopted, facility must maintain required information

- Regulations due two years after enactment, and effective 90 days after that
Nursing Home Transparency

• Nursing homes and SNFs must report staffing information, including:
  – Category of work performed
  – Resident census
  – Employee turnover and tenure

• Effective no later than two years after enactment
Outstanding Questions

- What happens once this information is reported?
- Reaction of patients, staff, donors, regulators?
- What opportunities are presented?
QUESTIONS?
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Agenda

- Enhanced Medicare and Medicaid Program Integrity Provisions
- New Provider Screening and other Enrollment Requirements
- Background checks for health care workers
- Enhanced Enforcement Tools
- Changes to Civil Monetary Penalties
- Requirement to maintain a compliance program
- RAC expansion to Medicaid
Background Checks

- Section 6201 establishes a “Nationwide Program” requiring a fingerprint-based State and national criminal records check on “direct patient access” employees and contractors.

- Expands the Background Check Pilot Program required by the MMA of 2003.

- Applies to:
  - Nursing Facilities and Skilled Nursing Facilities
  - Home Health and Hospice Services
  - Personal Care Services, Adult Day Care
  - LTC Hospital, ICF/MR
Provider Enrollment Issues

- Section 6401 requires CMS to establish screening of providers which shall include a license check, and may include
  - A criminal background check
  - Fingerprinting
  - Unscheduled and unannounced preenrollment site visits
- Screening will be required of:
  - All new providers and suppliers
  - All currently enrolled providers and suppliers two years from enactment
  - All providers and suppliers upon revalidation (every 5 years)
- Disclosure upon enrollment or revalidation
  - Previous affiliation with an entity that owes the government money, or has been suspended or excluded from federal health care programs
Provider Enrollment Issues

• Provisional Period for New Providers or Suppliers
  – For the first year of enrollment, new providers and suppliers will be subject to increased oversight which may include
    • Prepayment review
    • Payment caps
    • 90-day suspension of payments for new DME suppliers

• Temporary Moratorium on Enrollment
  – CMS may impose a temporary moratorium on the enrollment of new providers or suppliers if necessary to prevent fraud, waste or abuse

• Payment Adjustments for New Providers and Suppliers
  – CMS may adjust payments owed to new providers and suppliers if they share the same federal tax ID as a previously-enrolled entity that owes the government money
Enhanced Enforcement Tools

- Creation of an integrated data repository
  - Access to the OIG and other federal agencies to conduct data mining
- OIG access to physician medical records relating to items or services paid for under Parts B, C or D
- Permissive exclusion for an individual or entity that knowingly misrepresents a material fact in any application or contract to participate in a federal health care program
- Section 10606 provides enhanced subpoena authority to U.S. Attorneys to issue subpoenas without a grand jury or a judge
- An additional $95 million in FY11 to the OIG, DOJ, and FBI to fight fraud and abuse
Federal Sentencing Guidelines

• Section 10606 amends the Federal Sentencing Guidelines for persons convicted of a health care offense to provide that the aggregate dollar amount of fraudulent bills submitted to a federal health care program will constitute prima facie evidence of the amount of the intended loss by the defendant.

• Also requires the U.S. Sentencing Commission to provide increased penalties for persons convicted of health care fraud offenses in appropriate circumstances.
Civil Monetary Penalties

- Section 6402 allows the OIG to impose an administrative penalty on a physician or other enrolled individual who “knowingly participates in a health care fraud”
- Creates new civil monetary penalties for individuals who:
  - Order or prescribe an item or service while they are excluded
  - Knowingly make or cause to make a false statement on an application or agreement to participate in a federal health care program ($50,000 plus treble damages)
  - Knowingly makes a false statement material to a false or fraudulent claim ($50,000)
  - Know of an overpayment and fail to return it
  - Fail to grant timely access to the OIG for an audit, investigation or evaluation ($15,000 per day)
Compliance Programs

• Deficit Reduction Act (DRA) of 2005 required providers to have a compliance program if they received more than $5 million in payments from Medicaid annually

• Section 6401 of the Health Care Reform law requires all providers and suppliers in certain industries (TBD) to establish a compliance plan that has certain “core elements”

• Note: Section 6102 requires nursing facilities to establish compliance programs, and entities owning 5 or more facilities will be expected to establish a more formal program
Compliance Programs

• Core Elements
  – Clear standards (policies and procedures) that address key risk areas
  – Education and Communication of those standards
  – Periodic monitoring of those standards
  – Periodic auditing of those standards
  – Appropriate responses to compliance deficiencies
  – Corrective action plans established to address deficiencies and prevent them from occurring in the future

• Formal Structure for Larger Organizations
  – Full-time compliance officer
  – Compliance Committee (Ethics & Compliance Oversight Committee)
  – Board Oversight (Audit and Compliance Committee)
Anti-Kickback Statute

- **Hansleter Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)**
  - This case held that the government had to prove:
    - An individual intentionally entered into an arrangement that violated the Anti-Kickback Statute, and
    - When the individual entered into the prohibited arrangement, the individual knew that it violated the Anti-Kickback Statute

- Section 6402 overturns *Hansleter* by clarifying that an individual “need not have actual knowledge of this section or specific intent to commit a violation of this section.”
Unlawful Patient Inducements

- Section 6402 creates three new exceptions to the definition of “remuneration”
  - Coupons, rebates or other rewards from retailers given to all patients on equal terms, and not tied to the provision of health care services that are reimbursed by federal health care programs
  - Free items or services that have a reasonable connection to the medical services being provided, are not advertised, not tied to the provision of health care services that are reimbursed by federal health care programs, and provided after determining in good faith that the person is in financial need
  - Remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs (as defined in section 1128B(f) and designated by the Secretary under regulations)
Financial Assistance Policy

**Health Care Reform**
- Must have a written financial assistance policy
- No requirement for free care
- Explains the basis for calculating the amounts charged to patients
- Explains how the organization will collect debt
- Must publicize the policy within the community

**MN AG Agreement**
- Must have a policy that provides a discount to patients earning less than $125,000 per year
- No requirement for free care
- Requires a policy on debt collection practices to be reviewed by the CEO and Board
- Must educate staff on the policy and inform patients of the policy
Discounts

**Health Care Reform**
- Must provide a discount to patients who qualify for financial assistance according to the facility’s policy
- Discount must be equal to the “amounts generally billed” to individuals who have insurance covering such care

**MN AG Agreement**
- Must have a policy that provides a discount to patients earning less than $125,000 per year
- Discount must be equal to the discount provided to the third party payer from whom the provider received the most revenue in the previous year
### Billing and Collection Practices

#### Health Care Reform
- The organization must not engage in “extraordinary collection actions” until after it has made **reasonable efforts to determine that the individual does not qualify for financial assistance**.

#### MN AG Agreement
- Prohibits certain collection practices such as pre-judgment garnishments and credit reporting in certain situations.
- Must determine that you have appropriately billed any available third party payer and that there is no reason to believe that the person qualifies for free care before pursuing certain collection activities.
Ordering Home Health and DME

- Section 6405 requires a physician or other professional ordering DME or Home Health to be enrolled in Medicare.

- Section 6407 requires a physician or other professional to have a face-to-face encounter with patient before ordering Home Health or DME.

- Section 6406 provides that physicians or other suppliers who fail to maintain documentation supporting an order for a high risk item or service (such as DME or home health) may be suspended from participation in Medicare for one year.
Other Program Integrity Provisions

• Section 6402 requires a provider or supplier to:
  – Report an overpayment to the contractor
  – Explain the reason for the overpayment
  – Refund the overpayment
  – Do this by the later of the following:
    • 60 days after the date on which the overpayment was identified, or
    • The date any corresponding cost report is due

• Issues to wrestle with:
  – When was the overpayment identified?
  – Section 6404 shortens the timely filing window to 12 months
  – Consequences for failing to disclose – discussed in next presentation
Other Program Integrity Provisions

- Liability Protection for Free Clinics
  - Current law provides that a free clinic health professional shall be deemed an employee of the Public Health Service, with the protections afforded by the Federal Tort Claims Act (42 USC 233)
  
  - Section 10608 of the Health Care Reform law clarifies that this liability extends to: “an officer, governing board member, employee, or contractor of a free clinic”
Other Program Integrity Provisions

- Community Mental Health Clinics
  - Section 1301 of the Reconciliation law requires community mental health centers to provide at least 40 percent of its services to individuals who are not eligible for Medicare
MAC Prepayment Reviews

- Current law places limits on prepayment reviews that can be conducted by Medicare Administrative Contractors
  - Random prepayment reviews can only be conducted to develop contractor-wide or program-wide claims payment error rates
  - Non-random prepayment reviews can only be conducted on a provider or supplier following
    - identification of an improper billing practice, or
    - a likelihood of sustained or high level of payment error (i.e. the same standard that permits the use of extrapolation)

- Section 1302 of the Reconciliation law repeals this limitation on the use of prepayment medical reviews by MACs
Expansion of RAC to Medicaid

- Section 6411 requires each State to contract with a Recovery Audit Contractor by December 31, 2010
  - Payment to the RAC contractor must be on a contingent basis, with the amount of the contingency established by each State
  - Each State must have an adequate process to appeal any adverse determination

- Relationship with the Medicaid Integrity Contractors

- NOTE: Section 6506 extends the period of time the State is required to repay an overpayment to the federal government from 60 days to 1 year in the case of fraud if the overpayment is still in dispute
Effective Dates

• Date of Enactment (March 23, 2010)
  – Everything discussed in this section except those noted below
  – Some provisions require the Secretary to conduct rulemaking
    • Background checks
    • Provider enrollment screening
    • Compliance program core measures

• January 1, 2010
  – Enhanced Civil Monetary Penalties in Section 6008
  – Amendment to Timely Filing rule
QUESTIONS?

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Agenda

- Pro-whistleblower amendments to False Claims Act (FCA)
- Repayment duty, Antikickback, Stark now tied directly to FCA
- New Stark Self-Referral Disclosure Protocol
Amendments to False Claims Act

- “Public disclosure” jurisdictional bar is greatly weakened
- “Original source” exception is somewhat expanded
Long long ago, in a galaxy far far away . . .

- The story of Marcus Morris
- “What harm can there be if 10,000 lawyers in America are assisting the Attorney General of the United States in digging up fraud?”
  - U.S. Senator “Wild Bill” Langer of ND
“No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a [1] criminal, civil, or administrative hearing, in a [2] congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or [3] from the news media, unless . . . the person bringing the action is an original source of the information.”

- 31 U.S.C. § 3730(e)(4)
- A jurisdictional bar (show stopper) for court alone to decide
- “Public disclosures” not restricted to “federal” hearings, reports or investigations, or to proceedings that the feds were party to.
- “Congress could have easily limited the public disclosure bar to ‘federal criminal, civil, or administrative hearings,’ but chose not to do so. If the statutory language is clear, that is the end of our inquiry.”
  • *A-1 Ambulance Service* (9th Cir., Feb. 7, 2000)
“The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed

(i) in a Federal criminal, civil or administrative hearing in which the Government or its agent is a party;

(ii) in a Congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation; or

(iii) from the news media,

unless . . . the person bringing the action is an original source of the information.” (H.R. 3590 § 10104(j)(2))
What do these changes mean?

• No longer a jurisdictional bar
  – DOJ, rather than the court, decides whether bar applies
• Public disclosures now limited to FEDERAL proceedings; and only proceedings TO WHICH THE FEDS ARE A PARTY
  – Whistleblower suits based on publicly disclosed STATE proceedings, reports or investigations can go forward
    • Attorney general investigations
    • DOH surveys, investigations
    • DHS audits, etc.
  – Same for suits based on private civil proceedings in FEDERAL court
    • Federal antitrust litigation
    • Civil rights/discrimination/wrongful discharge cases
    • Shareholder suits
BEFORE Reform: the original “original source” rule

“For purposes of this paragraph, ‘original source’ means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.” (31 U.S.C. § 3730(e)(4)(B))
AFTER Reform: the new “original source” rule

“For purposes of this paragraph, ‘original source’ means an individual who either (i) prior to a public disclosure . . ., has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.” (H.R. 3590, § 10104(j))
What do these changes mean?

- Whistleblowers no longer need to have “direct” knowledge of the information underlying the allegations
  - Claims based on indirect or secondhand knowledge can proceed
  - BUT whistleblower still must have “independent” knowledge that “materially adds” to any publicly disclosed allegations
  - What does that mean? (TBD in future litigation, unless . . . )

- Remember: under the Reform Law amendments, even if there has been a “public disclosure,” and the whistleblower is not an “original source,” DOJ can still allow the whistleblower to proceed!
New tie-ins to FCA

- Reform Law codifies the government’s and whistleblowers’ “bootstrapping” theories of liability under the FCA:
  - 60-day repayment duty
  - Antikickback violations
  - Stark violations
Ancient History: “Implied Certification”

- In the past, whistleblowers could not bring Antikickback or Stark cases unless courts agreed with their “implied certification” arguments under the FCA.
  - Some courts bought it (i.e., 3rd Circuit, DC Circuit)
  - Some courts didn’t, or remained on the fence (i.e., 1st, 2nd, 4th, 5th, 7th, 8th and 9th Circuits)
- "The FCA is not intended ‘to operate as a stalking horse for enforcement of every statute, rule, or regulation.’ To hold that the mere submission of a claim for payment, without more, always constitutes an ‘implied certification’ of compliance with the conditions of the Government program seriously undermines this principle by permitting FCA liability potentially to attach every time a document or request for payment is submitted to the Government...." United States ex rel. Joslin, 984 F. Supp. at 384–85 (D. Md. 1997).
Pre-May 20, 2009: “Express Certification”

HHS attempted to bolster FCA-bootstrapped Antikickback and Stark cases by including express certifications, e.g.:

“I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.” (CMS Form 2552)
Post-FERA Amendments to FCA (and pre-Reform)

• Effective May 20, 2009, FCA amended to add liability for:
  – “knowingly conceals . . . an obligation to pay or transmit money or property to the Government,” or
  – “knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government”

• Definition of “obligation”:
  – “an established duty . . . arising from an express or implied contractual . . . fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.” But . . .
    • Does retention of simple overpayment create an “established duty”?  
    • Does an Antikickback violation create an “established duty”?  Stark?
    • Does simply not repaying an overpayment qualify as “avoiding”?

• Result: whistleblowers no longer needed implied/express certification arguments as long as they showed an “obligation.”
**AFTER Reform: the dots are now connected**

- Repayment duty, Antikickback, Stark violations now tied directly to FCA

- Repayment duty:
  - “Any overpayment retained by a person after the [60 day] deadline for reporting and returning the overpayment . . . is an **obligation** (as defined in [the False Claims Act] . . .)” (H.R. 3590 § 6402(a))

- *Ergo,* “concealing” a retained overpayment, or “improperly avoiding” its return, is grounds for FCA liability
  - *This is true even if your initial receipt of the payment was entirely innocent or accidental.*
Connecting the dots—Antikickback and FCA

- Antikickback violations:
  - “[A] claim that includes items or services resulting from a violation of [the Antikickback Act] constitutes a false or fraudulent claim for purposes of [the False Claims Act].” (H.R. 3509 § 6402(f))
- Ergo, a hospital claim for an item ordered by a physician who was induced by a manufacturer’s kickback is presumptively “false” under the FCA
  - Accuracy of claim, medical necessity of item/service no defense
  - Manufacturer also liable for “causing to be presented”
Connecting the dots: Stark and FCA

- Stark violations:
  - Stark statute: “shall refund . . . to the individual” (42 USC § 1395nn(g)(2))
  - Stark regulation: “must refund all collected amounts” (42 CFR § 411.353(d))

- This duty to refund likely constitutes an “obligation” (i.e., an “established duty . . . arising from . . . statute or regulation”) under the FERA amendments to the FCA.

- Ergo, whistleblowers now have a clear shot at profiting from Stark violations under the FCA
What does this mean?

- Overdue repayments and Stark, Antikickback violations are *automatically* a FCA issue
- Defendants stripped of significant legal defense, opportunity for early dismissal
- Settlement value of bootstrapped cases will be greater
- *However,* Reform Law may inadvertently bolster the defense against other “implied certification” cases (e.g., based on Medicare CoPs, other non-Stark/Antikickback regulatory violations)
  - Argument will be, if Congress intended to boot-strap other Medicare violations under the FCA, they could have done so expressly
Coming soon . . . the MN False Claims Act

- Minn. Stat. § 15C, effective July 1, 2010
- Parallels federal FCA, without FERA or Reform Law changes
- Significant unique statutory defenses:
  - No liability for “mere negligence, inadvertence, or mistake;”
  - Employer not liable for a “nonmanagerial employee” unless the employer “had knowledge of the act, ratified the act, or was reckless in the hiring or supervision of the employee;”
  - No liability if defendant repays within 45 days after being informed by an “original source” that false or fraudulent claims have been made
    - “original source” defined as a person with “direct and independent knowledge” of information not obtained from a “public source”
- May require amending if fails OIG review.
OIG Self-Disclosure Protocol

- Recognizing the Stark Law’s draconian penalties for even “innocent” mistakes, the OIG developed a self-disclosure option

- OIG Open Letters to health care providers:
  - April 2006: OIG promotes self-disclosure of Stark, Antikickback violations and indicates monetary settlements would “generally” be at the “lower end of the damages continuum”
  - BUT March 2009: OIG announces it will no longer accept self disclosures relating to Stark violations only
  - CMS has historically taken the position that it had no authority to negotiate down from the statutory damages set forth in the Stark Law (full recoupment)
  - MACs, FIs not equipped to handle Stark issues

- Net result: in 2009, no good options for resolving Stark violations
CMS Self-Referral Disclosure Protocol

• Reform Law now requires CMS (in cooperation with OIG) to develop a “Self Referral Disclosure Protocol” (SRDP) by September 23, 2010 to enable self-disclosures of actual or potential Stark Law violations

• SRDP must include directions on:
  – Person or office to report to; and
  – Instructions on the implications of the SRDP on corporate integrity/corporate compliance agreements.

• Must be disclosed on CMS’ website

• Separate from CMS’ Stark advisory opinion process
New CMS authority to compromise Stark claims

- Reform Law authorizes CMS to reduce the amount due for violations of the Stark Law based on the following factors:
  - Nature/extent of improper or illegal practice
  - Timeliness of self-disclosure
  - Cooperation in providing information
  - Other factors
Effective Dates

- “Public disclosure”/”original source” amendments to FCA: Mar. 23, 2010
- Overpayments, Antikickback violations tied to FCA: Mar. 23, 2010
- Stark regulations implementing physician-owned hospital changes: Jan. 1, 2012
- Payments made through private insurance exchanges subject to FCA: Jan. 1, 2014
Questions?

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Health Care Reform
Employer Responsibilities / Benefit Requirements

Maureen Maly
Overview

- New federal benefit mandates and administrative mandates on employer-sponsored group health plans
- Impact on collectively bargained arrangements
- Tax increases – high cost plans / retiree drug subsidy / Medicare taxes
- Impact on account-based plans (HSAs, FSAs, etc.)
- Consumer information requirements
- Federal high risk pool
- Insurance exchanges
- Employer and individual coverage mandates
New Federal Benefit Mandates and Administrative Mandates on Employer-Sponsored Group Health Plans

- Administrative Mandates
  - New Form W-2 Reporting Requirement for cost of employer-sponsored health coverage (1/1/11)
  - Change tax treatment for health coverage of adult non-dependent children (3/30/10)
  - Breaks required for nursing mothers (3/23/10)
  - New appeals process for appeals of coverage determinations and claims (plan years beginning on or after 9/23/10) – not applicable to grandfathered plans
  - Insured plans must meet nondiscrimination rules (plan years beginning on or after 9/23/10) – not applicable to grandfathered plans
  - New summaries of coverage – uniform definitions (3/23/12)
  - Detailed annual reporting to Secretary of Treasury regarding coverage, cost of coverage, employees covered, etc. (1/1/14)
New Federal Benefit Mandates and Administrative Mandates on Employer-Sponsored Group Health Plans

• Benefit Mandates
  – Unclear effective date
    • Auto-enrollment for full time employees (employers with more than 200 employees)
  – Effective for plan years beginning on or after 9/23/10:
    • Coverage of adult children to age 26
    • Restrictions on lifetime and annual dollar limits (no annual limits after 1/1/2014)
    • Limited rescission of coverage
    • No pre-existing condition exclusions for children under 19 / all plan participants 2014
    • Must cover emergency services without prior authorization and out-of-network as if in-network – not applicable to grandfathered plans
    • Must allow OB/GYN/Pediatrician to be designated as primary care provider – not applicable to grandfathered plans
    • First dollar preventive care – not applicable to grandfathered plans
New Federal Benefit Mandates and Administrative Mandates on Employer-Sponsored Group Health Plans

• Benefit Mandates (cont.)
  – Effective 1/1/14:
    • Guaranteed issue / guaranteed renewal – not applicable to self-funded plans or grandfathered plans
    • Cost sharing limits
    • No waiting periods over 90 days

• Optional
  – Voluntary public long-term care – effective 1/1/11
  – Increased wellness incentive to 30% – effective 1/1/14
  – Retiree reinsurance program – effective 6/21/10
Impact on Collectively Bargained Arrangements

- Grandfathered Status
  - Applies to both multiemployer and single-employer plans
  - To be grandfathered:
    - Plan is maintained under collective bargaining agreement
    - Agreement was ratified before March 23, 2010
  - Maintain grandfathered status until the expiration of the last CBA
  - Agreement can be modified to conform with provisions of the health care legislation without losing grandfathered status
  - Unclear: What happens when agreement expires?
Taxation of High Cost Plans / Retiree Drug Subsidies

- “Cadillac plan” tax
  - High cost plan excise tax
  - Effective 2018
    - 40% excise tax on value of employer-provided coverage over $10,200 (self) / $27,500 (other)
      - Increased levels for high risk jobs, multi-employer plans, plans with higher cost due to age / gender
    - Tax on all employer-sponsored health coverage
      - Includes FSA, HSA, on-site medical clinics, Medicare supplemental policies, but excludes stand-alone dental and vision, long-term care, accident and disability insurance, liability insurance, auto medical insurance, employee pay-all hospital indemnity and specified disease or illness policies
- Self-funded plans – employer pays tax
- Insured plans – insurance company pays tax
Taxation of High Cost Plans / Retiree Drug Subsidies

• Loss of deduction for 28% Medicare Part D drug subsidy
  – Effective in 2013, but accounting rules require employer to take immediate charge for quarter of date of enactment
  – Will cause employers to rethink retiree drug offerings – may switch to PDPs / other options
Other Tax Increases

- Additional Medicare tax on wages – 0.9% on wages over $250,000 (jt.) / $200,000 (others) (1/1/13)
- Unearned income Medicare contribution tax – new 3.8% tax on “net investment income” for taxpayers with modified AGI over $250,000 (jt.) / $200,000 (others) (1/1/13)
  - Net investment income – interest, dividends, capital gains, annuities, royalties and rents and certain trade or business income
  - Excludes qualified retirement plan distributions
  - Unclear whether includes nonqualified plan distributions
Impact on Account-Based Plans

- No OTC medications reimbursed under HSAs, FSAs, HRAs, except by prescription or insulin (effective for expenses incurred on or after 1/1/11)
- Limit FSA contributions to $2,500, indexed in future years (effective 1/1/13)
- HSA excise tax increase
  - 20% excise tax on withdrawals for non-medical expenses (effective 1/1/11)
Consumer Information Requirements

- Internet portal
  - HHS to develop Internet consumer tool to help individuals and small employers shop for affordable coverage
  - Effective 7/1/10

- Consumer assistance
  - Federal grants to states to establish health insurance consumer assistance offices to assist consumer with complaints, appeals, enrollment and premium tax credits
  - Effective 3/23/10
Creation of Federal High Risk Pool

- Temporary high-risk pool for uninsured with pre-existing conditions
  - Ninety days post-enactment until exchanges are operational
  - Insurer or employer who encourages individuals to disenroll and enroll in the high risk pool must reimburse the pool
 Creation of Health Insurance Exchanges

- By 2014
- State insurance market – run by government or non-profit entities
- For individuals and business < 100 employees; larger businesses may be allowed to buy in beginning 2017
- Will offer four comprehensive plans (varying co-pays / deductibles) and one catastrophic plan
- Employer requirement to provide written notice to employees about exchange and potential premium credits – effective 2013
Employer and Individual Coverage Mandates

• Employer Mandates
  – Effective 1/1/14
  – Applies to “large” employers (50+ employees)
    • Full time and part time employees (on full time equivalent basis) count to determine 50
    • Full time = 30+ hours / week, determined monthly
  – Penalties apply for no coverage / unaffordable coverage
Employer and Individual Coverage Mandates

• No Coverage Penalty
  – If employer fails to provide full time employees and dependents opportunity to enroll in minimum essential coverage and
  – One or more full time employees enroll in an exchange and receives a premium tax credit or cost-sharing reduction,
  – Employer penalty = $2,000 per full time employee
  – Minimum essential coverage means any employer-sponsored major medical coverage
  – If you have no employees with income < 400% of federal poverty level, this penalty will not apply:
    • For 2009, $43,230 individual, $88,200 family
Employer and Individual Coverage Mandates

- Unaffordable Coverage Penalty
  - If employer offers full time employees and dependents opportunity to enroll in minimum essential coverage and
  - One or more full time employees enrolls in exchange and receives premium tax credit or cost-sharing reduction because either:
    - Employee’s share of premiums > 9.5% of income, or
    - Actuarial value of coverage employer provides < 60% of full value, then

Employer penalty = $3,000 per full time employee who receives a tax credit or cost-sharing reduction
  - May not exceed penalty for no coverage
  - If you have no employees with income < 400% of federal poverty level, this penalty will not apply
Employer and Individual Coverage Mandates

• Free Choice Vouchers:
  – Effective 1/1/14
  – Applies to employers that offer coverage and pay part of the cost

• To qualify, employees must:
  – Meet lower income requirements (< 400% of federal poverty) and
  – Contribute 8-9.8% of income and
  – Not participate in employer plan
Employer and Individual Coverage Mandates

• Voucher = cost which employer would have paid if employee were covered under plan for which employer pays the largest portion of plan cost (self or family depending on employee’s election)
• Employer pays amount of exchange credits for cost of coverage employee elects
• Excess amounts paid to employee, tax-free
• Employee who gets voucher does not qualify for premium tax credit in exchange
• Need further guidance on how to calculate employee cost for employer’s plan, amount employer must contribute, etc. / how this program interacts with unaffordable coverage penalty
Employer and Individual Coverage Mandates

• Individual Mandate
  – Requires individuals to obtain minimum essential coverage or pay tax penalty
    • Starts at $95 / individual – 2014
    • Up to $695 / individual, $2,085 / family – 2016
    • Exemption if uninsured less than three months
Questions?

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