Healthcare Reform and Beyond: What Compliance Professionals Need to Know
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- 6 years Criminal Health Care Fraud Coordinator  
- 13 years as prosecutor  
- 5 years in white collar defense and health compliance
Health Care Reform

- Patient Protection and Affordable Care Act ("PPACA")
  - Signed into law March 23, 2010 (HR 3590)
  - Sidecar Bill (HR 4872)
  - Executive Order re: Abortion
  - Manager’s Amendment (student loans, rural subsidies, lower tax on medical devices)
  - Senate corrections (procedural issues)
  - House vote (because of Senate corrections)
Improving Coverage

- Limitation on deductibles for employer-sponsored plans
- No lifetime or annual limits
- No pre-existing condition exclusions
- Coverage of Preventive Health Services
- Extension of dependent coverage up to age 26
- Guaranteed availability of coverage
- Guaranteed renewability of coverage
- Can keep current coverage
- No Discrimination
  - Health status, medical condition, claims experience, receipt of health care, medical history, genetic info, evidence of insurability, disability, any other health status factor
Improving Coverage Compliance

- New service lines that hospitals have not done before
- Sicker insured patients with same reimbursement
  - Economic pressure can lead to bad choices
Medicaid Expansion

- Beginning in 2014, all state Medicaid programs are required to cover individuals up to 133% of the federal poverty level
  - Over 17 million new Medicaid recipients
  - New or expanded service lines
## Essential Health Services

- Ambulatory
- Emergency
- Hospitalization
- Maternity and newborn care
- Mental health and substance abuse
- Prescription drugs
- Rehabilitation and Rehabilitative services and devices
- Laboratory
- Preventive and wellness services
- Chronic disease management
- Pediatric, including oral and vision
Essential Health Services

Compliance

- More things reimbursed
- New services by providers?
- Reimbursement rules
- Policies and Procedures
Individual Responsibility

- Individuals must maintain Minimum Essential Coverage by 1/1/2014
  
  * This is the Constitutional fight

- Maximum monthly penalties for not doing so
  
  - 2014: $23.75
  - 2015: $87.50
  - 2016 and following: $187.50

- There are limits based on ability to pay
Demonstration Projects

- Wellness programs
- Integrated care around a hospitalization
- Medicaid global payments
- Pediatric accountable care organizations
- Medicaid emergency psychiatric
- Maternal, infant, early childhood home visits
- Postpartum depression
- Personal responsibility education
- Value based hospital purchasing tied to quality
- Encouraging development of new patient care models
- “Center for Medicare and Medicaid Innovation”
- Hospital readmissions reduction program
Prevention Services

- Smoking cessation
- Weight management
- Stress management
- Physical fitness
- Nutrition
- Heart disease prevention
- Healthy lifestyle support
- Diabetes prevention
New Projects and Services Compliance

- New service lines that hospitals have not done before
- New specific risk areas
- New policies and procedures
- Auditing and monitoring
Quality Reporting

To improve

- Case management
- Care coordination
- Chronic disease management
- Education and care compliance
- Use of Medical Homes

To prevent readmissions

- Discharge planning
- Education
- Post-discharge reinforcement
- Increased safety, fewer errors
Quality Reporting

Compliance

- Interaction between compliance and quality
- New compliance policies
- Change in data systems
- Data accuracy
- Quality drives reimbursement
Quality Improvement Program for Hospitals with high severity adjusted readmissions

Community based care transitions program

Extension of gainsharing demonstration

Permitting physician assistants to order post-hospital extended care services
Mandatory Compliance Plan

- All suppliers and providers enrolled in Medicare, and all providers enrolled in Medicaid, required to implement a compliance plan that contains core elements laid out by the Secretary of HHS.
Fraud and Abuse

- Anti-Kickback Statute (AKS)
  - Specific intent requirement relaxed
  - A violation of AKS now constitutes a false or fraudulent claim under FCA
  - Definition of remuneration is amended for the beneficiary inducement provisions to exclude any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs
- Watch out for expanded FCA liability
- Definition of remuneration now has a broad exclusion that many activities may come within
Fraud and Abuse

- False Claims Act Qui Tam Public Disclosure Bar
  - FCA amended to provide that the public disclosure bar is not jurisdictional and does not require dismissal if the government opposes dismissal
  - State proceedings and private litigation are not qualifying public disclosures
  - Original source exception amended to eliminate direct knowledge requirement
Fraud and Abuse
Compliance

- Adds significant litigation complexity and cost to declined qui tam actions
- Ensures that DOJ has a prominent role in determining a relator’s status to proceed with the declined qui tam action
Fraud and Abuse

- Overpayments and FCA liability
  - Identified overpayments must be reported and repaid within 60 days
  - Retention of overpayments after 60 days constitutes an “obligation” under the FCA

Compliance

- What is an “identified” overpayment? Gov’t could find any delay in processing a known overpayment to create FCA liability
Fraud and Abuse

- Limitations on Stark Law Exceptions
  - Limits Whole Hospital and Rural Provider exceptions to hospitals that have Medicare provider agreements and physician ownership or investment as of 12/31/2010
    - Limitation on expansion of facility capacity
    - Additional disclosure requirements
  - Retroactively imposes disclosure requirements on In-Office Ancillary Services exception
Fraud and Abuse

- Stark Law Self-Disclosure Protocol
  - Statutory disclosure protocol created for violations of the Stark Law
  - Provides for agency discretion to resolve Stark violations and authorizes HHS to reduce the amount due and owing for all Stark violations, considering such factors as the nature and extent of the improper practice and timeliness of the disclosure
Fraud and Abuse

- Expanded RAC Activities
  - RAC audits of providers will increase and expand to Medicaid, Medicare Part D and Medicare Advantage programs

  **Compliance**
  - Check your internal audit activities and your responses to record requests and audits
The Medicaid RACs are (Almost) Here!

- Final regulations finally promulgated 9/16/11
- >100 pages of preface and comment responses
- 5 double-spaced pages of regs
Thoughts on Medicaid RACs

- Like Medicare RACs (sort of)
  - Focused on payment compliance
  - Contingent fees
  - Different appeal processes
  - Different grounds for appeal
- $2.1 Billion in savings over 5 years, with $900 Million to states
- States have to implement by January 1, 2012
  - Opportunity to influence your state?
- Another kind of audit added to the arsenal
- Lack of coordination
- Limited funding to States
  - FFP available to States for admin cost of operation and maintenance of Medicaid RACs
Medicaid RAC Program Regs

- States must enter into contracts consistent with State law
- Report effectiveness of RAC program to CMS
- Identify and recoup overpayments, identify underpayments
- Payments under Medicaid programs, but not Medicaid managed care
- States coordinate with RAC on recoupment
- States coordinate RAC activities with other auditing entities
- Make referrals of suspected fraud, abuse to MFCU or appropriate law enforcement agency
Medicaid RAC Program Regs

- State must set limits on number and frequency of records to be reviewed
- 1.0 FTE Medical Director
- RAC must hire certified coders, unless State determines not necessary for effective review of Medicaid claims
- Education and outreach, including audit policies and protocols
- Toll-free customer service line
- Maintain provider-approved points of contact
- Mandatory acceptance of electronic submissions
Medicaid RAC Program Regs

- Notify providers of overpayments in 60 days
- Cannot go back beyond 3 years unless State approves (Note: CMS has said something else)
- No audit of previously audited claims or those under audit
- Fees to RAC only from amounts recovered
  - Must be % contingency
  - Not greater than Medicare RAC fee % to get federal match
- Appeal rights under state law
Fraud and Abuse

- Healthcare Fraud Criminal Statute and US Sentencing Guidelines amended
- Expansion of administrative penalties, including exclusion
- Government has new resources, including expanded subpoena power and additional funding

**Compliance**

- Risks and consequences of enforcement actions are intensified and expanded
PPACA mandates transparency in device and pharmaceutical company payments to physicians

- Transparency Reports
  - Requires manufacturers of any drug, device, biological or medical supply that is eligible for Medicare, Medicaid, or SCHIP coverage to submit annual reports of payments or transfers of value to physicians
Program Integrity

- Screening and Disclosure Requirements
  - Employee and vendor screening requirements
  - Financial disclosure requirements
  - Providers must include their national provider identifier on all applications and claims
PPACA adds new requirements for tax exempt status of charitable hospitals

- Conduct community health needs assessments
- Meet financial assistance policy requirements
- Limits amounts hospitals can charge for emergency or medically necessary care to individuals qualifying for financial assistance to the amount generally charged to insured patients
- Make reasonable efforts to determine whether individuals qualify for financial assistance before engaging in extraordinary collection efforts
The Private Practice of Medicine is Under Attack

- Physicians are experiencing financial pressures that make private practices increasingly difficult to sustain
  - Overall downward pressure on physician reimbursement
  - Growth in Medicaid and Medicare
  - Increased malpractice, EHR and other operating costs
  - PPACA creates new models that create incentives for collaboration
Common Issues in Practice Acquisitions

- Managing expectations, with respect to control, purchase price and compensation
  - Fair market value for tangible and intangible assets
  - Fair market value compensation methodology
  - Allow physicians day-to-day control of practice
  - Sufficient reserved powers
- Providing appropriate “outs” for each party
- Conducting thorough due diligence to identify potential pitfalls
  - Be reasonable as process is likely new to physicians and staff
PPACA Implementation Timeline

- Upon enactment- March 23, 2010
  - Fraud and abuse provisions
- 90 days after enactment
  - Temporary Retiree Reinsurance Program
  - National High-Risk Pool
- 6 Months After Enactment
  - Coverage for adult children up to age 26
  - Plans prohibited from rescinding coverage
  - Restricts annual limits on coverage
  - No preexisting limitation for coverage of children under age 19
PPACA Implementation Timeline

- Year 2010
  - Better coverage for kids and dependents
  - Small employer tax credit
  - Reporting on medical loss ratio
  - Medicare beneficiaries who hit the doughnut-hole receive a $250 rebate
  - Fraud and abuse provisions
PPACA Implementation Timeline

- Year 2011
  - Insurers must provide rebates to consumers based on amount spent
  - Fee on Pharma begins
  - Prohibition on physician ownership referral
PPACA Implementation Timeline

- Year 2012:
  - Allow providers organized as accountable care organizations (ACOs) that voluntarily meet quality thresholds to share in the cost savings they achieve for the Medicare program
  - Excess readmissions provision goes in effect
  - Drug manufacturers must report information relating to drug samples
PPACA Implementation Timeline

- **Year 2013**
  - Transparency reporting begins
  - Increase tax on investment income for high-income taxpayers
  - Contributions to Flex Spending Arrangements capped at $2500
  - Medical device tax begins
Year 2014

- No pre-existing condition exclusions or annual limits on coverage
- Individual and Employer mandate
- Employers with more than 200 employees must automatically enroll employees
- Essential health benefits package established
- Expanded Medicaid eligibility
- Health insurance exchanges
- Annual fee on health insurance providers
Year 2015:
- Penalty to hospitals for not adopting EHR
- Establishment of Independent Payment Advisory Board to propose changes in Medicare payments
PPACA Implementation Timeline

- Year 2016:
  - Interstate Health Choice Compacts

- Year 2017:
  - Large employer participation in Exchanges

- Year 2018:
  - Tax on Cadillac plans
Responses and Prevention

- Get involved in new arrangements
- Establish or update compliance programs and policies
- Address possible new FCA exposure
- Understand risk of whistleblowers
- Reevaluate HIPAA privacy and security plans, and amend business associate contracts
- Scrutinize physician relationships
Thank you.
Questions?

Additional Media:
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