Enforcement and Compliance Implications of Health Care Reform

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Topics For Today’s Discussion

1. Improved Coverage and Medicaid Expansion
2. HHS – OIG Work Plan
3. False Claims Act
4. Anti-Kickback Statute
5. Overpayments
6. Tax-Exempt Health Organizations
7. Physician Payment Sunshine Act
8. HIPAA
9. Billing
10. Accountable Care Organizations
11. Medicaid RACs
12. Takeaway Compliance Strategies
Improved Coverage and Medicaid Expansion

Essential Health Services
Prevention Services
Medicaid Expansion

- Where does your state stand?
- More things reimbursed
- Reimbursement rules
- Policies and procedures
- New and sicker patient populations
- New service lines
- New specific risk areas
- New policies and procedures
- Auditing and monitoring
- Economic pressure…bad choices?
- Mandatory Compliance Plans
Improved Coverage and Medicaid Expansion

State Decisions for Creating Health Insurance Exchanges and Expanding Medicaid, as of April 2, 2013

Status of State Exchange Decision

- Default to Federal Exchange
- Declared State-based Exchange
- Planning for Partnership Exchange

• **New Programs and Initiatives**
  
  - Pre-existing Condition Insurance Plans
    - “Review controls HHS and States have in place to prevent and identify fraudulent health care claims for individuals covered by PCIPs”
  - Early Retiree Reinsurance Program
  - Health Insurance Web Portal
  - Affordable Insurance Exchanges
  - Consumer Operated Oriented Plan Program
HHS OIG Work Plan- FY 2013
Affordable Care Act Reviews

- Existing Programs—Medicare
  - Hospitals – Same Day Readmissions
  - HHAs – Home Health Face-to-Face Requirement (New)
  - Power Mobility Devices – Supplier Compliance with Payment Requirements (New)
  - Program Integrity – Onsite Visits for Medicare Provider and Supplier Enrollment and Reenrollment (New)
  - State Health Insurance Assistance Programs’ Provision of Medicare Fraud Information (New)
  - RACs – Identification and Recoupment of Improper and Potentially Fraudulent Payments and CMS’ Oversight and Response
  - Part C – Special-Needs Plans, CMS Oversight of Enrollment and Special-Needs Plans
  - Part D – Coverage Gap, Quality of Sponsor Data Used in Calculating Coverage-Gap Discounts
Existing Programs—Medicaid

- Manufacturer Rebates – Federal Share of Rebates
- Manufacturer Rebates – New Formulations of Existing Drugs
- Health-Care-Acquired Conditions – Prohibition on Federal Reimbursements
- State Terminations of Providers Terminated by Medicare or Other States
- Completeness and Accuracy of Managed Care Encounter Data
- State Enrollment and Monitoring of Medicaid Medical Equipment Suppliers (New)
HHS OIG Work Plan- FY 2013
Affordable Care Act Reviews

- **Existing Programs—Public Health**
  - HRSA – Community Health Centers’ Compliance with Grant Requirements of ACA
  - HRSA – Monitoring of Recipients’ Fulfillment of National Services Corps Obligations
  - SAMHSA – Grantees’ Use of Funds From the Prevention and Public Health Fund
False Claims Act

TATTLETALE!

I PREFER "WHISTLEBLOWER."

COOKIES
False Claims Act

- FY 2012: DOJ record of nearly $5 billion in civil recoveries
  - 2/3 of that amount was recovered in whistleblower suits
- False Claims Act Qui Tam Public Disclosure Bar
  - Easier for *qui tam* relators
    - Narrows definition of “publicly disclosed” information
- Expands FCA exposure
- Adds significant litigation complexity and cost to declined *qui tam* actions
- Ensures that DOJ has a prominent role in determining a relators status to proceed with the declined *qui tam* action
False Claims Act

- New group of whistleblowers
  - Physicians
  - Compliance Officers
  - Internal Auditors
  - “Professional Whistleblowers”

- EX: *United States ex rel. Dittman v. Adventist Health System/Sunbelt Inc.* (M.D. Fla. July 30, 2012) → whistleblowers were a Compliance Officer and a physician

- EX: *United States ex rel. Ruhe v. Masimo Corp.* (C.D. Cal. July 9, 2012) → whistleblowers were former sales reps

- New breed of whistleblowers’ counsel
“Original Information”

- Create an accurate and clear record
- Appearance and actuality

Considerations

- Phone calls - logs, texts, voice messages
- E-mail - multiple accounts
- Social networking sites
- Chat functions
- Internal documents – presentations, draft documents, memoranda, meeting agendas and minutes

Self Reporting
False Claims Act

- Investigate Complaints
  - Culture of no retaliation
  - Privilege issues
  - Who should be Counsel?
  - Counsel’s role
  - Develop work plan with focus on possible outcomes

- Interview Witnesses
  - Culture of no retaliation
  - *Upjohn* warnings
  - Skillful questioning
  - Procedures around process
Anti-Kickback Statute

- Specific intent requirement relaxed
  - Individual does not have to have actual knowledge of the AKS
  - Eliminates requirement to demonstrate the individual had intent to violate the AKS
  - Ref. Hanlester decision
- A violation of the AKS now constitutes a false or fraudulent claim under FCA
Overpayments

- 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
- What is an “identified” overpayment in a fragmented organization?
- Government (or relator) could assert that failing to act with “deliberate speed” is an FCA violation
• Financial assistance policy for low income patients
• Written policies for provision of emergency care
• Limitation on charges and collection activities for certain individuals
• Community health needs assessment
Certain manufacturers of drugs, biologicals and medical supplies are required to annually report to CMS certain payments or other transfers of value to physicians and teaching hospitals

- Data collection
- Reasonable, good faith effort to determine value of a payment or transfer of value
- Content of report

The manufacturers and GPOs are also required to annually report certain physician ownership and investment interests

- Direct and indirect interests
Physician Payment Sunshine Act

- Increased transparency
- What systems need to be in place?
- Do you need to train staff?
- Public relations considerations
- Educational and outreach activities
- Litigation implications—more data for plaintiff’s bar
HIPAA

- Redefines “business associate”
  - Look at functions the business associates perform
- Expands business associates’ liability
  - Evaluate your relationships
  - Structure appropriately to mitigate risks
- HIPAA audit protocols
  - Short time frame for response
  - Show implementation and enforcement of policies
  - Develop proof of effective implementation
- Marketing and fundraising implications
- Expands individuals’ rights to access electronic health information
New standard for breach notifications
“Compromised” instead of “significant risk”
4 Factors to assess
- Nature and extent of PHI, including types of identifiers and likelihood of re-identification
- Authorized person who used the PHI or to whom the disclosure was made
- Whether the PHI was actually acquired or viewed
- Extent to which risk to PHI has been mitigated
- Increase on due diligence for acquisitions
- Professional fee compliance
- EMR vs. paper records
  - Meaningful use vs. appropriate use
  - Compliance review of templates
  - Increased time by compliance
  - Cloned documentation
  - Clinic workflow (student, resident, doctor)
- Different billing systems
- Hospitals paid by IP DRG based on correct diagnosis
- Doctors paid by RBRVS for each day patient in hospital
Accountable Care Organizations ("ACOs")

- **Goals**
  - High quality
  - Efficient service

- **Questions**
  - Best way to achieve goals
  - CMS incentives
  - Alignment

- **Physician and hospital relationships**
  - Historical perspective
  - Define objectives
  - Due diligence: people, behavior, practices
  - Compliance at the table
Health-care law driving doctors away from small practices, toward hospital employment

By J.D. Harrison, July 19, 2012

The health-care reform law is accelerating a shift away from private practices as doctors, fearful of new costs and regulations, “run for cover” under the protection of large hospitals.

During a hearing before the House Small Business Committee on Thursday, health-care professionals explained that the shift has already been picking up momentum in recent years, driven largely by growing regulatory and administrative burdens, rising malpractice costs and declining reimbursements from insurers — all of which they say have hit small practices especially hard. Consequently, doctors are shying away from the traditional solo practitioner model in favor of employment at large hospitals, which amid constant industry changes, can provide more financial security and take responsibility for keeping up with new regulations.
ACOs—Process vs. Policy

- Conflicts of interest
- Certification trail
- Waivers
- Mechanisms to report probable violations of the law
- Compliance Officer and Board reporting
ACOs—Process vs. Policy

- Inducements for healthy behavior
- Marketing materials
- Patient freedom of choice
- Patient access
- Record retention
Medicaid RACs

- Massive defense
- Time consuming appeals
- Revenue challenges
- Competing guidance
- Case managers involved
Medicaid RACs

- Audit staffing challenges
- Skill set changing (clinical and IT)
  - Data analytics and historical patterns
  - Data mining skills
  - EMR templates
- Risk based audits
Takeaway Compliance Strategies

- Invest in Compliance Resources
  - Review and update policies and procedures
  - Assess Compliance Program
  - Training and education
  - Internal controls
  - Evaluate auditing and monitoring – past and current practices
  - Involve leadership
  - Culture of no retaliation

Be Proactive!
Takeaway Compliance Strategies

- Address possible new FCA exposure
  - Understand risk of whistleblowers
  - Evaluate internal investigation processes
- Auditing of overpayments
  - Verification steps
  - Reporting obligations
- Assess billing practices

Be Proactive!
Takeaway Compliance Strategies

- Determine your growing patient base and needs
- Get involved in new arrangements
- Reevaluate HIPAA privacy and security plans, and amend business associate contracts
- Scrutinize physician relationships
- Do your own data prospecting

Be Proactive!
Thank you.
Questions?

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