The Road Ahead and How to Navigate It

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Agenda

- General environment
- PPACA provisions
- Increased enforcement
- New arrangements
- Electronic health records
General Environment

• National debate over health care reform
  • Patient Protection and Affordable Care Act ("PPACA") passed March 2010
  • Some regulations have been issued
  • House held a symbolic vote to overturn reform
• Increased enforcement actions and recovery
  • Government is touting the financial recoveries
• New regs will drive ACOs and other new arrangements

PPACA PROVISIONS
PPACA

• 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

60 day report and repay provision
  – Healthcare providers that identify overpayments from government programs can violate the FCA if they don’t report and repay within 60 days
  – Even if they received an overpayment innocently
**PPACA**

- 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

**PPACA**

- 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
**PPACA**

- **Expanded RAC Activities**
  - RAC audits of providers increased and expanded to Medicaid, Medicare Part D and Medicare Advantage programs
  - Medicaid RAC audits will be separate from the Medicaid integrity program (MIP) audits that are already being completed by Medicaid integrity contractors (MICs) in many states

**PPACA**

- **Fraud and Abuse**
  - Healthcare Fraud Criminal Statute and US Sentencing Guidelines amended
  - Expansion of administrative penalties, including exclusion
  - Gov’t has new resources, including expanded subpoena power and additional funding
INCREASED ENFORCEMENT

Increased Enforcement

• Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative will gain more momentum
  • Has been promoted by Attorney General Holder and HHS Secretary Sebelius
• Summits
Increased Enforcement

- FBI has 800 people employed to combat health care fraud
- OIG now has 400 agents focusing on health care cases
  - Will grow to 550 by Fall of 2011

Increased Enforcement

- Government reported that it recovered $4 billion in its fight against healthcare fraud last year
- HCFAC received $266.4 million in mandatory appropriations from its fraud fighting efforts, plus an additional $311 million in discretionary funding
  - ROI since 1997=$4.90 for every $1 expended
  - 3 year ROI average from 2008-2010 was $6.80 for every $1 expended
Increased Enforcement

- The government will need to pursue large entities to replicate their unprecedented financial recoveries
- Providers and suppliers should fortify their compliance efforts to proactively find and remedy mistakes

Increased Enforcement

- HIPAA Enforcement Activity Increasing
  - $4.3 million fine against Cignt Health
  - $1 million settlement with Massachusetts General Hospital
  - States are active in issuing fines for data security breaches
Hospital relationships with physicians

- Look for the government to take a harder line against physicians who are parties to challenged relationships
  - $30 million settlement with Detroit Medical Center regarding leases and independent contractor arrangements that were allegedly either not at FMV or not memorialized in writing

Implantable Cardiac Defibrilators

- The Department of Justice is conducting an ongoing multi-state, multi-provider investigation into billing compliance relating to hospitals’ provision of Implantable Cardioverter Defibrillators (ICDs) and related services
  - It is the most widespread known healthcare investigation at the moment
**Implantable Cardiac Defibrilators**

- DOJ has sent highly detailed and extensive Civil Investigative Demands (CIDs) and more general demands to hospitals and health systems.
- A key area of interest is the timing of the ICD implantation.
  - For example, Medicare does not cover implantation of ICDs in patients who lack a history of arrhythmia if the implantation occurred within a certain period of time after specific cardiac events or procedures.

**Implantable Cardiac Defibrilators**

- RACs have identified implantation and interventional cardiology DRGs as issues for review.
- The OIG has issued CIDs and letters related to ICDs.
Observation vs. Inpatient Admission

- OIG continues to review Medicare Part B payments for outpatient observation services
- Government settled a voluntary disclosure matter on observation vs. inpatient admission for $3.3 million

Data Prospecting

- There will be more predictive modeling for questionable claims patterns
  - Government is using data to decide where to mine for fraud
  - Providers may see their reimbursement put on hold
  - PPACA allows the government to suspend payments pending credible allegation of fraud
Medicaid Enforcement

- Medicaid enforcement is picking up across the country
- States were required to have contracted with Medicaid RACs by the end of 2010; implementation postponed

NEW ARRANGEMENTS
Accountable Care Organizations

• ACOs are a new model for delivering health services that offers doctors and hospitals financial incentives to provide good quality care to Medicare beneficiaries while keeping down costs
  • PPACA- January 2012

Accountable Care Organizations

• The Congressional Budget Office estimates that ACOs could save Medicare at least $4.9 billion through 2019
• On March 31, 2011 CMS released proposed ACO regulations
• Simultaneously, the FTC/DOJ, IRS and OIG issued guidance regarding how they will regulate ACOs
What’s in the Proposed Rule

• What is an ACO?
  – Eligible entities
  – Legal structure
  – Governance
• Beneficiary Assignment & Opt Out
• Risk-Sharing
• Quality Reporting and Performance Measurement

What’s in the Proposed Rule (continued)

• Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting and Coordination of Care
• Patient Centeredness Criteria
• Program Integrity Requirements
ACO’s: Other Agency Guidance

- CMS/OIG – Seeking comments regarding possible waivers of Anit-Kickback Statute, Stark Law and Civil Monetary Penalties Law
- FTC/DOJ – Antitrust enforcement policy for ACOs
  - Safety Zone – less than 30% combined share of services in each ACO participant’s Primary Service Area
  - Mandatory Review – greater than 50% combined share of services in Primary Service Area
  - Gray Area – between 30% and 50% combined share of services
- IRS – Seeking comments regarding whether guidance is needed for tax-exempt organizations

Service Line Co-Management Model

- Interested physicians with the ability to effect change and the Hospital form a management company to manage the day-to-day operations of the entire orthopedic/cardiovascular/oncology service line of the Hospital.
- Among other things, the management company will be responsible for:
  - the development of the strategic plan and operating and capital budgets for the orthopedic/cardiovascular/oncology service line, and
  - management oversight of the staffing, equipment, and supplies for the orthopedic/cardiovascular/oncology service line.
Service Line Co-Management Model

– The physicians and the Hospital will hold appropriate equity interests in the management company. The physician investors and the Hospital will each hold one-half of governing power of the management company board.

– While certain material business decisions must be subject to final approval by the Hospital board (to meet certain regulatory requirements), the management company develops the fundamental operating policies for and oversees the day-to-day operations of the hospital’s orthopedic/cardiovascular/oncology service line.

Service Line Co-Management Model

– The Hospital pays the management company a fair market value fee for management services.

– An independent compensation consultant is retained to confirm that the proposed compensation arrangement is consistent with fair market value for the management services rendered.
Service Line Co-Management Model

–Usually one-half of the fee is fixed and one-half is based upon meeting certain performance standards for:

–quality (e.g., SCIP/AMI/CHF core measures, surgical care infection prevention, post-procedure complication rate, readmission rates, correct implant/device usage, patient satisfaction, development of care pathway protocols), and

–efficiency (e.g., operating room/cath lab turnaround time, on time starts, number of cancellations/appropriate block scheduling).

ELECTRONIC HEALTH RECORDS
EHR

- American Reinvestment and Recovery Act (2009) contained provisions to encourage electronic health record (EHR) adoption and health information exchange (HIE)
  - Allocates $44.7 billion to Medicare and Medicaid EHR Incentive Program
  - Provides 100 percent Federal funding for incentive payments to participating providers

EHR

- Incentive payments to eligible professionals and hospitals to become “meaningful users” of electronic health record (EHR) technology
  - In 2015, the incentives turn to penalties by way of reduced Medicare reimbursement if “meaningful use” is not demonstrated
EHR

Achieving Meaningful Use | Concerns with Meaningful Use
---|---
• Providers must use Federally-certified EHR system software and annually report clinical quality measurements specified by CMS. | • Providers will need to upgrade to Federally certified systems and first attest and then demonstrate meaningful use.

• First year: Medicaid and Medicare eligible providers attest to series of questions that capture data and results of clinical quality measures. | • Requires providers to collect structured data consistently and to reporting quality measures.

• Subsequent years: Medicaid and Medicare eligible providers demonstrate meaningful use by submitting electronic data. | • Providers may not be able to demonstrate meaningful use in the future.

EHR

• Risks and Challenges
  • CMS at risk for making erroneous payments to Medicare providers and state Medicaid agencies, states at risk for Medicaid provider payments
  • Providers at-risk for attesting to eligibility and receiving payments in error
  • State and Federal agencies charged with developing methods to monitor and identify fraud and abuse
EHR

- Prepare for Unintended Consequences
  - EHRs change how clinicians practice -- they can cause complacency
  - EHR coding errors can cause patient care errors
  - Templates and macros can lead to imprecise wording in records

Thank you.
Questions?

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