**Health Care Compliance Association**
**Gulf Coast Regional Annual Conference**
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## Health Care Reform Compliance Enforcement Ahead

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## Agenda

- Compliance Environment
- New compliance challenges under health care reform
- Compliance land mines associated with new initiatives
- Auditing and monitoring tips to address these new challenges and initiatives

## Compliance Environment

- Office of Inspector General Semiannual Report to Congress
  - Summary of activity for 6 month period ending September 30, 2011
  - OIG Recommendations to improve HHS programs
    - Investigated fraud and abuse
    - Executed enforcement actions
    - Offered industry stakeholders new compliance training
  - Technology has a tremendous potential to enhance OIG program integrity
    - Data mining
    - Predictive analytics
    - Trend evaluation and modeling

## Compliance Environment

- Office of Inspector General Semiannual Report to Congress
  - Technology provides OIG with analytical foundation to build upon and improve
    - Enterprise view of activities
    - Trends
    - Patterns
    - Predictive analytics
    - Prevention opportunities
  - Traditional approaches
    - Conducting reviews and investigations

## Compliance Environment

- Office of Inspector General Semiannual Report to Congress
  - Summary of Fiscal year 2011 Accomplishments
    - Expected recoveries of $5.2 billion
      - ❖ $627.8 million in audit receivables
      - ❖ $4.6 billion in investigative receivables
    - $19.8 billion in savings estimated for FY2011 as a result of legislative, regulatory or administrative actions that were supported by OIG recommendations

## Compliance Environment

- Office of Inspector General Semiannual Report to Congress
  - Summary of Exclusions
    - 2,662 individuals and entities from participation in Federal health care programs
    - 723 criminal actions against individuals or entities that engaged in crimes against HHS programs
    - 382 civil actions, which included false claims and unjust-enrichment lawsuits filed in Federal District court, civil monetary penalties, (CMP) settlements, and administrative recoveries related to self disclosure matters

## Compliance Environment

- Office of Inspector General Semiannual Report to Congress
  - HEAT: Health Care Fraud Prevention and Enforcement Action Team
    - Medicare Fraud Strike Force Teams
  - Prescription Drug Investigations
  - Medicare Part A and Part B Reviews and Enforcement Actions
  - Medicaid Reviews

## New Payment Initiatives

## New Structure/Payment Initiatives

- ACOs / Shared Savings Programs
- Medical Homes
- Global Payments / Bundled Payments
- Quality Measures
- Value Based Purchasing

## Accountable Care Organizations/Shared Savings Programs

- Coordination and cooperation among providers to improve the qualify of care and reduce unnecessary cost
- Designed to improve beneficiary outcomes and increase value by:
  - Promoting accountability for the care
  - Requiring coordinated care for all services
  - Encouraging investment in infrastructure and redesigned care processes

## Medical Homes

- An approach to providing comprehensive primary care that facilitates partnerships between individual patients, and their personal providers, and when appropriate the patients family
- Purpose is to provide better access to care and increase satisfaction with care and improve health

## Global Payments/Bundled Payments

- Process of one payment for a service or combination of services, provided by a group of health care providers

## Quality Initiatives

- Measures of health care quality that make use of readily available hospital inpatient administrative data.
- Readmissions Reduction Program
- Includes:
  - Prevention Quality Indicators
  - Inpatient Quality Indicators
  - Patient Safety Indicators
  - Pediatric Quality Indicators

## Value Based Purchasing

- Improve clinical quality, make appropriate use of services, focus on patient-centered care, decrease adverse events, improve patient safety, avoid unnecessary costs, and make performance results transparent and usable by consumer
- Focus on value, outcomes and innovations instead of basing payment on merely volume
- 1% reduction in DRG Payments to be earned back through quality scores

## Why New Initiatives?

- Medicare program insolvency
- State budget limitations
- Cost reduction
- Improve quality of care
- Coordination of care among providers to control costs
- Promote preventative health care
- Gain competitive edge

## Compliance Landmines

## Compliance Landmines

- ACOs / Shared Savings Programs
  - Antitrust
  - Stark / Kickback
  - Quality and Clinical Issues
- Medicare Requirements
  - CMS will grant Stark, Anti-Kickback and Civil Monetary Penalty Waivers to ACOs participating in the Shared Savings Program.

## Compliance Landmines

- Medicare Requirements (Continued)
  - Waivers are narrow and apply only to:
    - Shared savings distributions to or among ACO participants; and
    - Activities necessary for and directly related to participation in the Shared Savings Program.
    - Waivers from the Anti-Kickback and Civil Monetary Penalty Statute will be granted for other financial relationships only if the other relationship fits within a Stark exception.
  - Accordingly, ACO relationships (such as ACO/Physician relationships and capitalization of the ACO) will have to be carefully structured to comply with Stark.

## Compliance Landmines

- Medical Homes
  - Stark/Kickback Issues
  - Relationships among providers
- Global Payments/Bundled Payments
  - Structure/Payment Issues (Contractual; PHO; Other)
  - Gain sharing
  - Licensing/Insurance
  - Financial Risk – who takes the risk?

## Compliance Landmines

- Quality Measures
  - Reverse kickback
  - LOS payments
  - Inducements to reduce care
  - False claims for poor care
- Value Based Purchasing
  - Data reporting – credibility of information (Clinical process measures, patient experience and mortality(2014))
  - Physician services – satisfaction of patients
  - Financial – Medicare = 2% reduced payment by FFY 2017
  - Staffing/Monitoring of quality indicators
  - IT infrastructure

## Auditing and Monitoring

## Auditing Issues – General

- Does current compliance plan cover new initiatives?
- Separate compliance plan and policies may be needed or required
- Does current compliance training program address new initiatives?
- Do existing contracts need to be modified?
- Do new provider relationships need to be documented? If so, how?
- Are quality measures being audited and monitored?
- Are new financial arrangements supported as FMV?
- If part of a government sponsored program (Medicare ACO or demonstration project), is the organization "following the rules"?

## Auditing Issues – VBP/Quality

- Validation reviews for VBP data submissions
- Quality data submitted – Has it been reviewed by hospital and documentation maintained?
- What procedures are being performed to internally test?
- Can the quality measure data elements be recreated under audit?
- Must meet a correlation of at least 75% for data to be considered reliable.
- Risk – Loss of 2% add on payment
- Can hospital afford not to comply with new requirements?
- Who is responsible for maintaining clinical measures?
- What department or area within the hospital will measurement and maintenance of data fall under?
- How will this information be communicated to the compliance officer and committee

## Auditing Issues – ACOs

- Was the ACO set up correctly?
- Are the participants of the Governing Board in compliance with the requirements of the structure?
- How is the organization monitoring its process compared to the application submitted to organize the ACO?
- Is the ACO following the structure outlined in the ACO application?
- Have state licensure issues been evaluated, checked, and monitored?
- How will the organization monitor validation of Quality Assessment and Performance Improvement (QAPI), including performance standards?
- What practices are in place to monitor patient centered care?
- What procedures and documentation are in place to monitor the treatment of at risk beneficiaries?

## Auditing Issues – ACOs

- Did the ACO get its marketing materials approved by CMS? Documentation maintained? Where? By whom?
- How do the participants in the ACO publicize their participation? Are signs posted in noticeable places in the organization?
- Has the ACO communicated to CMS changes in legal structure, sanctions or investigations by regulatory agencies?
- Contracts with others – Do all contracts include a requirement to adhere to the terms of the ACO with CMS?
- Have the antitrust issues been analyzed? Complied with?

## Auditing Issues – Medical Home

- How are patients' physical and mental health care needs met?
- What is the structure of the medical home? Suite of providers affiliated with one another? Suite of providers operating in a virtual team of care providers?
- What is the relationship between the acute care provider and the medical home?
- Who pays for the infrastructure of the medical home? Are there any issues with the payment for infrastructure? Inducement? Referrals?
- Is the payment for coordinating patient care in line with the services provided?
- Are there any unwritten agreements with providers of services?
- Are the payments in line with the patients best interest and at fair market value related to other payments of this nature?
- Have contracts with payers who are sponsoring the Medical Homes been reviewed? Has the review been documented?

## Questions?

## How to Contact Us

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