1. Current Issues and Trends
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- Penalty levels increased in FCA
  - Will be reflected in state Acts that track the federal FCA
  - Will keep interest up in all FCA suits
    - February 3, 2017
      - $10,957 to $21,916 (up from $10,781 to 21,563)

- Focus on Individual Accountability
  - Yates Memo
  - Park Doctrine

  - Will be reflected at state level, especially in state cases jointly shared with federal government

  - Still in force despite change in administration
  - Memo to USDAG employees – DOJ will engage in six steps aimed at assuring “individual accountability” for corporate wrongdoing including:
    - Focus on actions of individuals in criminal and civil investigations
    - Denying release of liability to individuals when corporation settles
    - No resolution / settlement with corporation without considering individuals and their roles
1. Current Issues and Trends

- **Park Doctrine**
  - Series of FDA warning letters
  - Any person having "responsible share in furtherance of [illegal] transaction" can be criminally or civilly liable
  - Executives potentially liable for actions of companies
    - Even if they did not participate in transaction, or even know of it
  - Corporate integrity agreements (CIAs) requiring companies to recoup executive bonuses in event of violation

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1. Current Issues and Trends

- **Government interest – increased and sustained**
  - DRA incentive for whistleblower laws – OIG approvals continue
  - New administration has affirmed its ongoing interest in fighting healthcare fraud

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1. Current Issues and Trends

- Increased interest by whistleblowers in “smaller” players
  - Nationally, the “big” rebate, marketing cases are declining
  - Whistleblowers & their lawyers are looking towards new players and new theories
1. Current Issues and Trends

- Increased interest by whistleblowers in "smaller" players
  - Hospital systems
  - Nursing home chains
  - Pharmacies, PBM, etc.
  - Regional targets

- Increased interest in theories that were previously considered difficult to maintain
  - Lack of medical necessity
  - Failure of care / worthless services

- Increased state activity in federal whistleblower cases
  - Concurrent with heightened interest in regional & smaller defendants
  - Increased state sophistication in qui tam practice
    - Interventions, litigation
1. Current Issues and Trends

- Predictive analytics
  - More than data analysis
  - Examples
    - Pattern detection
    - Comparison to other sources of information
    - Comparison to social media
    - "Link analysis" – people, claims, locations, associations

- 60-day overpayment rule
  - ACA: Provider must repay overpayment within 60 days of "identifying" the overpayment
  - Applies to Medicaid overpayments
  - Combined with "reverse false claims" theory, this can provide another avenue for a state to assert liability against the provider
  - Reverse False Claims: Knowingly avoiding an obligation to repay

- Managed care
  - Losses often shared between MCO and FFS
  - Many Medicaid programs heavily utilize MCO
    - 73.5% of Medicaid beneficiaries received managed care in 2013
  - Claims submitted to MCOs for government programs are clearly within the ambit of claims to the government under federal FCA (2009 FERA amendments to fix "Allison Engine") and state FCAs that are analogous
1. Current Issues and Trends

- Managed care
  - Data acquisition and enforcement issues
    - Acquiring data from diverse systems
    - “Putting the horse back in the barn”
  - Calculation of damages can present a challenge
  - State contracts with MCO are being revisited
    - Enforcement, oversight, data provisions
  - States are leading in collection of MCO damages

1. Current Issues and Trends

- Managed care
  - CMS 2390-F Final Rule imposes requirements on states contracting with MCOs
    - Submission of encounter data, as well as sufficiency and format
    - Fraud management procedures
    - Screening of network providers

1. Current Issues and Trends

- Expansion of Medicaid population
  - Including numbers of enrollees, types of coverage
1. Current Issues and Trends

• Greater whistleblower awareness

1. Current Issues and Trends

• Closer scrutiny of the status of providers’ employees
  ○ Licensure
  ○ Status to work in the U.S.
  ○ Exclusion

1. Current Issues and Trends

• Opioids
  ○ Declared “crisis” by FDA
  ○ Rescheduling of some Hydrocodone products
    • III -> II
  ○ Greater scrutiny by states
    • Manufacturer behavior, diversion, etc.
2. Legal Landscape

- Escobar fallout in state court
  - Escobar and its progeny will be persuasive in states whose FCAs closely match the federal one
  - Battlegrounds will likely be similar to those in federal court – “materiality”
    - Agency decision-making, discussions
    - Claims payment / denial history
    - Notice to agency / other agencies of actual fraud
    - Nature and specificity of the claim submitted

3. Protecting Yourself and/or Your Clients

- Understand what’s being reviewed
  - Higher billings (on adjusted basis) than neighbors or norms
  - Higher-than-expected acuity or E&M levels
  - Conflicts with other providers
    - Such as home health when client is in hospital
3. Protecting Yourself and/or Your Clients

- Understand what’s being reviewed
  - High rejection or recoupment rates
  - Complaints from beneficiaries
  - Data mining
  - Medically necessary v. routine practice

- Kickback evidence
  - Relationships between entities
  - Payments and how they are characterized
  - Other benefits – staff, grants, etc.

- Stark evidence

3. Protecting Yourself and/or Your Clients

- Provide, require, and document employee training
  - Coding
  - Compliance

- Benefits include better output and greater credibility
- Efforts to understand coding do have weight with government
3. Protecting Yourself and/or Your Clients

- Understand specific program rules
  - Medicare rules may not translate to other programs
  - Obtain and review manuals and bulletins on regular basis

- Call the programs with unresolved questions
  - Documents your code choice
  - Helps document good faith
  - Question might be answered!

- Check status of licensed employees on a regular basis
  - Include within your SOPs
  - Check name variations
  - Include new employees, current employees, contractors, etc.
  - Include federal databases and state licensure agencies
  - Avoid hiring sanctioned persons in any role
### 3. Protecting Yourself and/or Your Clients

- **Document heavily**
  - Times
  - Medical necessity
  - Levels of intervention / involvement

- **Screen your documentation**
  - Compare caregiver documentation to other information
  - Watch for excessive care, high codes, etc.
  - Look for forms signed in blank
  - Ensure proper staffing levels and qualifications

- **Be cognizant of after-the-fact adjustments**
  - Example: Found out later that client was hospitalized
  - Example: Employee license expired but salary was included in cost report
3. Protecting Yourself and/or Your Clients

- Be aware of deadlines for returning funds
  - PPA / ACA imposes 60-day limit
  - Relates to “reverse false claims”

- Encourage self disclosure
  - Very likely to be better received by government
  - Provides evidence that a good compliance program is in place
    - Government programs likely to consider lower damages multipliers, etc.
    - May reduce the likelihood of a CIA
  - More consistent with an ethical environment
  - Can impact relators’ success against company
  - Can potentially reduce relators’ recoveries

- Institute your own Corporate Integrity Program
  - Make sure your audits include compliance with rules, codes
  - Maintain awareness of prior issues, denials
  - Document the measures taken
  - Do follow-up audit after a time period
  - Avoid allegations of repeating same mistakes