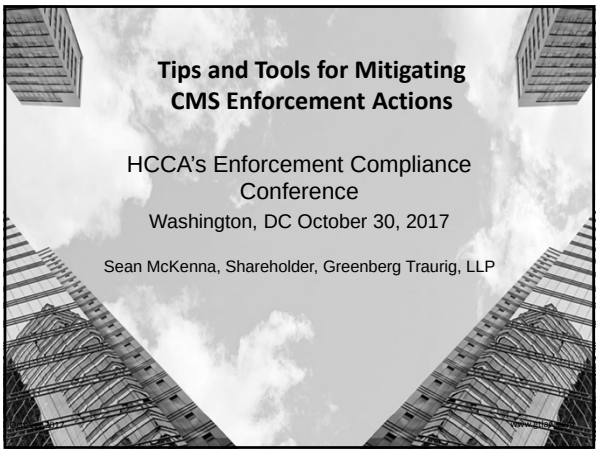


Overview

- Enforcement Agenda
- Underlying CMS Actions
- Responding to CMS and Investigations
- Takeaways from Enforcement Actions
- Conclusions

Enforcement Outlook in 2017

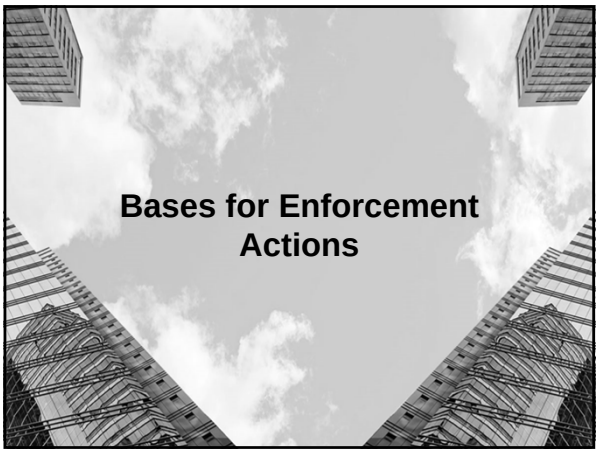
- Federal and State health care budget shortfalls
- Perception that fraud due to quality deficiencies/opioid abuse is rampant
- More state and federal enforcement officials investigating quality of care issues
- New reimbursement models increasing misconduct allegations
- Greater collaboration DOJ, CMS, and States use of data analytics will continue to drive enforcement
- Increased focus on individual executives and clinicians
  - *See* Yates Memorandum

Recent DOJ Activity

- DOJ recovered more than $4.7 billion in FY 2016
  - Up from FY 2015 $3.8 billion recovery
  - ROI for the Health Care Fraud and Abuse Control Program $6 returned for every $1 expended
- Continues 4-year record of recoveries over $3 billion
- Of $4.7 billion –
  - $2.5 billion from health care industry, including $330 million from hospitals
  - $2.9 billion (more than half) from cases filed by whistleblowers under FCA
- Number of qui tam suits exceeded 700
  - Up from FY 2015 600
  - But way up from 1987's 30
  - Whistleblowers received $519 million

DOJ's Yates Memorandum

- Yates Memo (9/9/2015): "Individual Accountability for Corporate Wrongdoing"
- Emphasizes DOJ's commitment to combat fraud "by individuals."
- Recommends:
  - Not to give cooperation credit unless company provides facts re: individuals
  - To focus investigations on individuals "from the inception"
  - Not to release "culpable individuals" from liability absent "extraordinary circumstances"
  - Not to settle with company without "clear plan to resolve related individual cases"



False Claims Act

- A false claim or statement for payment to the United States, 31 U.S.C. § 3729(a)
  - Conspiracy
  - "Reverse" false claims is the knowing retention of a known overpayment
  - Failure of care violations
- Claim must be submitted "knowingly"
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard
  - No specific intent to defraud required
- Other state/federal law violations may be bases for liability

FCA, cont'd.

- Six-year statute of limitations
  - Three years from date material facts are known or reasonably should be known by responsible official
    - DOJ is the official, not agent
  - Not more than 10 years after the violation
- Remedies
  - Damages not required
  - If found liable, mandatory treble damages and penalties
  - Attorneys' fees and costs
- Increased penalties for violations after Nov. 2, 2015
  - Minimum per claims penalties: $10,781 from $5,500
  - Maximum per claim penalties: $21,563 from $11,000

Escobar: Key Supreme Court Case

- *Universal Health Servs., Inc. v. U.S. ex rel. Escobar,* 136 S. Ct. 1989 (2016)
  - Unanimous decision
  - Implied certification can be a basis for liability under certain circumstances
  - Allowed implied certification BUT relied on whether "material" to payment decision
  - Courts continue to parse Escobar regarding materiality requirement

Civil Monetary Penalties Law

- HHS-OIG administrative remedy, 42 U.S.C. § 1320a-7a(a)
  - Permissive exclusion and civil monetary penalties for specific violations like quality or failure of care
- Mirrors FCA but not governed by civil rules of procedure or evidence
  - Limited discovery
  - Hearsay admissible
- OIG usually releases this authority in exchange for compliance obligations

HHS-OIG's Exclusion Authority

- Exclusion only apply to misconduct from the past 10 years
- Early Reinstatement Process
- Aggravating Factor Threshold Elevated
  - Amount will have to be at least $50,000 in several scenarios
- Mitigating Factor for Exclusions
  - Patient access to care significantly harmed by exclusion
- Audit Obstruction Policy

Challenges Facing CMS

- CMS mission to protect patients, ensure quality services, and preserve public fisc
- Medicare has currently:
  - 7,300 participating hospitals
  - 1.5 million enrolled physicians (plus extenders)
  - 4 million claims submitted daily
- Estimated 11% of all fee-for-service payments improper
  - Medically unnecessary items and services
  - Does not include Stark and kickbacks violations
  - Estimated $41 billion annually in improper payments
- Uncertainty of reimbursement under ACA or successor legislation
- Appeal backlogs impacting provider's ability to deliver care to patients

Initiatives and Trends

- Recent CMS quality of care initiative addresses:
  - Hospitals
  - Nursing homes
  - Physicians and clinics
  - ERSD care
  - Home health
- Use of data analytics and sets to increase quality and lower costs
- Reliance on demonstration projects and contractors
- *See* https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html

Initiatives and Trends, cont'd.

- Movement away from fee-for-service to bundled payments
- Increased post-payment review, suspensions, and coverage denials to lower costs and ensure quality
- Support of medical necessity cases under the FCA
  - National skilled nursing chain paid $53.6 million to resolve FCA *qui tam* lawsuits alleging false claims for medically unnecessary hospice and therapy services and materially substandard care
  - Evidence of illegal kickbacks through an evaluation of medical necessity of items or services

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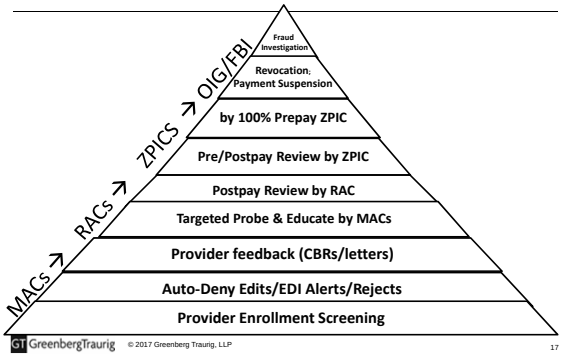
CMS Reviews



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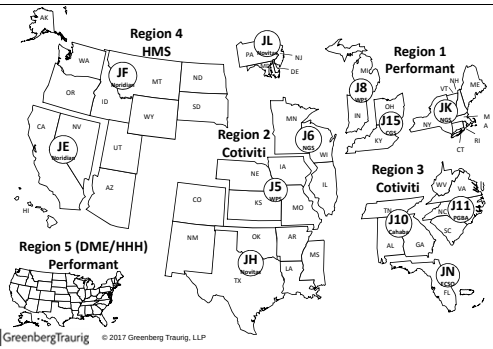
New Recovery Audit Contractors



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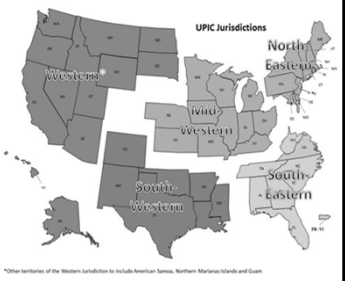
Unified Program Integrity Contractor

- The purpose of the UPIC is to:
  - Coordinate provider investigations across Medicare and Medicaid;
  - Improve collaboration with States by providing a mutually beneficial service; and
  - Increase contractor accountability through coordinated oversight.



*Other territories of the Western Jurisdiction to include American Samoa, Northern Marianas Islands and Guam

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Current Status of UPICs

- Midwestern Jurisdiction – awarded to AdvanceMed Corporation
- Northeastern Jurisdiction – awarded to SafeGuard Services, LLC
- Western Jurisdiction - currently under protest
- Southeastern Jurisdiction – currently under protest
- Southwestern Jurisdiction – scheduled to be awarded by the end of FY2017

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Possible Outcomes

- Suspension of payments
- Termination from programs
- Civil recoveries from responsible parties
- Criminal convictions and restitution
- Exclusion/debarment/revocation
- Licensure actions
- Compliance or integrity obligations
- Private litigation
- *Cost of responding*
- *Loss of business/goodwill/morale*

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Sources of Investigative Cases

- Partnering by enforcement agencies
- Data mining
- Initiatives, working groups, and task forces
- Competitor complaints
- Patient/family complaints
- Self-disclosures
- Whistleblowers
- Social media
- Traditional media

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Internal Investigations 101

- Tracking all reports/assessments
- Documenting investigation plan
- Preservation of information
- Protections to ensure confidentiality
- Conducting investigation
- Determining scope of disclosure
- Reporting of conclusions/findings to appropriate parties
- Corrective actions for responsible persons/departments
- Discipline of bad actors
- Non-retaliation reinforcement
- Taking remedial measures (repayment or disclosure)

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Common Internal Investigation Triggers

- Hotline calls
- Reports to management or compliance
- Vendor communications
- Departing employees
- Industry rumors
- News articles
- Subpoenas or other government requests
- Government interviews of employees or related parties
- Private litigation

Risk Areas, cont'd.

- Clinical visits and documentation
- Referral to ancillaries for:
  - Pharmaceuticals
  - Laboratories services
  - Therapy
- Physician conflicts of interest
  - Directorships, space, and equipment rentals
- Lack of operational and clinical integration among locations
- Locum tenens and leased/temporary staff
  - Continuity of care issues
- Survey and certification deficiencies
  - Results in private litigation and federal investigations

Working to Develop a Response

- Identify potential quality of care and potential misconduct
  - Factual vs. legal
- Leverage internal/external resources
- Locate responsible individuals
  - Initial targets
  - May change
- Steps to be taken:
  - Document preservation and collection
  - Gather information
  - Review and research deadlines and projects
- Reassess if known government action or timelines
- Implementation and monitoring of corrective and remedial actions

Handling Repayment and Disclosure

- FIRST fix any problems
- Federal law requires repayment of known Medicare/Medicaid overpayments within 60 days
  - CMS issued final rule at 77 Fed. Reg. 9179 (Feb. 16, 2016)
- Disclosure to DOJ
  - Possible non-prosecution of business entity
    - *See* USAM § 9-28.000, *et seq.*
  - Limited civil FCA multiplier
    - *See* False Claims Act § 3729
- HHS-OIG Self-Disclosure Protocol
  - Lower damages/no integrity obligations
- CMS Voluntary Self-Referral Disclosure Protocol
  - Do not disclose both to CMS and OIG
  - Use OIG protocol if implicates other laws

Dos and Don'ts of Corrective Action

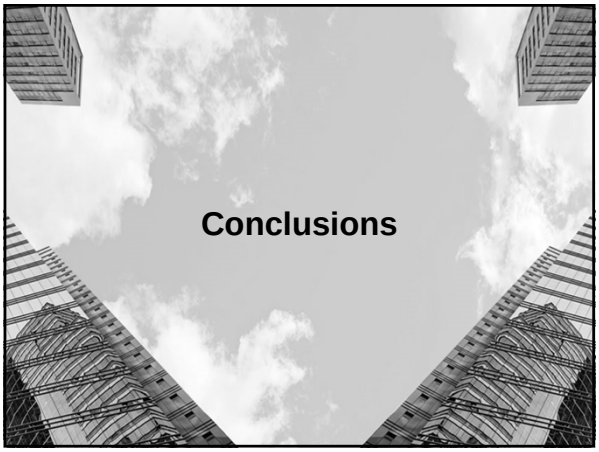
- Who best can communicate the plan
- Target high-risk areas
  - Monitoring
  - Auditing
  - Admissions in CAPs could lead to other problems
- Disciplinary actions
- Training
- Policy revisions
- Corrective communications
- Culture adjustments
- Monitoring and implementation
- *Evidence of the Above?*

Dos and Don'ts, cont'd.

- Implement an effective corrective/compliance program
- Notify insurance coverage
- Evaluate ALL liability
  - Criminal
  - Civil
  - State and federal administrative
  - Licensure
  - Private
- Overall strategy has implications for all the foregoing

Dos and Don'ts, cont'd.

- Preserve documents
  - Scope of hold notice
  - Beware of ramifications of company-wide notices
- Protect privileges/protections
  - Critical given current case law
- Compile right team
  - Consultants
  - Clinical and billing
  - Statisticians
- Communications with regulators
  - Early and often



Compliance Matters

- If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place

Resources for Enforcement Information

- Advisory opinions
- Published cases
- OIG Compliance program guidance publications
- State and federal work plans/audits/evaluations
- Settlement/integrity agreements
- Press releases
- GAO reports
- Comments/preambles to safe harbors/exceptions

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Questions?

Sean McKenna, Shareholder

- Former Assistant U.S. Attorney, Attorney with U.S. Office of Counsel to the Inspector General for HHS and U.S. Department of HHS, Office of General Counsel
- mckennas@gtlaw.com
- 214.665.3617