Today’s Agenda

• Enforcement Update – 2018 and Beyond
• Compliance Today
• Effectiveness
• Selling Compliance
• Conclusion
Enforcement and Compliance Update

Enforcement Outlook in 2018

- Federal and state health care budget shortfalls
- Perception that fraud is rampant
- Payor actions
- New reimbursement models increasing referral “tensions”
- New DOJ guidance
- Use of data analytics will continue to drive enforcement
- Investigation and prosecution of medical necessity
- Continued increased focus on individual actors
Outlook, cont’d.

OIG Work Plan recently released updates regarding new initiatives including:
• Medicare Part B Claims for Telehealth Services
• Medicaid Claims for Opioid Treatment Program Services
• Medicare Payments for Unallowable Home Health Services
• Medicare Payments for Unallowable Hospice Claims
• Medicaid Coverage and Reimbursement of Specialty Drugs
• Medicare Payments for Bariatric Surgery

Enforcement Players

• Department of Justice
• Local District Attorneys
• States Attorneys General
• Offices of Inspector General - Federal and State
• Medicaid Fraud Control Units
• Centers for Medicare & Medicaid Services

• Medicaid State Agencies
• Tricare Management Authority
• Federal/State Contractors
• Commercial Payor “Special Investigative Units”
• Licensing Boards
• Whistleblowers
Recent DOJ Activity

- As of May 31, 2017 the Medicare Fraud Strike Force has recovered more than $2.5 billion in FY 2017
  - 1,791 criminal actions
  - 2,326 indictments
- DOJ recovered more than $4.7 billion in FY 2016
  - Up from FY 2015’s $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 healthcare 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’s 600
  - Way up from FY 1987’s 30
  - Whistleblowers received $519 million

Current Administration Agenda

DOJ has stated it will continue the previous administration’s stance on Corporate Misconduct:

- The department will continue to investigate and prosecute individual wrongdoers for corporate misconduct
- The federal government will “not use criminal authority unfairly to extract civil payments”
- BUT new guidance recently issued could limit enforcement
  - See Granston and Brand memos
DOJ’s Yates Memorandum

- Issued September 9, 2015
- “Individual Accountability for Corporate Wrongdoing”
- Emphasizes DOJ’s commitment to combat fraud “by individuals”
- Purposes and Benefits:
  - Proper parties are held responsible for their actions
  - Results in a change of corporate behavior
  - Serves as a deterrent to future fraudulent behavior
  - Increases public confidence in the justice system
  - Increases consistency in handling outcomes of federal investigations

Granston Memo

- Leaked and dated January 10, 2018
- Michael D. Granston, Director DOJ Commercial Litigation Branch
- Addressed to all AUSAs handling False Claims Act cases
- Dismissal under FCA section 3730(c)(2)(A)
- Increase in *qui tams*, but not DOJ resources
- 7 “Granston Factors”
Brand Memo

- January 25, 2018
- “. . . the Department may not use its enforcement authority to . . . Convert agency guidance documents into binding rules.”
- Example: Definition of “reasonable and necessary”
- United States ex. Rel. Polukoff v. St. Mark’s Hospital
- Uncertain future for HHS-OIG Advisory Opinions in FCA and criminal cases

Escobar: Key Supreme Court Case

- Allowed implied certification BUT relied on whether material to payment
- Unanimous decision
- Implied certification can be a basis for liability under certain circumstances
- Courts continue to parse Escobar regarding materiality requirement
  - Circuit splits have developed
Compliance Investigations

Risk Areas

- False or fraudulent claims
  - Billing for items or services not rendered
    - Upcoding and product substitution
  - Misrepresenting nature of items or services
    - Seeking reimbursement for unallowable costs
- Retention of overpayments
  - Refusal to return erroneous payments
- Improper financial relationships/referrals
  - Sham compliance with safe harbor or exception
  - Excessive payments
  - Percentage-based compensation
- Insufficient documentation of work performed
Risk Areas, cont’d.

- Conflicts of interest
- Out of network billing
- Collection policies
- Referrals to ancillaries
  - Pharmacy, laboratories, therapy, monitoring
  - Physician-owned entities
- Space and equipment rentals
- Medical director positions
- Practice acquisitions
- Locum tenens and leased/temporary staff

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
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)

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
Implementing Corrective Action

• Who best can communicate the plan
• Target high-risk areas
  • Monitoring vs. auditing
• Disciplinary actions
• Training
• Policy revisions
• Corrective communications
• Culture adjustments
• Monitoring and implementation
• Evidence of the Above?

Repayment and Disclosure

• FIRST fix any problems
• Federal law requires repayment of known Medicare/Medicaid overpayments within 60 days otherwise FCA violation
  • 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
## Resources for Compliance 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

### Compliance Effectiveness:
**Leading Practices**
Seven Elements of the OIG Model Compliance Program as an area to focus your evaluation

1. Compliance Officer & Program Oversight
2. Policies & Procedures
3. Education
4. Audit
5. Corrective Actions to Identified Problems
6. Open Communication
7. Enforcement Violations

Elements to Consider in Your Evaluation Efforts

- Hotline Calls
- Education
- Audit/Monitoring
- Potential Areas of Trending Your Coding, Billing Results
- Audit Benchmarking Scorecard
- Other Data Points to Trend by Year
  - Refunds
  - Physician arrangements
  - Survey results
- Annual Audit Work Plan Completion
- Budget Analytics
### Applicable Government Guidance on Compliance Programs

- DOJ Compliance Program Guidance on Evaluation of Corporate Compliance Programs (Feb. 2017)

### Measurement of Compliance Performance

- Define expectation of performance or standard
- Report achievement
- Measurement of result – attention on variance
- Example:
  - Annual compliance education:
    - Every senior leader (n=20) will receive 2 hours
    - 16 achieved standard
    - Result – 75% achievement
    - Report reasons for variance and year to year comparison of results
Elements to Consider in Your Evaluation Efforts

- Hotline Calls
  - Staff
  - Physicians - Focus Arrangements
  - Board
  - Executives
- Education
- Audit/Monitoring Results
- Potential Areas of Trending Your Coding, Billing Results
- Audit Benchmarking Scorecard
- Annual Audit Work Plan Completion
- Budget Analytics
- Other Data Points to Trend by Year

Hotline Calls – Evaluation

- Do you include just calls or all matters “logged” by Compliance?
- Need to ensure you have a consistent measurement
- How many of those matters resulted in:
  - Investigations?
  - Remediation?
  - Paybacks?
  - Disciplinary actions?
  - Other?
- Trending data is the key
- What is your baseline?
- Deal with the compliance naysayers in your organization
  - “This is only for HR matters”
  - “it is a waste of time”
Education – Evaluation

- How much compliance education is enough?
- Follow DHHS OIG CIA requirement or establish your own expectations?
  - Have Board support
- Establish standard for different groups – “I like the following:”
  - Staff except housekeeping and food service – 1 hour annually
  - Executives – 2 hours annually
  - Physicians – 2 hours annually
  - Board – 2 hours annually
  - *Exception – those involved in negotiating physician or referral arrangements 2 hours plus specific training on Stark and Anti-Kickback Statute by an expert...
- Can your organization tolerate this?
  - Answer will tell you about your compliance culture

Board Education – Governance

- Tailor this to what is occurring (internally and externally)
- Risk (organization and personal)
- Compliance officer can communicate with the board whenever he or she wants without hesitation?
- Does CCO report to the board?
- Are board members involved in the compliance program oversight?
- What is the compliance knowledge level of the board?
- Engage experts to assist in program functioning and validation of “effectiveness” of compliance program
- Can you get assistance (externally) when you deem necessary?
- Information flow from entity
- Is the board receiving all necessary information?
Chief Compliance Officer Independence

• Can you make the proper decision without fear of some sort of retaliation?
• Examples:
  • The lead admitter of patients to your hospital is in violation of the medical records completion policy – can you revoke privileges as policy states?
  • The president’s spouse is asking to review sensitive and confidential information related to an upcoming community fundraiser. Can you treat her as if she were a normal citizen?
• Who validates this independence?

Chief Compliance Office Knowledge and Experience

• The compliance officer should be a subject matter expert
  • Certification to validate
  • Conferences attended, presentations made to industry, etc.
• However, no one in this business knows everything
• It is OK to say “I need help” – are you able to get help when you need it?
  • Example: coding and reimbursement issues
Audit/Monitoring – Evaluation

- Looking for improvement
- Be careful – creative people can make audit results look better than they are
  - Must establish **consistent** measurements
- Consider using *Net Dollar Value Error Rate* on consistent universe annually as one review
  - 50 claim randomly selected probe sample – consistent with OIG requirements
  - Five percent or below is an acceptable error rate
  - Great way to have a consistent measurement year after year
- Complement with other planned and focused reviews and trend the results
- How many “for cause” reviews performed annually – comparison

Coding, Billing Results / Topics to Review

- Short stays/outpatient/observation
- E&M
- Consultations
- DRG – focused areas
- Research billing
- Demonstrate corrective actions
- Validate that no “pattern or practice” evident
- Attorney-client privilege considerations
Audit Benchmarking Scorecard

<table>
<thead>
<tr>
<th>Risk Area</th>
<th>Net Dollar Value Error Rate yr 1</th>
<th>Net Dollar Value Error Rate yr 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Review</td>
<td>3.5%</td>
<td>5.2%</td>
</tr>
<tr>
<td>Risk Area 1</td>
<td>10.9%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Risk Area 2</td>
<td>6.0%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Risk Area 3</td>
<td>2.1%</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

Annual Audit Work Plan Completion

- Based upon approved annual work plan
  - By Compliance/Audit Committee or Board
- How many projects were on original plan?
- How many projects were added during year?
- How many were completed? Not completed?
- Trend to answer resources and accurate planning
- If you are missing either bad budget or operational problem
Budget Analytics

- Based upon operating and FTE budgets approved by Board or Compliance/Audit Committee
- Operating budget variance ($ and %)
  - Why a variance? Consultants?
- FTE budget variance ($ and %)
  - Is there turnover? Why?
  - Are there unfilled vacancies? Why?
  - What corrective action is proposed?
- Trending of budget and actual expenses over past several years
- Good management dictates that you operate department within acceptable budget
  - Being under budget doesn’t mean you are doing a good compliance job!

Budget and Resources

- Who defines what is appropriate?
- Any validation efforts that have been performed to review the potential ROI of your compliance program
- Specific activities
  - Sanction screening
  - *Contract management and reporting
    - Dealing with Focused Arrangements
  - Audits (routine and for-cause)
Other Data Points to Trend by Year

- Compliance presentations to senior management and medical staff
- New and renewed Focus Arrangements
- Payments made to non-employed physicians without an agreement
- Payments made to non-employed physicians without evidence of time and effort approval
- Refunds
- Survey Results
- Quality Involvement... LD 04.03.09 “Clinical Vendors Evaluation”

Relevant evaluation components (as just described) should include:

- Objective Measurements:
  - Stats
- Subjective Measurements:
  - Pressure testing on how things occur or don’t occur
  - Reviewing in relationship to Best Practice
  - Require ability to be “independent”
Who should perform a Compliance Program Evaluation?

- Each circumstance is probably different
- General thoughts:
  - Consider an independent external review at some pre-determined interval of time (i.e. – every two or three years)
  - Contract via the Board and include in budget
  - Report to the Board
  - Assure you have someone doing this who is experienced and bring value – interview them
  - Utilize findings for improvement and then review again - good auditing approach, which can pay dividends in long run
  - Develop scorecard of good statistics

Compliance Resources

- 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
Concluding Thoughts

Validation

- Ask your board to support a periodic assessment of the compliance program
  - Focus on any gaps to improved practices
- Have findings presented to board, audit committee and compliance committee
- Use as a competitive advantage
- Demonstrate your worth
Benefits

If an organization is investigated for violations of state or federal laws, the government may offer a reduction in penalties if an effective, demonstrated compliance program exists.

Questions
Sean McKenna

- Founder and Principal of Law Office of Sean McKenna, PLLC
- 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
- sean@seanmckennalaw.com
- 786.973.3762