Today’s Agenda

• Enforcement Update – 2018 and Beyond
• Compliance Today
• Effectiveness
• Selling Your Compliance Program
• 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
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 $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 600
  - But way up from 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

### 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
Compliance Today

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

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
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

Elements to Consider in Your Compliance Effectiveness Evaluation Efforts
Applicable Government Guidance on Compliance Programs

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

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. Enforce Violations
**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
- 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”

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**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 / 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

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<td>10.9%</td>
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<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”
Elements to Consider in Your Evaluation Efforts

Other Data Points to Trend by Year
- Refunds
- Physician arrangements
- Survey results

Budget Analytics

Annual Audit Work Plan Completion

Audit Benchmarking Scorecard

Hotline Calls

Education

Audit/Monitoring

Potential Areas of Trending Your Coding, Billing Results

How Best to Perform the Compliance Program 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 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
Selling Your Compliance Program

Education

• Ability to be creative in education venues
• Do you give quizzes to assess retention of information?
• You need to do some personalized education
• You need to be selling the program constantly
• There is value in having an outside speaker
  • Especially important for C-suite and board (in many situations)
To Whom Do You Talk When You Are Having a Tough Day, Week, Year?

- Networking with fellow compliance officers
- Budget for an external coach, validator
- You need to understand that your actions and decisions many times are not going to win you friends
- How do you keep your sanity?

Validation of the Compliance Program

- Ask your board to support a periodic assessment of the compliance program
  - Focus on any gaps to Best Practice
- Your colleagues will like to hear you are getting audited!
- Have findings presented to board, audit committee and compliance committee
Intangibles

Conclusion

• The Compliance Officer position is not easy
• The tools described could make it easier to be successful in your professional endeavors
Compliance Is Pretty Basic

Seven Elements of the OIG Model Compliance Program:

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

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.
Concluding Thoughts

Bret S. Bissey
MBA, FACHE, CHC, CMPE

BACKGROUND
- Bret is a nationally recognized expert and veteran in healthcare compliance.
- Bret has more than 30 years of diversified healthcare management, operations and compliance experience, and presented at more than 100 regional and national industry conferences and meetings on numerous compliance topics.
- Bret is a fellow of the American College of Healthcare Executives.
- Bret is the author of The Compliance Officer’s Handbook, which was published in 2006.
- From 2010 to 2013, he was the Senior Vice President, Chief Ethics and Compliance Officer of the University of Medicine and Dentistry of New Jersey (UMDNJ). There he successfully re-engineered the nation’s largest sector compliance and ethics program under a rigorous Corporate Integrity Agreement (CIA) with the HHS OIG.
- Bret has taught undergraduate and graduate courses as an adjunct faculty member at College of St. Francis, Joliet, Illinois and Allentown College of St. Francis De Sales, Center Valley, Pennsylvania.
- Bret has taught undergraduate and graduate courses as an adjunct faculty member at College of St. Francis, Joliet, Illinois and Allentown College of St. Francis De Sales, Center Valley, Pennsylvania.
- Bret is certified in the Health Care Compliance Association and the Medical Group Management Association. He is a past president (2001-2003) for Region 2 of the HCCA.

PROFESSIONAL & INDUSTRY EXPERIENCE
- Bret is a recognized thought management leader experienced in performing consulting engagements and providing compliance expertise to hospital and healthcare clients.
- At UMDNJ, the largest public sciences university in the country, Bret reported to the Chairman of the Audit Committee of the Board of Trustees and University President. There he managed 40 compliance, ethics and investigations professionals and an annual operating budget of $5.2 million.
- Bret has extensive experience in providing Compliance Effectiveness Reviews for clients.
- Bret provides compliance education to a wide variety of healthcare clients.
- Bret was responsible for the development and ongoing management of the Corporate Compliance Program, which resulted from the nation’s first Voluntary Disclosure Settlement (October, 1998) at a specialty hospital with more than 90 employed physicians. HCCA recognized the compliance program as a “Best Practice.”

CONTACT
Phone: 609-618-7249
Email: bisseybret@gmail.com

PROFILE
Provides compliance expertise to hospital and healthcare organizations.

EDUCATION & HONORS
BS – Business Administration, Shippensburg University
MBA – Marketing and Healthcare Administration, Wilkes College
Health Care Compliance Association Certified
Medical Group Management Association – CMPE
Fellow of the American College of Healthcare Executives
Sean McKenna focuses his practice on health care enforcement and regulatory issues, representing individuals and providers under civil or administrative investigation by the Department of Justice, Offices of Inspector General, and Attorneys’ General Medicaid Fraud Control Units, as well as in criminal investigations and matters involving the United States and State Attorneys General. As a former ten-year Assistant United States Attorney, three-plus Associate Counsel to the Inspector General and Associate Regional General Counsel for the U.S. Department of Health and Human Services, Sean focuses his practice on matters involving the health care industry and regularly represents clients before Medicare, Medicaid and commercial contractors. Sean’s work also includes assisting clients with internal investigations and compliance reviews, as well as advising companies on compliance with state and federal fraud and abuse rules. He is a frequent invited speaker at national, regional, and local conferences.

CONTACT
Phone: 214-665-3617
Email: mckenna@gtlaw.com

PROFILE
Former 10-year Assistant U.S. Attorney

EDUCATION
JD – University of Houston Law Center
BA, University of California at Santa Barbara