



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

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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

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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

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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

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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*

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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

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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(e)(2)(A)
- Increase in *qui tams*, but not DOJ resources
- 7 “Granston Factors”

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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

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Sources of Investigative Cases

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

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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

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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

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Escobar: Key Supreme Court Case

Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989 (2016)

- 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

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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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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

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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?*

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Repayment and Disclosure

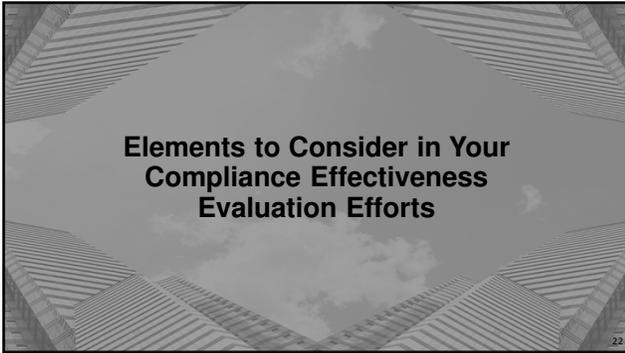
- FIRST fix any problems
- Federal law requires repayment of known Medicare/Medicaid overpayments within 60 days otherwise FCA violation
 - CMS issued final rule at 77 Fed. Reg. 9179 (Feb. 16, 2016)
- Disclosure to DOJ
 - Possible non-prosecution of business entity
 - See USAM § 9-28.000, *et seq.*
 - 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

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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

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Applicable Government Guidance on Compliance Programs

- DHHS OIG Compliance Program Guidance for Hospitals, Home Health, 3rd Party Billers (1998); Hospice, Nursing Facilities (1999); Physician Practices (2000), Supplemental for Hospitals (2005)
- DOJ Compliance Program Guidance on Evaluation of Corporate Compliance Programs (Feb. 2017)
- Resource Guide, Compiled from HCCA-OIG Compliance Effectiveness Roundtable Meeting, January 17, 2017 (Issued March 27, 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
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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

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Elements to Consider in Your Evaluation Efforts

-  Hotline Calls
 - Staff
 - Physicians - Focus Arrangements
-  Education →
 - Board
 - Executives
-  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

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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

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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?

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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?

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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...

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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

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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

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Audit Benchmarking Scorecard

	Net Dollar Value Error Rate yr 1	Net Dollar Value Error Rate yr 2
ANNUAL REVIEW	3.5%	5.2%
RISK AREA 1	10.9%	3.3%
RISK AREA 2	6.0%	4.5%
RISK AREA 3	2.1%	1.2%

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- ## 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
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- ## 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!
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Budget and Resources

- Who defines what is appropriate?
- Any validation efforts that has 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)

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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"

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Elements to Consider in Your Evaluation Efforts



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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"

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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

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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)

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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?

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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

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Intangibles



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Conclusion

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

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Compliance Is Pretty Basic

Seven Elements of the OIG Model Compliance Program:



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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.

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Concluding Thoughts

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