



# **Enforcement Trends: Compliance Investigations and More**

**HCCA Philadelphia Regional  
Compliance Conference**

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## **Today's Agenda**

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- Enforcement Update – 2018 and Beyond
  - Compliance Today
  - Effectiveness
  - Selling Compliance
  - Conclusion
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## Enforcement and Compliance Update

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### Enforcement Outlook in 2018

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- 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.

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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

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|--|--|
| • Department of Justice                            | • Medicaid State Agencies                        |
| • Local District Attorneys                         | • Tricare Management Authority                   |
| • States Attorneys General                         | • Federal/State Contractors                      |
| • Offices of Inspector General - Federal and State | • Commercial Payor “Special Investigative Units” |
| • Medicaid Fraud Control Units                     | • Licensing Boards                               |
| • Centers for Medicare & Medicaid Services         | • Whistleblowers                                 |

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## Recent DOJ Activity

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- 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

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## Current Administration Agenda

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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

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- 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

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- 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”

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## Brand Memo

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- 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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## Escobar: Key Supreme Court Case

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*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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# Compliance Investigations

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## Risk Areas

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- 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.

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- 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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## Sources of Investigative Cases

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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

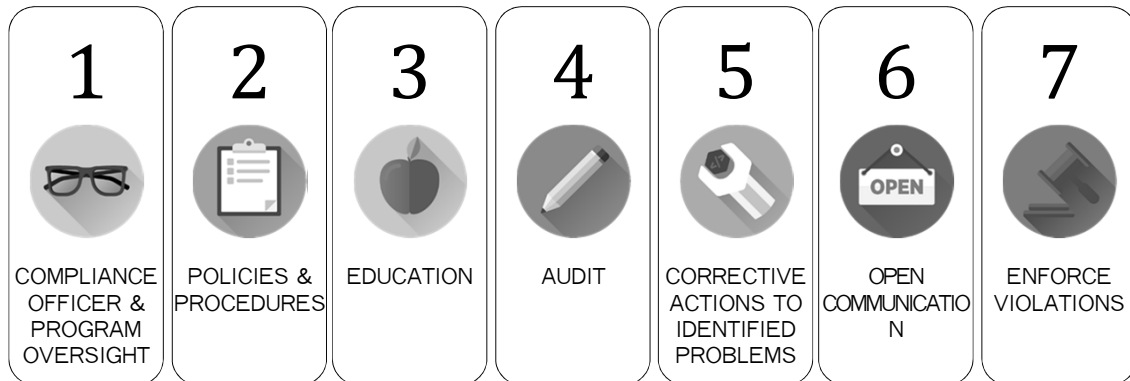
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## Compliance Effectiveness: Leading Practices

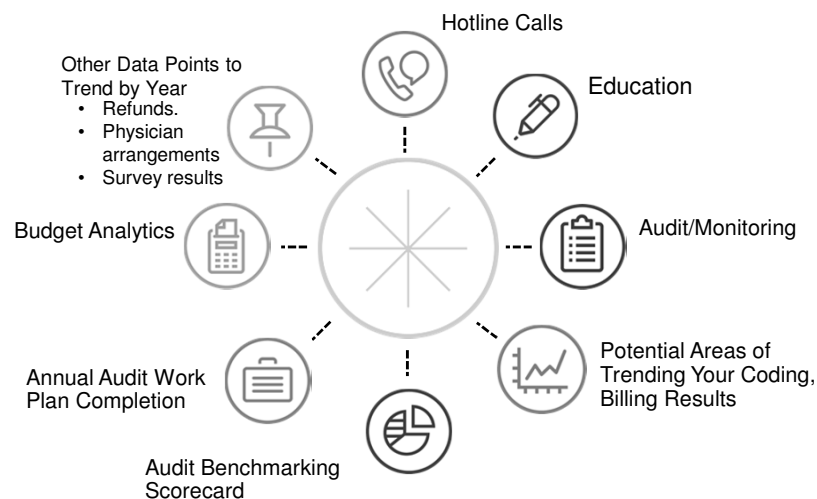
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## Seven Elements of the OIG Model Compliance Program as an area to focus your evaluation



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## Elements to Consider in Your Evaluation Efforts



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## Applicable Government Guidance on Compliance Programs

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- 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)

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## Measurement of Compliance Performance

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- 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

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- 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 and Experience

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- 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

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- 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

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- 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	<b>3.5%</b>	<b>5.2%</b>
RISK AREA 1	<b>10.9%</b>	<b>3.3%</b>
RISK AREA 2	<b>6.0%</b>	<b>4.5%</b>
RISK AREA 3	<b>2.1%</b>	<b>1.2%</b>

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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

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- 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

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- 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)

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## Other Data Points to Trend by Year

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- 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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## Relevant evaluation components (as just described) should include:

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- 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?

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- 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


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## Compliance Resources

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- 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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## Concluding Thoughts

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## Validation

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- 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

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## Benefits

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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.

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## Questions

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