Using Data & Statistics to Defend Health Care Enforcement
Healthcare Enforcement Compliance Institute

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Agenda

• Overview of “Big Data” in Healthcare
  – Defining “Big Data”;  
  – Government uses of data & recent FCA cases;

• Pre-Litigation Strategies for Data Management
  – Best practices for ongoing operations and compliance;
  – Considerations for whistleblower prevention;

• Responding to Enforcement Actions
  – Strategies for defending allegations using data analysis
“Big Data” in Today’s Healthcare Industry

Defining Big Data

• “Big Data” is all information and data we produce in the course of our lives.
• It can be interpreted with analytics to provide feedback on trends or patterns.
• Companies can leverage analytical techniques to decipher data, gain insight and reach conclusions.
• Big data is common in most industries, but healthcare has been slow to move.
• Examples include claims analysis, customer loyalty, EMR/HER systems, financial data.
Why All the Attention?

- CMS Fraud Prevention System (FPS)
  - Initiated in 2011 – Reviews 4.5 million claims per day
  - Over $1.5 billion in savings; 11.6:1 ROI
- CMS released a variety of charge data to the public in 2014
  - Medicare provider charge data
  - National and state summaries of charge data
- Health Information Technology for Economic and Clinical Health (HITECH)
  - Up to $40 billion in incentive payments for providers to use EMRs
  - Targeting 70-90% participation by 2019
  - $2 billion for EMR training and infrastructure improvements
- Payer audits focusing on the use of data
- Repeal of ACA?
Recent Relevant Enforcement
Compounding Pharmacies

- **Compound Pharmacy:** Custom tailored to unique needs of individual patient;
- **Overview:**
  - Targeted Tricare with pain/scar/wound creams
  - Some cases ranging from $4K to $40K per script
  - DHA was forced to request additional $2B in 2015
- **Schemes:**
  - Physician Kickbacks
  - Marketer Kickbacks
  - Patient Kickbacks
- **Targeted Data for Enforcement**
  - High volume prescribing physicians
  - Doctors/patients in different states
  - Multiple/identical compounds for same patient

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Recent Relevant Enforcement
Cases involving Statistical Sampling

- **U.S. ex rel. Wall v. Vista Hospice Care Inc. et al.**
  - 3:07-cv-00604 (M.D. Tex. 2016)
- **U.S. ex rel. Martin v. Life Care Centers of America**
  - 2014 WL 4816006, Case No. 08-cv-251/12-cv-64 (E.D. Tenn., Sept. 29, 2014)
- **United States v. AseraCare, Inc. (“AseraCare I”)**
- **United States v. AseraCare, Inc. (“AseraCare II”)**
- **U.S. ex rel. Michaels v. Agape Senior Community, Inc.**
Recent Relevant Enforcement
Focus on Internal Audit Data / Findings

• Focus on internal audit findings and work papers during government enforcement
• Importance of the traditional audit function: *Risk Assessment, Monitoring, Reporting*, etc.
• Highlights *knowledge* in FCA cases; i.e. what did the company know?
• *U.S. ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.*
  o Ms. Keltner [the whistleblower] alleged that Lakeshore did annual audits of its doctors’ billing from 2002 through 2010, reviewing samples of their claims, identifying as high as a 10% failure rate;
  o The practice repaid the specific overpayments identified in the sample audits;
  o However, it did not go back and review all other claims to identify and repay any other similarly upcoded claims [nor did they extrapolate their audit finding results to determine greater repayment amounts].
  o 2015 WL 3903675 (D. SC., June 25, 2015)

Section Two

Strategies for Ongoing Data Management

*Pre-Litigation*
Fraud Waste Abuse Data Analysis
Data Analysis performed using multiple analysis types

**Monitoring**
- Post payment “rules-based” analytics
- Prepayment analytics

**Analysis**
- Statistical Sampling
- Regression analysis

**Reporting**
- Control limits
- Clustering and segmentation

**Special Projects**
- Peer Collaboration
- Participation in state and federal FWA projects

Pre-Payment Analytics
Detecting fraud, abuse and error BEFORE payment

- Predictive analytics to deny fraudulent claims before they are paid
- Prevents pay and chase
- Dramatically improves claims processing accuracy, payment integrity, and compliance
- Utilizes adaptive predictive analytic models to analyze pre-pay claim lines

Software tools:
- SAS – A Statistical Analysis System for advanced analytics
- Lexis Intelligent Investigator – Rules-based post-payment software
- FICO – Pre-pay and Post-pay predictive analytic software
Post-Payment Rules Based Analytics

Rules-based fraud detection that identifies patterns of suspicious behavior across all health types

<table>
<thead>
<tr>
<th>Monthly/quarterly reports analyzing claim data for fraud scenarios</th>
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<tbody>
<tr>
<td>• Upcoding, Dups, Unbundling of services</td>
</tr>
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<td>• Provider billing pattern changes</td>
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<tr>
<td>• High dollar providers within provider type</td>
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<tr>
<td>• Add on CPT codes without the primary CPT code</td>
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<tr>
<td>• Provider spike reports</td>
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</table>

<table>
<thead>
<tr>
<th>Baseline for analytics is historical claim payment pattern</th>
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<tr>
<td>• Focuses on Medical, Dental and Pharmacy Claims</td>
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<td>• Identifies providers that are outside of the norm</td>
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<td>• Scores providers from 0-1000, with 1000 having highest indicator of fraud, waste and abuse</td>
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Best Practices for Ongoing Compliance

• **Remember: Data will be the skeleton upon which the story is told…**
  – Intent is always scrutinized in hindsight by regulators

• **Develop and communicate the business case … this is a cost center!**
  – When you have top-down buy-in vs. when you do not; manage up/down chain accordingly
  – Know your audience; articulate risk in terms of tangible financial and business impact
  – Avoid just being the doomsday voice
  – Help leaders learn how to meet their goals

• **Build relationships with internal clients**
  – Getting to “Yes” in an AKS world can take time, but don’t waste the time
  – Provide training inside/outside of the legal function to develop awareness
  – Stay relevant and communicate interesting cases and articles → Yates (DOJ) Memo!

• **Think global (if you are)**
  – Likely that no one approach works in all jurisdictions
  – Consult the experts when business crosses multiple borders
Best Practices for Ongoing Compliance (cont’d.)

- Harmonizing regulatory/compliance expertise with commercial expertise
  - Subject matter experts and legal business partners: which model is right?
  - How does Legal and Compliance work together?
  - How to manage privilege properly?

- Scale your compliance function according to your risk
  - Hotlines: intake, triage, investigation, resolution
  - Addressing internal confidentiality; is it ever ok to treat perceived “reputational” threats to senior leaders differently?
  - The importance of listening during an investigation!
  - Be mindful of creating self-disclosure scenarios

- Proactively identify red flags to help prioritize your efforts
  - Approaching potential violators with the data can be an efficient compliance tool
  - Be wary of “unique patient demographics” and always confirm justifications
  - Examine statistical outliers according to your own data
  - Harmonize Compliance and billing functions to account for 60-Day Rule implications

Section Three

Responding to FCA Litigation with Data
Recent Approaches to Refute FCA Claims

- **Statistical Sampling – Refuting opposing analysis and preparing your own**
  - Recent FCA cases involve the use of sampling for both damages and liability;
  - Aggressively scrutinize the government’s analysis in the early stages;
  - Consider your own sampling and extrapolation analysis for presentation to the government;

- **Implied Certification Cases – Quantifying causation and materiality**
  - Anti-Kickback cases rely on the intention of inducement;
  - Regression analysis can help quantify the revenue attributed to kickbacks;

- **Ability to Pay Analysis – Avoid the discussion of damages**
  - Provide the government with analysis of the companies cash flow projections;

- **Take Advantage of Your Compliance Programs – Part of the investigation**
  - Collect results of relevant audits and analysis of the relevant area;
  - Collect relevant disclosures and certifications from employees and/or relator.

Statistically Valid Random Sample

**Medicare Program Integrity Manual Guidance:**

*If a particular probability sample design is properly executed, i.e., defining the universe, the frame, and the sampling units; using proper randomization; accurately measuring the variables of interest; and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are “not statistically valid” cannot legitimately be made.*
What Can You Do With a Good Sample?

- **Extrapolation**: Projecting the results of your sample onto the entire population.
  - Observed ratios:
    - Proportion of red M&Ms
    - Proportion of voters who prefer candidate X
    - Failure rate of an audit or investigation
  - Observed descriptive statistics:
    - Mean household income
    - Mean overpayment per claim (i.e., damages)
- Extrapolations yield results within a specified **level of significance**.
  - Different sample sizes will yield results with different levels of significance
    - If selected properly, larger sample sizes yield greater significance
  - **Confidence level** (i.e., 95%, 99%, etc.)
  - **Margin of error** or precision level (i.e., ±3 percentage points)
    - e.g., Candidate X is expected to receive 47% of votes, ±2 percentage points, at a 90% confidence level

Preparing a Sampling Plan

*Define the following:*

- **Population of Interest (POI)** This can help you prepare your request for data
- **Sampling Unit** Population of interest is composed of all possible sampling units
- **Sampling Frame** Population from which the sample is drawn (explain if not equal to POI)
- **Sample Size Minimum** or any other procedural requirements/thresholds
- **Required Level of Precision and Confidence** possibly 95% confidence ±2% precision
- **Sample Design** Simple, Stratified, Clustered, etc. Specify strata or cluster criteria
- **Source of Random Numbers** often RAT-STATS
- **Method of Selecting Sampling Units** Ensure random numbers are applied without bias
- **Procedures for Missing Data** Typically failures, however spares may be appropriate
- **Estimation Methodology** Also referred to as extrapolation methodology
RAT-STATS Statistical Software

- RAT-STATS is statistical software developed by the U.S. Government
  - Free software available online, along with user-guide and companion-manual
  - Key tool used by the government to help identify and quantify improper claims
- Functionally, RAT-STATS is a calculator with three main functions:
  - Calculating sample size
  - Generating random numbers to aid sample selection
  - Extrapolating (estimating) results of the sample to a broader population
- RAT-STATS is a tool to be used in conjunction with a broader statistical strategy

** Sampling Plan **

Best Practices for Responding to FCA Claims with Data

- Ensure compliance programs and policies are robust before litigation ensues
  - Effectively capturing, analyzing and responding to red flags can significantly mitigate risk
- Initiate a timely internal investigation
  - Data collected in the investigation will become the foundation for refuting government claims
- Recognize and take advantage of all data at your disposal
  - Don't limit yourself to billing and utilization data; Partner with HR, finance, operations, etc.
- Be comfortable with retaining the right expert
  - Scope your internal and external resources/spend according to the relative risks
- Scrutinize the government's analysis and prepare your own
  - Courts are hesitant to exclude analysis without evidence of clear errors
  - Jurys may play a larger role in how data is analyzed and presented in FCA cases
Questions?

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2017 HCCA Healthcare Enforcement Compliance Institute

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Appendix
Government Use of Big Data

- Centers for Medicare & Medicaid Services released billing data for 880,000 doctors
- More than $77 billion in government payouts to these healthcare providers
- In one case, a single Florida ophthalmologist received just under $21 million.

<table>
<thead>
<tr>
<th>Provider type</th>
<th>Number of procedures</th>
<th>Total paid in millions</th>
<th>Average amount paid per provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology/Oncology</td>
<td>7,774</td>
<td>52,719.9</td>
<td>6,817.2</td>
</tr>
<tr>
<td>Radiation oncology</td>
<td>4,527</td>
<td>3,999.8</td>
<td>889.0</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>17,097</td>
<td>5,385.0</td>
<td>316.3</td>
</tr>
<tr>
<td>Medical oncology</td>
<td>2,963</td>
<td>956.9</td>
<td>325.2</td>
</tr>
<tr>
<td>General surgery</td>
<td>3,588</td>
<td>205,210.0</td>
<td>56,990</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>4,656</td>
<td>1,045.3</td>
<td>223.8</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>1,202</td>
<td>1,685.6</td>
<td>1,400.5</td>
</tr>
<tr>
<td>Cardiology</td>
<td>22,296</td>
<td>4,965.3</td>
<td>223.8</td>
</tr>
<tr>
<td>Dermatology</td>
<td>10,076</td>
<td>3,220.9</td>
<td>322.0</td>
</tr>
<tr>
<td>Interventional pain management</td>
<td>1,916</td>
<td>906.1</td>
<td>471.2</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>78</td>
<td>14.5</td>
<td>186.5</td>
</tr>
<tr>
<td>Hematology</td>
<td>667</td>
<td>127.9</td>
<td>193.6</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>1,297</td>
<td>246.0</td>
<td>193.6</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>2,996</td>
<td>489.9</td>
<td>163.0</td>
</tr>
<tr>
<td>Urology</td>
<td>8,796</td>
<td>1,283.4</td>
<td>148.6</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare and Medicaid Services.

Outlier length of stay for specific DRGs
- Can identify targets for enforcement
- High volume unique procedures
- Outliers continue to attract attention
Government Use of Big Data

- Analytics can also help to assess the utilization of certain tests
- Comparing physician's data to peers can establish benchmarks
- Ability to effectively explain why you are an outlier is critical
- Don’t wait for the Government to identify your outliers

Government Search Sample Report

- Internal Correspondence
- Data Sharing
- Search by
  - Sender
  - Date
  - Subject
  - Keyword combinations
- Deleting files rarely really deletes them
Pre-Pay Case Examples

1. Procedures typically provided in a facility billed as outpatient resulting in significant overpayment.
2. Provider billing same procedure under two different IDs
3. Multiple DME providers billing same members for same supplies on same dates of service
4. DME providers billing supplies too frequently
5. Providers using incorrect modifiers resulting in non-covered items paying
6. Identified internal errors such as manual pricing errors, contracts entered incorrectly and claim system configuration issues

Post-Pay Case Examples

1. Family Practice provider billing high volume of questionable injections. Analytics was able to connect associated CT scans taken with each injection.
2. Non-participating genetic lab billing for non-covered services by billing covered codes instead of codes for services performed.
3. DME Company billing for high numbers of wound supplies which lead to a full investigation resulting in DME termination, $1.8 M recovery
4. Physician ordering medically unnecessary compound drugs for members due to aggressive marketing tactics.
5. Optometrist duplicate billing for glasses and frames outsourced to another vendor that was also billing for glasses and frames.
6. Nurse practitioner and physician billing services used for research studies.
Government Use of Big Data

• Analysis of financial relationships can provide critical information – Follow The Money!
• Visualization charts are commonly prepared to identify financial beneficiaries