



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

October 2017

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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

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Section One

"Big Data" in Today's Healthcare Industry

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### 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.




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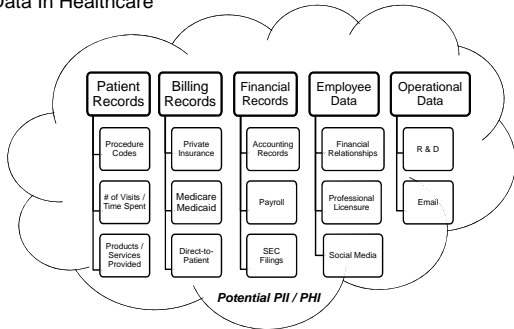
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### Big Data In Healthcare




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### 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?

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Section Two

Strategies for Ongoing Data Management  
*Pre-Litigation*

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Fraud Waste Abuse Data Analysis  
Data Analysis performed using multiple analysis types

<p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>• Post payment "rules-based" analytics</li> <li>• Prepayment analytics</li> </ul>	<p><b>Reporting</b></p> <ul style="list-style-type: none"> <li>• Control limits</li> <li>• Clustering and segmentation</li> </ul>
<p><b>Analysis</b></p> <ul style="list-style-type: none"> <li>• Statistical Sampling</li> <li>• Regression analysis</li> </ul>	<p><b>Special Projects</b></p> <ul style="list-style-type: none"> <li>• Peer Collaboration</li> <li>• Participation in state and federal FWA projects</li> </ul>

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

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

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### Post-Payment Rules Based Analytics

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

<p>Monthly/quarterly reports analyzing claim data for fraud scenarios</p> <ul style="list-style-type: none"> <li>• Upcoding, Dups, Unbundling of services</li> <li>• Provider billing pattern changes</li> <li>• High dollar providers within provider type</li> <li>• Add on CPT codes without the primary CPT code</li> <li>• Provider spike reports</li> </ul>	<p>Baseline for analytics is historical claim payment pattern</p> <ul style="list-style-type: none"> <li>• Focuses on Medical, Dental and Pharmacy Claims</li> <li>• Identifies providers that are outside of the norm</li> <li>• Scores providers from 0-1000, with 1000 having highest indicator of fraud, waste and abuse</li> </ul>
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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

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### 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

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Section Three

Responding to FCA Litigation with Data

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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.

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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.*

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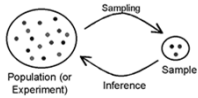
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### What Can You Do With a Good Sample?

- **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.  $\pm 3$  percentage points)
    - e.g. Candidate X is expected to receive 47% of votes,  $\pm 2$  percentage points, at a 90% confidence level




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### 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  $\pm 2\%$  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

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### 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




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### 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
  - Juries may play a larger role in how data is analyzed and presented in FCA cases

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### Questions?

#### Using Data & Statistics to Defend Health Care Enforcement

2017 HCCA Healthcare Enforcement Compliance Institute

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### Appendix

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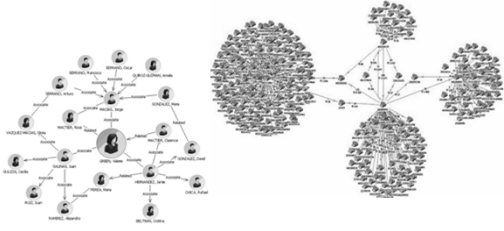






### Government Use of Big Data

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



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