

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

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Healthcare Enforcement Compliance Institute

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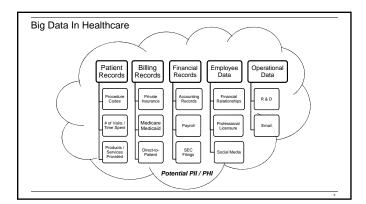
- Overview of "Big Data" in Healthcare
- Defining "Big Data";
- Government uses of data & recent FCA cases;
- Pre-Litigation Strategies for Data Management
- Best practices for ongoing operations and compliance;
- Considerations for whistleblower prevention;
- Responding to Enforcement Actions
- Strategies for defending allegations using data analysis

Section One "Big Data" in Today's Healthcare Industry

#### Defining Big Data

- "Big Data" is <u>all information and data</u> 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 ompounding Pharmacies	
Monthly Tricare Compounding Spend	Compound Pharmacy: Custom tailored to unique needs of individual patient;
Figure 1. TRICARE Monthly Spending on Compound Drugs October 2012 Through April 2015	Overview:
	<ul> <li>Targeted Tricare with pain/scar/wound creams</li> </ul>
	<ul> <li>Some cases ranging from \$4K to \$40K per script</li> </ul>
5	<ul> <li>DHA was forced to request additional \$2B in 2015</li> </ul>
	Schemes:
1 - 1	- Physician Kickbacks
2 a	- Marketer Kickbacks
	- Patient Kickbacks
1111 - 3	Targeted Data for Enforcement
	High volume prescribing physicians
manuthitititititititititititititititi.	Doctors/patients in different states
1	<ul> <li>Multiple/identical compounds for same patient</li> </ul>
Source DMA	

## Recent Relevant Enforcement Cases involving Statistical Sampling

- U.S. ex rel. Wall v. Vista Hospice Care Inc. et al.
  - o 3:07-cv-00604 (M.D. Tex. 2016)
- U.S. ex rel. Martin v. Life Care Centers of America
  - o 2014 WL 4816006, Case No. 08-cv-251/12-cv-64 (E.D. Tenn., Sept. 29, 2014)
- United States v. AseraCare, Inc. ("AseraCare I")
  - o 2014 WL 6879254, Case No. 2:12-CV-245-KOB (N.D. Ala., Dec. 4, 2014)
- United States v. AseraCare, Inc. ("AseraCare II")
- o 2016 WL 1270521, Case No. 2:12-CV-245-KOB (N.D. Ala., Mar. 31, 2016)
- U.S. ex rel. Kane, et al. v. Healthfirst, Inc., et al.
- o 120 F. Supp. 3d 370 (S.D.N.Y., Aug. 3, 2015)
- U.S. ex rel. Michaels v. Agape Senior Community, Inc.
  - o 2015 WL 3903675 (D. SC., June 25, 2015)

# 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.
- $\bullet \ \ \mbox{Highlights } \mbox{\it knowledge} \ \mbox{in FCA cases; i.e. what did the company know?}$
- U.S. ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.
  - 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;
  - <u>However</u>, 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)

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Section Two	Strategies fo	r Ongoing Data Management on	-		
Fraud Waste Abuse Data Analysis performed  Monitoring  Post payment "ru analytics  Prepayment ana  Analysis  Statistical Sampl  Regression analytics	d using multiple a	Reporting  Control limits  Clustering and segmentation  Special Projects  Peer Collaboration  Participation in state and federal FWA projects			
Pre-Payment Analyti Detecting fraud, abuse a  Predicti analytics to frauduent of the paid  Prevents and cha	ve deny slaims y are proposed sing accuracy, a compliance single specific proposed single specific processing accuracy, and accuracy are single specific processing specific processing specific processing specific process	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	<u> </u>		

#### Post-Payment Rules Based Analytics

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

Monthly/quarterly reports analyzing claim data for fraud scenarios

- Upcoding, Dups, Unbundling of
- Provider billing pattern changes
- High dollar providers within provider type
- Add on CPT codes without the primary CPT code
- Provider spike reports

Baseline for analytics is historical claim payment pattern

- Focuses on Medical, Dental and Pharmacy Claims
- Identifies providers that are outside of the norm
- Scores <u>providers from 0-1000</u>, with 1000 having highest indicator of fraud, waste and abuse

#### 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?

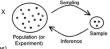
  - How does Legal and Compliance work together? How to manage privilege properly?
- Scale your compliance function according to your risk
- Hotlines: intake, triage, investigation, resolution
- Troumes, manage, measurement, resonance
   Addressing internal confidentiality; is it ever ok to treat perceived "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 <u>always</u> 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	
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. Ctatistical Compline - Defeating appealing analysis and preparing your sure	•
<ul> <li>Statistical Sampling – Refuting opposing analysis and preparing your own</li> <li>Recent FCA cases involve the use of sampling for <u>both damages and liability</u>;</li> </ul>	
Aggressively scrutinize the government's analysis in the early stages;	
<ul> <li>Consider your own sampling and extrapolation analysis for presentation to the government;</li> </ul>	
<ul> <li>Implied Certification Cases – Quantifying causation and materiality</li> </ul>	
<ul> <li>Anti-Kickback cases rely on the intention of inducement;</li> </ul>	-
<ul> <li>Regression analysis can help quantify the revenue attributed to kickbacks;</li> </ul>	
<ul> <li>Ability to Pay Analysis – Avoid the discussion of damages</li> </ul>	
<ul> <li>Provide the government with analysis of the companies cash flow projections;</li> </ul>	
<ul> <li>Take Advantage of Your Compliance Programs – Part of the investigation</li> </ul>	
Collect results of relevant audits and analysis of the relevant area;	
<ul> <li>Collect relevant disclosures and certifications from employees and/or relator.</li> </ul>	
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Statistically Valid Random Sample	
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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	
formulas for estimation, then assertions that the sample and its resulting	
formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made.	
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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 (<u>i.e. damages</u>)



- 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

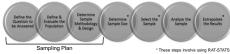
#### Preparing a Sampling Plan

#### 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**

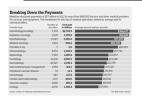
- RAT-STATS is statistical software developed by the U.S. Government
- Free software available online, along with user-guide and companion-manual
- Key tool used by the government to help identify and quantify improper claims
- . Functionally, RAT-STATS is a calculator with three main functions:
- Calculating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



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 <u>all</u> 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	
<ul> <li>Jurys may play a larger role in how data is analyzed and presented in FCA cases</li> </ul>	
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Questions?	
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2017 HCCA Healthcare Enforcement Compliance Institute	
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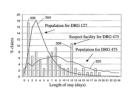
### Government Use of Big Data

- 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.





## Government Use of Big Data

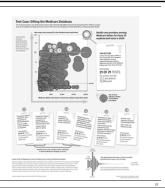


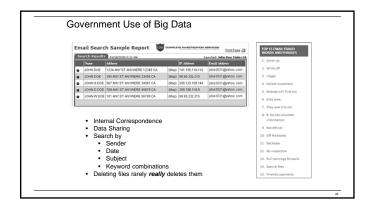


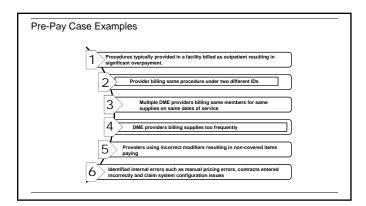
- Outlier length of stay for specific DRGs
   Can identify targets for enforcement
   Outliers continue to attract attention

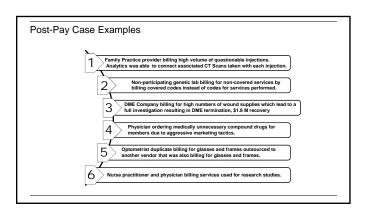
## Government Use of Big Data

- 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









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