



Health Care
Compliance
Association

HCCA

**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

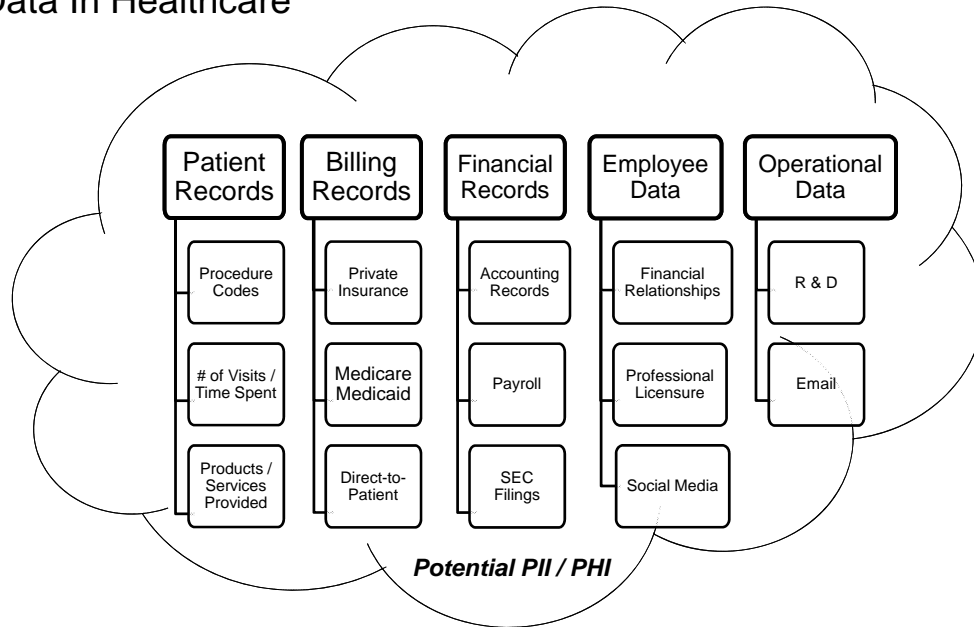
Section One**“Big Data” in Today’s Healthcare Industry**

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.



Big Data In Healthcare



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Why All the Attention?

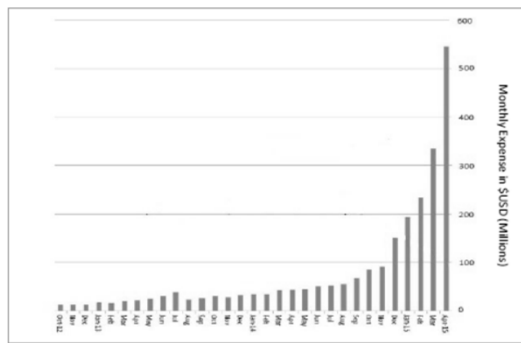
- CMS Fraud Prevention System (FPS)
 - Initiated in 2011 – Reviews 4.5 million claims per day
 - Over \$1.5 billion in savings; 11.6:1 ROI
- CMS released a variety of charge data to the public in 2014
 - Medicare provider charge data
 - National and state summaries of charge data
- Health Information 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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Recent Relevant Enforcement Compounding Pharmacies

Monthly Tricare Compounding Spend

Figure 1. TRICARE Monthly Spending on Compound Drugs October 2012 Through April 2015



Source: DHA

- **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”)*
 - 2014 WL 6879254, Case No. 2:12-CV-245-KOB (N.D. Ala., Dec. 4, 2014)
- *United States v. AseraCare, Inc. (“AseraCare II”)*
 - 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.*
 - 120 F. Supp. 3d 370 (S.D.N.Y., Aug. 3, 2015)
- *U.S. ex rel. Michaels v. Agape Senior Community, Inc.*
 - 2015 WL 3903675 (D. SC., June 25, 2015)

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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.*
 - 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;
 - The practice repaid the specific overpayments identified in the sample audits;
 - 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].
 - 2015 WL 3903675 (D. SC., June 25, 2015)

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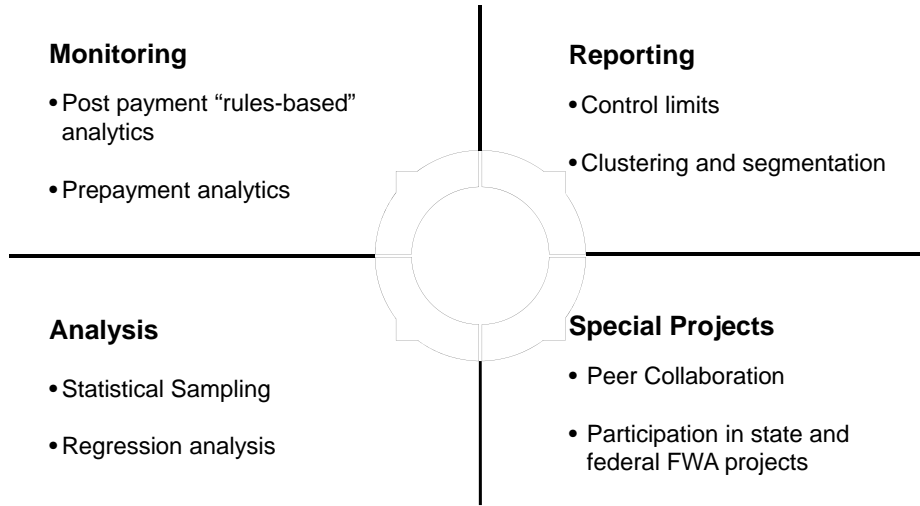
Section Two

Strategies for Ongoing Data Management

Pre-Litigation

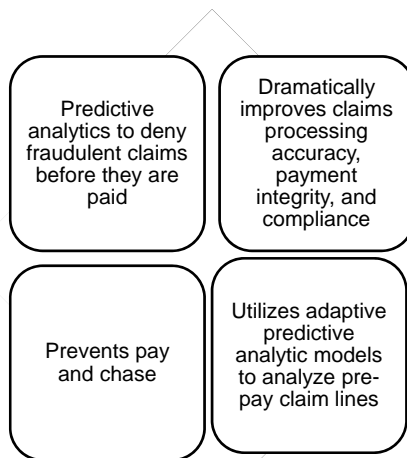
Fraud Waste Abuse Data Analysis

Data Analysis performed using multiple analysis types



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

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 services
- 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 providers from 0-1000, with 1000 having highest indicator of fraud, waste and abuse

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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

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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What Can You Do With a Good Sample?

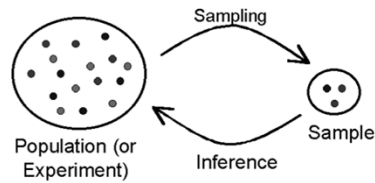
- **Extrapolation:** Projecting the results of your sample onto the entire population.

– 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

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Preparing a Sampling Plan

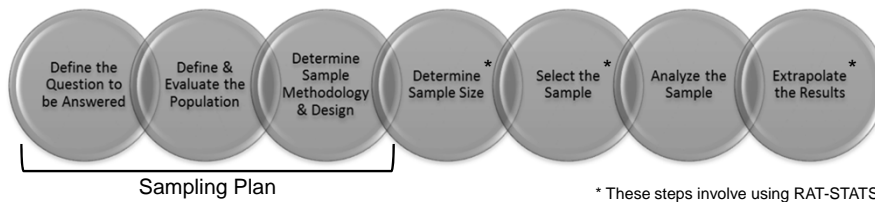
Define the following:

- **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
 - Jurys 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

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.


Breaking Down the Payments

Medicare disclosed payments of \$77 billion in 2012 to more than 880,000 doctors and other medical providers for services and equipment. The breakdown for the top 15 medical specialties ranked by average paid to individual billers:

Provider type	Number of providers	Total paid in millions	Average amount paid per provider
Hematology/oncology	7,374	\$2,703.9	\$366,677
Radiation oncology	4,135	1,499.6	362,656
Ophthalmology	17,067	5,585.0	327,239
Medical oncology	2,613	806.6	308,702
Portable Xray	7	2.0	288,020
Rheumatology	4,053	1,044.5	257,701
Nephrology	7,503	1,685.6	224,657
Cardiology	22,241	4,965.3	223,348
Dermatology	10,507	2,235.3	212,745
Interventional pain management	1,856	366.1	197,229
Peripheral vascular disease	74	14.3	193,441
Hematology	687	127.6	185,757
Cardiac electrophysiology	1,117	204.0	182,641
Vascular surgery	2,696	485.3	180,019
Urology	8,791	1,385.4	157,589


Source: Centers for Medicare and Medicaid Services

The Wall Street Journal



Evangelos G. Geraniotis
Hyannis, Mass., urologist
Received nearly \$1 million from Medicare in 2012 for cystoscopy-and-fulguration procedures

Dr. Geraniotis received significantly more for the procedures, which burn cancerous lesions in the bladder, than any of the other top 20 Medicare doctors who performed them.



\$1.00 million from Medicare for the procedures

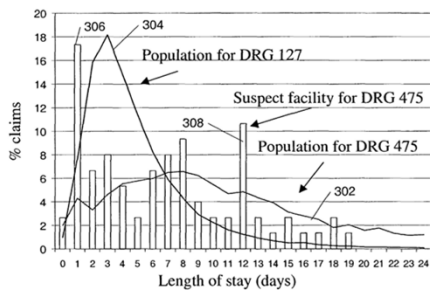

— Dr. Geraniotis billed for two variations of the procedure 1,757 times.

Doctor with second-highest payout billed for them 533 times.

*Based on total amount paid by Medicare for these procedures
Sources: WSJ analysis of Medicare data; Urology Associates of Cape Cod (photo)

The Wall Street Journal

Government Use of Big Data

Gary L. Marder
Port St. Lucie, Fla., dermatologist
Received \$2.41 million from Medicare in 2012 for a radiation procedure for which only two other doctors billed the program

Doctor	Total number of treatments billed	Average number of treatments per patient	Total paid by Medicare for treatment, in millions
Dr. Marder	15,610	166	\$2.41
Doctor 2	8,315	18	1.04
Doctor 3	370	9	0.05

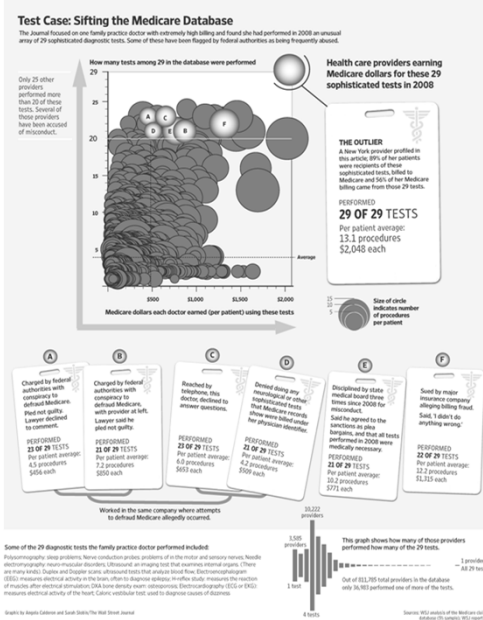
Sources: WSJ analysis of Medicare data; Marder Dermatology (photo)

The Wall Street Journal

- 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 Use of Big Data

Email Search Sample Report COMPLETE INVESTIGATION SERVICES Print Page

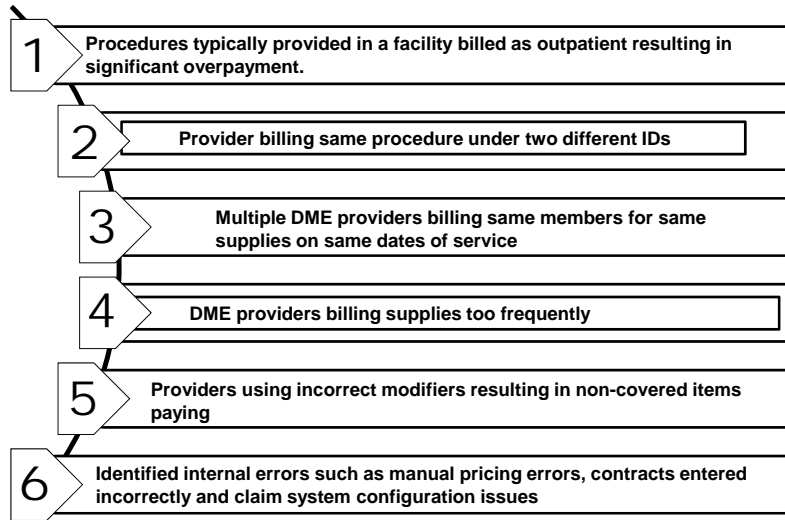
Search Results 01/18/2008 0:12 AM Searched: John Doe State=CA

Name	Address	IP Address	Email Address
JOHN DOE	1234 ANY ST ANYWERE 12345 CA	(Map) 141.155.118.110	jdoe3021@yahoo.com
JOHN DOE	345 ANY ST ANYWERE 23456 CA	(Map) 98.95.232.215	jdoe3021@yahoo.com
JOHN S DOE	567 ANY ST ANYWERE 34567 CA	(Map) 205.123.168.144	jdoe3021@yahoo.com
JOHN D DOE	789 ANY ST ANYWERE 45678 CA	(Map) 205.188.116.9	jdoe3021@yahoo.com
JOHN W DOE	101 ANY ST ANYWERE 56789 CA	(Map) 98.95.232.215	jdoe3021@yahoo.com

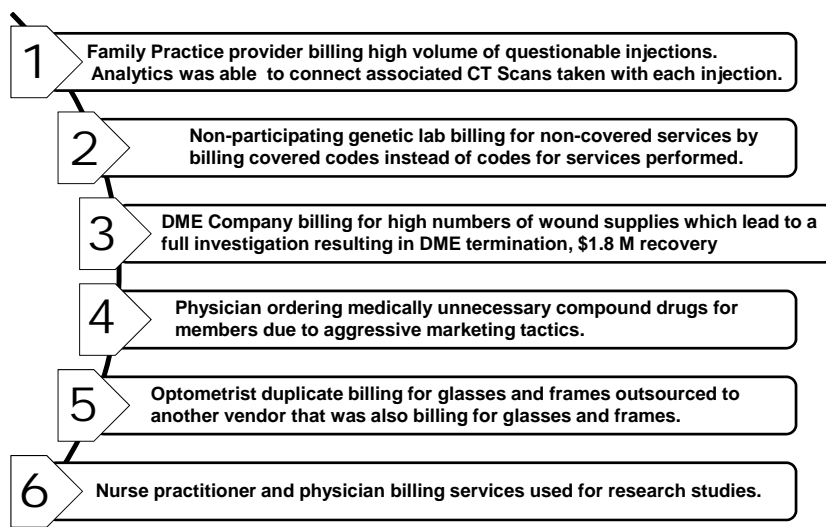
- Internal Correspondence
- Data Sharing
- Search by
 - Sender
 - Date
 - Subject
 - Keyword combinations
- Deleting files rarely **really** deletes them

- TOP 15 EMAIL FRAUD WORDS AND PHRASES**
1. Cover up
 2. Write off
 3. Illegal
 4. Failed investment
 5. Nobody will find out
 6. Grey area
 7. They owe it to me
 8. Do not volunteer information
 9. Not ethical
 10. Off the books
 11. Backdate
 12. No inspection
 13. Pull earnings forward
 14. Special fees
 15. Friendly payments

Pre-Pay Case Examples



Post-Pay Case Examples



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

