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## DATA ON DEFENSE: INVALIDATING FCA ALLEGATIONS BASED ON STATISTICAL SAMPLING AND EXTRAPOLATION

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Statistical sampling and extrapolation have become accepted tools for establishing damages in health care administrative proceedings and False Claims Act (FCA) litigation over the past 30 years. In the last decade, statistical sampling transitioned from being a mechanism primarily utilized to calculate damages to a means to support the core elements of FCA liability.[1] However, the law surrounding both the application and the limitations of asserting and supporting a demand against a property interest has evolved dramatically and remains hotly contested. This article examines the origins of statistical sampling and extrapolation, the shift of statistical sampling to a core element of FCA suits, the need for proper application of the process to data analysis in litigation based on health care claims, and the growing body of law regarding procedural and constitutional limitations in FCA litigation. Finally, this article analyzes some successful legal challenges and provides practical guidance on strategies for invalidating improper statistical samplings and extrapolated demands.

## Sampling and Extrapolation: A Necessary Tool

### Origin of Sampling and Extrapolation

In 1986, the Health Care Financing Administration (HCFA), the predecessor to the Centers for Medicare & Medicaid Services (CMS), determined that a contract auditor was permitted to use sampling and extrapolation as opposed to a claim-by-claim review because:

- The government has a significant interest in cost-effective recovery of improper payments;

- Even though there was no express authorization, there was also no express prohibition; and

- Providers were not denied due process because of their ability to appeal extrapolated findings through the administrative appeals process.[2]

Despite citing no statutory or regulatory authority within the ruling, CMS Ruling 86-1 asserted that the use of sampling and extrapolation grew out of the government's "federal common law right" to recover property. CMS has relied on this decision to justify the use of statistics to support a demand for repayment of claims billed to federal health care programs and has set off a dramatic evolution of how data analytics could be used across the legal spectrum of administrative, civil, and criminal law.

Similar to CMS administrative proceedings, statistical sampling has historically been used in FCA litigation to determine damages when it is impractical to undertake

a claim-by-claim analysis.[3] Recently, the government has started making a concerted effort towards using statistical sampling methods to prove liability.[4] By utilizing statistical sampling to prove liability, FCA plaintiffs do not have the burden of establishing liability for each individual claim.[5]

FCA plaintiffs are not required to utilize any specific statistical sampling methods to prove violations, but the application of such methods must be statistically valid, sufficiently documented, and replicable.[6] Within the administrative context, CMS Ruling 86-1 sets forth that the provider appellant challenging the statistical sampling methods has the burden of establishing that the statistical sampling methodology used was invalid.[7] However, in FCA litigation, the burden is on the government to prove that the statistical sampling plan utilized was factually sound.[8] Providing proof of specific claims is not an FCA statutory requirement; rather, the statutory requirements to prove liability under the FCA are "falsity, causation, knowledge, and materiality."[9]

### United States v. Life Care Centers of America, Inc.

In *United States v. Life Care Centers of America, Inc.*, the court determined that the FCA neither explicitly established nor explicitly prohibited the use of statistical sampling to prove liability in FCA claims.[10] However, the use of statistical sampling and extrapolation in FCA claims has limitations. In *Life Care Centers of America*, the court explicitly held that statistical sampling could be used to prove liability in Medicare overpayment claims brought under the FCA; however, it would be up to each fact finder to determine how much weight to give to the use of statistical sampling and extrapolation.[11] Further, "statistical sampling may be used to prove claims brought under the FCA involving Medicare overpayments, but it does not and cannot control the weight that the fact finder may accord to the extrapolated evidence."[12] Additionally, some circuit courts have held that statistical sampling cannot be used to prove liability in instances where payment hinges on a patient's medical necessity, as statistical sampling cannot substitute for expert medical judgment.[13] However, circuit courts have been split on this issue, and some circuits allow statistical sampling to prove a lack of medical necessity.[14] Moreover, use of statistical sampling is also limited when "a thorough review of the detailed medical chart of each individual patient" is required, such as when a physician must use "subjective clinical judgment" to determine a patient's life expectancy for the purpose of determining hospice eligibility.[15] Legal challenges to statistical sampling range from technical arguments to denials of due process.[16]

As the law surrounding appropriate use and limitations on statistical sampling and extrapolation continues to evolve, the need for such tools in the dramatically expanding health care revenue cycle continues to grow.



### *Big Picture on Claims Data Analysis*

The mechanics of data analytics within the FCA context can be broken down into two generalized processes: 1. statistical sampling, and 2. inference or extrapolation. Statistical sampling occurs when random number generation is used to select a subset of a discrete population. Extrapolation is the second step of the process, where values are extended by inferring unknown values from trends in the known data in order to make determinations about the population as a whole. If done correctly, this is a highly effective way to predict patterns in data. If done incorrectly, it can result in a significantly warped representation of the actual data set.

For example, in August 2020, the Office of Inspector General (OIG) issued a report related to overpayment reviews by Medicare Administrative Contractors (MACs) and according to the OIG's report, MACs have been inconsistent in their calculation methodology and statistically valid sample sizes for extrapolated overpayments during the provider appeals process.[17] This resulted in approximately US$42 million in extrapolated overpayments being overturned from 2017–2018. Despite the inappropriate application of sampling and extrapolation, the need for efficient evaluation of voluminous claims data is only growing.

Recent reports from the Department of Health and Human Services (HHS), OIG, and the Department of Justice (DOJ) illustrate the scope of health care fraud and improper payments the government has sought to recover in 2021.

**HHS Fiscal Year (FY) 2021 Financial Report[18]**

- Medicare and Medicaid accounted for US$134.2 billion of estimated improper payments

- Medicare fee-for-service had a 6.26% error rate = US$25.03 billion (a historic low)

- Medicare Advantage plans had a 10.28% error rate = US$23.19 billion

- Medicaid had a 21.69% error rate = US$98.7 billion (a historic high)

- HHS-OIG Fall Semiannual Report (Dec. 2021)—targeted investigations only; no global error reporting

**OIG Press Release[19]**

- US$4 billion in expected recoveries for FY2021

- US$787 million based on audit findings

- US$3 billion based on investigation recoveries

**DOJ FY2021 Report[20]**

- From FY1987–2021, government has initiated 5,548 of 20,343 (27%) of FCA cases that recovered a total of US$21.9 billion

- In 2021, 203 of 801 (~25%) of FCA cases did not involve a relator and US$3.98 billion of the US$5.65 billion (70.5%) collected in all FCA cases that year were not the result of a Qui Tam suit brought by a relator

   – Over US$5 billion of the US$5.6 billion involved health care entities

As these figures demonstrate, the extraordinary volume of claims and error rate illustrate the necessity but also the flaws of the government's use of statistical sampling and extrapolation in health care cases. While sampling and extrapolation is a tool used at the end of a data analysis to support specific findings, the government's ability to gather and analyze claims data from investigation to litigation has expanded dramatically in recent years.



## Development of Collaborations (CPI, DOJ, Attorneys General, Task Forces) for Application of Claims Data Analysis

Perhaps the most central entity in the health care fraud analysis arena throughout the U.S. health care system is the CMS Center for Program Integrity (CMS-CPI), a specific division of CMS that is the focal point of all national and statewide Medicare, Medicaid, and Children's Health Insurance Program integrity fraud and abuse issues.[21] CMS-CPI oversees all CMS interactions and collaborations with stakeholders relating to program integrity, including the DOJ, HHS-OIG, state law enforcement agencies, and other federal entities for the purpose of detecting, deterring, monitoring, and combating fraud and abuse, as well as taking action against those that commit or participate in fraud.[22] CMS-CPI is the heart of health care fraud investigation, and the claims data is the blood that it pumps through the Fraud Prevention System—a complex software system that reads and analyzes more than one billion claims processed per year.[23]

In 2012, CMS-CPI began the Health Care Fraud Prevention Partnership with 20 public and private partners focused on data and information sharing, which has now grown to include 241 partners.[24] More recently, CMS-CPI began the Major Case Coordination program, which is a collaboration between CMS-CPI, HHS-OIG, and the DOJ that led to large-scale enforcement actions like Operation Brace Yourself[25] and Operation Double Helix.[26]

The DOJ is directly collaborating with CMS contract auditors, and government-initiated FCA cases may originate from the referral of auditors. Unified Program Integrity Contractors (UPICs) have become the primary vehicle for CMS to investigate and data-mine for fraud in Medicare and Medicaid claims processing.[27] UPICs perform integrity work with Medicare Parts A and B, durable medical equipment, home health and hospice, Medicaid, and the Medicare-Medicaid data match program.[28] The UPIC program was specifically created with the intent to consolidate all CMS integrity work to facilitate better coordination with the CMS-CPI, the Federal Bureau of Investigation (FBI), HHS-OIG, the DOJ, and local law enforcement.[29]

Additionally, the Medicare Fraud Strike Force,[30] established under HHS-OIG, and the DOJ's Health Care Fraud Strike Force[31] were created in 2007 to harness data analytics through federal, state, and local resources.

Most recently, the COVID-19 Fraud Enforcement Task Force[32] was established in May 2021 and is comprised of the civil and criminal divisions of the DOJ; the Executive Office of U.S. Attorneys; and the FBI. This task force has been using data analytics to identify Public Health Emergency-related fraud through data mining, as explained further below.

There have been several significant big data cases in 2021 that highlight the collaborations, the DOJ's data mining practices, and use of statistical sampling and extrapolation. For example, in September 2021, the DOJ criminally charged 138 people, including 42 medical professionals in 31 federal districts across the United States.[33] The charges target about US$1.1 billion in alleged fraud committed using telemedicine, US$29 million involving alleged COVID-19 health care fraud, US$133 million connected to substance abuse treatment facilities, and US$160 million in other alleged health care fraud and illegal opioid distribution schemes. Further, the DOJ intervened in an FCA Medicare Advantage fraud case[34] alleging payer Independent Health and its medical analytics subsidiary DxID submitted inaccurate information about their beneficiaries' health, cheating the U.S. government out of tens of millions of dollars. At least two dozen other whistleblower cases have alleged fraud by Medicare Advantage plans related to manipulating patient risk scores to boost revenues. It is a rare move but possibly a new trend for the DOJ to pursue FCA claims against a data-mining company.

As the government's sophistication and ability to better harness data analysis to support FCA claims continues to develop, participants in government programs must educate themselves on how to identify potential abuses and raise challenges.

## Limitations of Sampling and Extrapolation to Support FCA Allegations

### Early Applications of Sampling and Extrapolation to FCA Cases (e.g., Trial Limitations, Bellwether)

Over the last decade, relators have regularly attempted to substitute statistical sampling and extrapolation in place of individual claim-by-claim analysis with varying degrees of success. In making such attempts, plaintiffs are seeking to avoid the costly and time-consuming task of reviewing each claim line to show that providers knowingly submitted false claims to the government.

In *United States ex rel. Loughren v. UnumProvident Corp.*,[35] statistical sampling was used to extrapolate the total number of false claims for the purpose of determining damages. However, this was allowed only after the court held a bellwether jury trial to determine whether sufficient evidence existed regarding the defendant's pattern and practice of submitting false claims. Accordingly, despite supporting the use of extrapolation, Loughren can be limited to the robust mechanisms put into place by the court to evaluate intent. Other courts have allowed extrapolation only when claim-by-claim review is impracticable.[36] However, in United States ex rel. *Michaels v. Agape Senior Community, Inc.,*[37] the U.S. District Court for the District of South Carolina reached the opposite conclusion, demonstrating that courts are still unsure of how to approach these procedures.

Until the courts adopt a more uniformed approach on how statistical sampling and extrapolation are utilized in FCA claims, defendants must be prepared for the possibility of courts permitting multiple types of statistical methods as legitimate.

### Developing Limitations (e.g., Pure Medical Necessity Disputes, Presumptions for Default)

Courts have developed limitations on when plaintiffs are allowed to utilize statistical sampling and extrapolation to support FCA claims. Most notably, courts have limited plaintiffs' ability to use statistical sampling to prove a lack of medical necessity.

Some federal circuit courts have held that statistical sampling cannot be used to prove liability in instances where payment hinges on a patient's medical necessity, as statistical sampling cannot substitute for expert medical judgment.[38] In reaching such determinations, circuit courts have acknowledged the limitations of statistical sampling. In particular, such decisions reinforce the idea that expert medical judgment remains a key factor in deciding FCA cases.

In *Life Care Centers of America*, the court created a limitation of the use of statistical sampling for determining medical necessity.[39] The court determined that when all patients' medical charts were "intact and available for review by either party" the use of statistical sampling was not appropriate, even though the available medical records were voluminous.[40]

### Developing Applications (Government Initiated FCAs Based on Data Analysis)

Recently, the federal government has started utilizing its own data analytics methods to identify outlier providers, support damages, and allege liability for FCA violations.[41] Although data analytics were more frequently used in the civil context, the DOJ's Criminal Division's Health Care Fraud Unit launched a new data analytics team in 2017 with the primary goal being to utilize data analytics to identify fraud and prosecute fraud under the FCA.[42] The greater degree of government sophistication with data analytics has led to more government-initiated (i.e., nonrelator) FCA cases.

In 2021, the U.S. Attorney's Office for the Eastern District of Pennsylvania was able to secure three settlements totaling nearly US$2 million after using its own data analytics mechanisms to P-Stim electro-acupuncture device identify providers who engaged in fraudulent billing and bring an FCA case against the providers.[43] By using its own data analytics, the U.S. Attorney's Office for the Eastern District of Pennsylvania was able to identify inconsistent and improper billing methods to support their demands and as evidence of liability.[44]
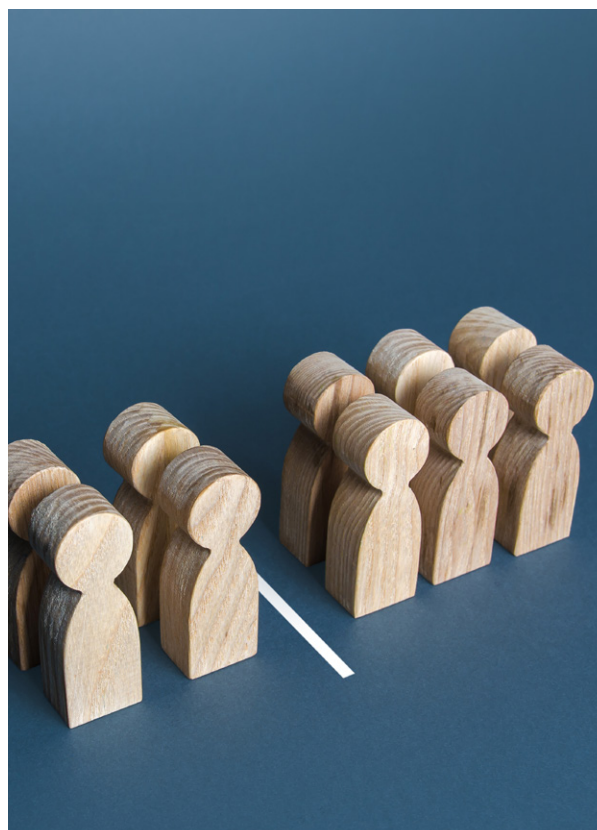


# Defending Improper Use of Sampling and Extrapolation and Using Data as a Shield

### Due Process Essentials

The Medicare Program Integrity Manual (MPIM), Chapter 8, Section 4, provides detailed requirements for CMS contractors in developing an audit plan, a sample frame and set, and a sampling process.[45] These requirements are intended to produce a randomly chosen sample set to objectively reflect the findings across the rest of the claims in the sampling frame.[46] The Office of Audit Services for HHS-OIG[47] uses a statistical software called RAT-STATS[48] and is supposed to conduct all auditing and extrapolations in accordance with Government Auditing Standards (GASAS) developed by the Government Accountability Office (GAO).[49] Both the MPIM and GASAS standards are often used and applied by HHS-OIG and the DOJ in establishing a global fraud loss, and these same standards can be used to evaluate weaknesses in the auditing and sampling processes used to determine the findings in the sample set prior to the error rate or falsity rate being extrapolated.

Due process affords appellants the right to examine the audit results to mount a proper challenge to the statistical sampling and extrapolation processes. This includes:

> An explicit statement of how the universe is defined and elements included shall be made and maintained in writing. Further, the sample frame and specific details as to the period covered, definition of the sampling unit(s), identifiers for the sampling units (e.g., claim numbers, carrier control numbers), and dates of service and source shall be specified and recorded in the contractor's record of how the sampling was done. If the sample frame does not contain the elements used to define the universe because the sampling unit does not permit it, then an electronic copy of the universe will be kept by the contractor.

> A record shall be kept of the random numbers used (if used) in the sample and how they were selected. Documentation shall be kept in sufficient detail so that the sample frame can be re-created should the methodology be challenged. The contractor shall keep an electronic copy of the sample frame.[50]

Failure to comply with this MPIM mandate to carefully document, preserve, and produce a statistical sampling and extrapolation from start to finish denies a provider the opportunity to recreate or replicate the process to determine if it was performed correctly and determine if a valid challenge should be raised. Denying a provider the information necessary to make this evaluation is a failure of due process, an improper taking of property without adequate notice, and is in violation of CMS Ruling 86-1.

### Distinguishing Data Patterns and Presumptions from Intent (Caselaw Limitations)

Recently, several data analysis companies have become whistleblowers, reviewing the mountains of Medicare claims data that CMS has made publicly available, looking for patterns that are indicative of fraud. Then, they work to develop independent, nonpublic information confirming that the patterns were a product of fraud and accordingly initiate FCA suits.

One such company is Integra Med Analytics, which initiated lawsuits in the Fifth and Ninth Circuits against hospitals alleging fraudulent billing for secondary diagnoses following CMS's increase in the number of secondary diagnoses eligible for additional reimbursement. In *Integra Med Analytics, LLC v. Baylor Scott & White Health*,[51] the Fifth Circuit found Integra's statistical analysis was "consistent with both Baylor having submitted fraudulent Medicare reimbursement claims to the government and with Baylor being ahead of most healthcare providers in following new guidelines from CMS." Further, the court noted that, although Baylor's

use of certain codes was higher than other hospitals, the data showed coding rates of various hospitals starting to converge and there was evidence that Baylor was simply ahead of the curve in implementing the new CMS guidelines. In *Med Analytics LLC v. Providence Health & Services*,[52] the Ninth Circuit found that Integra's claim failed to cross "the line between possibility and plausibility" because "Integra does not rule out an obvious alternative explanation[:] that Providence . . . was simply ahead of others in its industry," so the higher reimbursements could very well be indicative of lawful, "rational and competitive business strategy."[53]

Both of these cases were dismissed at the pleadings phase for failure to state a claim upon which relief could be granted and demonstrate that statistical outliers and anomalies alone are not sufficient to state a claim for fraud. Rather, these statistics-heavy, facts-light allegations, which lack any insider knowledge, are insufficient to plausibly plead fraud. Such allegations cannot rule out the obvious explanation that some health care providers are simply better at lawfully analyzing, understanding, and adapting to complex billing regulations and requirements. Further, these lawsuits were in violation of "the public disclosure bar," which states that a whistleblower lawsuit cannot be based on information that is broadly, publicly available and that takes no specialized expertise to interpret.

### Using Comparative Analysis of the Same Universe or Comparable Providers to Defend Presumptions (e.g., CBRs, PEPPERs, Individual Provider/ Physician Versus the Practice Analysis)

In addition to direct challenges to presumptive estimates from sampling in FCA litigation, there are a number of comparative analysis methods that can be persuasive in defending against FCA allegations. Such methods include comparative analysis of data from the Program for Evaluating Payment Patterns Electronic Report (PEPPER),[54] Comparative Billing Reports (CBRs),[55] defendants' prior favorable reviews, and Public Use Files (PUFs).[56]

PEPPER reports, which are "an electronic report that provides provider-specific Medicare data statistics for discharges/services vulnerable to improper payments,"[57] are generated for short-term hospitals, long-term hospitals, critical access hospitals, hospices, inpatient rehabilitation facilities, partial hospitalization programs, skilled nursing facilities, inpatient psychiatric facilities, and home health agencies.[58] By CMS's own admission, PEPPER reports cannot identify payment errors.[59] However, these reports have proven to be a useful enforcement mechanism by the government, as they allow enforcement agents to identify outliers across a state, a MAC jurisdiction, and the country.[60] PEPPER outliers are defined as "facilities outside the 20th or 80th percentile of all facilities in the United

States."[61] Providers can use PEPPER reports to defend against statistical sampling in FCA suits by demonstrating that they are not outliers, may have been unaware of allegations asserted by a relator or the government, and lack the requisite knowledge to form intent.

CBRs can also be used as a defense mechanism in FCA suits. CBRs provide "comparative billing data to an individual health care provider. CBRs contain actual data-driven tables and graphs with an explanation of findings that compare provider's billing and payment patterns to those of their peers on both a national and state level."[62] Providers can use CBRs to illustrate that their billing patterns and practices are consistent with those of other similarly situated providers. Additionally, providers can utilize data in PUFs to compare their practice methods with that of other providers. Finally, a valuable defense tool at a provider's disposal is previous favorable reviews conducted by CMS and its contractors, including Zone Program Integrity Contractors[63] and UPICs,[64] which found that same or similar prior conduct by the provider was proper.

As statistical sampling and extrapolation based on data analyses have dramatically increased in FCA litigation due to the increased sophistication of relator and government technical abilities, it has become imperative for FCA defendants to understand how to challenge the processes and presumptions of such applications to support allegations of fraud and equally important to proactively arm themselves with the tools to ward off potential liability. With this new elevation of risk to participants in government programs, the need to increase compliance using data analytics to self-assess has equally increased.

K&L Gates has a knowledgeable and experienced Health Care practice for FCA litigation and is on the forefront of the developing law surrounding statistical sampling and extrapolation and data analytics with a national and international network to support the most complex of cases.

## Endnotes

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2    HCFA Ruling No. 86-1 (Feb. 20, 1986).

3    Lester J. Perling & Jamie B. Gelfman, *Statistical Sampling in the Medicare Program: How to Use It and How to Challenge It*, 2018 HEALTH L. HANDBOOK 14 (2018)

4    Thomas Reilly, *The Extrapolation Conundrum: Finding a Unified Theory for the Use of Statistical Sampling in Medicare Fraud Cases Brought under the False Claims Act*, 47 SETON HALL L. REV. 1103 (2017).

5    Perling, *supra* note 3.

6    *Id.*

7    CMS Ruling 86-1-11 (Feb. 20, 1986); see also *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 89–90 n.7 (2d Cir. 1991) (stating that the use of statistical sampling and extrapolation to calculate overcharges does not violate a defendant's due process rights "[g]iven the low risk of error and the government interest in minimizing administrative burdens").

8    Joel D. Hesch & Mia Yugo, *Can Statistical Sampling Be Used to Prove Liability under the FCA or Does Each Provision of the Statute Require Individual Proofs?*, 41 AM. J. TRIAL ADVOC. 335 (2017).

9    *Id.* at 350.

10   114 F. Supp. 3d 549, 560 (explaining that one of the reasons courts permit the use of statistical sampling in cases regarding fraud against the government is that "in view of the enormous logistical problems of [enforcement of government programs], statistical sampling is the only feasible method available") (quoting Ill. *Physicians Union v. Miller*, 675 F.2d 151, 157 (7th Cir. 1982)).

11   *Id.*

12   *Id.* at 570.

13   See *supra* note 3.

14   *Id*

15   *United States ex rel. Michaels v. Agape Senior Comm.*, Inc., No. 0:12-3466-JFA, 2015 WL 3903675 (D.S.C. June25, 2015); Milene Vega, *Should Statistical Sampling Be Used to Prove Liability under the False Claims Act in Healthcare Fraud*, 91 S. CAL. L. REV. 551 (2018).

16   See, e.g., Perling, *supra* note 3.

17   HHS, OIG, Medicare Contractors were not Consistent in *How They Reviewed Extrapolated Overpayments in the Provider Appeals Process* (Aug. 25, 2020), https://oig.hhs.gov/oas/reports/region5/51800024.asp

18   FY 2021: *HHS, Agency Financial Report* (2021), https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf

19   Press Release, HHS, OIG, Taxpayers Could Save Nearly $4 Billion Dollars as a Result of HHS-OIG Work in FY 2021 (Dec. 2, 2021) https://oig.hhs.gov/newsroom/news-releases-articles/2021-fall-sar/.

20   FCA Cases U.S. Dep't of Just., Fraud Statistics – Overview (Sept. 30, 2021), https://www.justice.gov/opa/press-release/file/1467811/download.

21   See HHS, Center for Program Integrity (last visited Dec. 14, 2020), https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CPI

22   *Id*

23   CMS, Fraud Prevention System Return on Investment Fourth Implementation Year (last visited Dec. 14, 2020), https://www.cms.gov/About-CMS/Components/CPI/Downloads/Fraud-Prevention-System-Return-on-Investment-Fourth-Implementation-Year-2015.pdf; see also CMS, Investing in Data & Analytics (last visited Dec. 14, 2020), https://www.cms.gov/About-CMS/Components/CPI/CPI-Investing-In-Data-and-Analytics.

24   CMS, About the Partnership, CMS.gov (Feb. 7, 2022), https://www.cms.gov/hfpp/about

25   CMS, Medicare and Medicaid Integrity Programs, FY 2018 Annual Report Oct. 1, 2017–Sept. 30, 2018 (last visited Dec. 14, 2020), https://www.cms.gov/files/document/medicare-and-medicaid-integrity-program-fy-2018-annual-report.pdf

26   Press Release, DOJ, Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over $2.1 Billion in Losses in One of the Lar Care Fraud. Schemes Ever Charged (Sept. 27, 2019), https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against

27  Medicare Program Integrity Manual ("MPIM"), Ch. 4.

28  *Id.*

29  *Id.*

30  HHS, OIG, Medicare Fraud Strike Force, Office of the Inspector General (Sept. 30, 2021), **https://oig.hhs.gov/fraud/strike-force/**

31  DOJ, Strike Force Operations, **https://www.justice.gov/criminal-fraud/strike-force-operations**.

32  Press Release, DOJ, Attorney General Announces Task Force to Combat COVID-19 Fraud (May 17, 2021), **https://www.justice.gov/opa/pr/attorney-general-announces-task-force-combat-covid-19-fraud**.

33  Press Release, DOJ, National Health Care Fraud Enforcement Action Results in Charges Involving over $1.4 Billion in Alleged Losses (Sept. 17, 2021), **https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion**

34  Press Release, DOJ, United States Intervenes and Files Complaint in False Claims Act Suit Against Health Insurer for Submitting Unsupported Diagnoses to the Medicare Advantage Program (Sept. 14, 2021), **https://www.justice.gov/opa/pr/united-states-intervenes-and-files-complaint-false-claims-act-suit-against-health-insurer**; Complaint, *United States ex rel. Ross v. Indep. Health Ass'n*, Case No. 12-CV-0299(S) (W.D.N.Y 2021), **https://www.justice.gov/opa/press-release/file/1432501/download**

35  604 F. Supp. 2d 259 (D. Mass. 2009).

36  *United States ex rel. Martin v. Life Care Centers of America, Inc.*, No. 1:08-cv-251, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014)

37  2015 WL 3903675 (D.S.C. June 25, 2015).

38  Perling, *supra* note 3; e.g., Agape Senior Cmty., 2015 WL 3903675 at *8 (stating that each claim would require a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient").

39  *Life Care Ctrs. of Am.*, 114 F. Supp. 3d at 560; Peter T. Thomas, *Trial by Formula: The Use of Statistical Sampling and Extrapolation in Establishing Liability Under the False Claims Act*, 74 WASH. & LEE L. REV. ONLINE 215 (Nov. 2, 2017), **https://scholarlycommons.law.wlu.edu/wlulr-online/vol74/iss1/11**

40  *Life Care Ctrs. of Am.*, 114 F. Supp. 3d at 560.

41  Jason Mehta & Jennifer A. Short, *Big Data Makes Big Cases: How Data Analytics Is Shaping False Claims Act Enforcement*, 67 FED. LAW. 43 (2020).

42  DOJ Fraud Section Year in Review 2017.

43  Press Release, DOJ, U.S. Attorney Announces Four Additional Enforcement Actions as Part of Data-Driven National Effort to Combat P-Stim Fraud Scheme and Recover Millions (Oct. 14, 2021), **https://www.justice.gov/usao-edpa/pr/us-attorney-announces-four-additional-enforcement-actions-part-data-driven-national**.

44  *Id.*

45  MPIM, Ch. 8, § 8.4, **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf**.

46  *Id.*

47  HHS-OIG, Office of Audit Services (last visited Dec. 15, 2020), **https://oig.hhs.gov/about-oig/office-audit-services/**.

48  *Id.*

49  GAO, Government Auditing Standards, 2018 Revision, **https://www.gao.gov/assets/700/693136.pdf**.

50  See MPIM Ch. 8, § 8.4.4.4.1.

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52  No. 19-56367, 2021 WL 1233378 (9th Cir. Mar. 31, 2021).

53  *Id.* at * 8–9.

54  PEPPER, *Welcome to PEPPER Resources, Program for Evaluating Payment Patters Electronic Report*, **https://pepper.cbrpepper.org**.

55  PEPPER, *Welcome to CBR Resources, Comparative Billing Reports*, **https://cbr.cbrpepper.org/home**.

56  CMS, Health Insurance Public Use Files (Exchange PUFs), **https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf**.

57  CMS, Data Analysis Support and Tracking, **https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Data-Analysis**.

58  *Id.*

59  *Id.*

60  Katie Pawlitz & Greg Russo, *Proactively Responding to Government Investigations Using Data Analytics: An Examination of Data Considerations in the Post-Acute Context*, 29 HEALTH LAW. 23 (2017) at 26.

61  *Id.*

62  Data Analysis Support and Tracking, *supra* note 57.

63  CMS, Review Contractor Directory, **https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map**.

64  *Id.*

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