RECENT DEVELOPMENTS IN FRAUD AND ABUSE

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Overview of Topics

- HHS & DOJ Health Care Fraud and Control Program
  - Annual report, FCA Statistics
- Litigation Updates
  - *Life Care Centers of America, Inc., ManorCare, Inc., Sava Senior Care, Kindred/Rehabcare*
- Material FCA Decisions
  - *U.S. ex rel. Paradies et al. v. AseraCare, Inc.* – Objectively False Claim
  - *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.* – Objectively False Claim
  - *UHS v. Escobar* – Implied False Certification
  - Interpretations/Developments in *Escobar* and *AseraCare*

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Overview of Topics-Cont.

- Developments in the use of Extrapolation
  - *United States ex rel. Michaels v. Agape Senior Cmty. Inc.*
  - Other
- *Jimmo v. Sebelius* - update
- Key Areas of Risk
- Government Investigations
  - CIDs, Subpoenas

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The Federal False Claims Act

- The FCA provides a cause of action against any person who, among other things, "(A) **knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim** . . . ." 31 U.S.C. § 3729(a)(1)(A)-(B).

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Federal False Claims Act

Elements of FCA Case:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . ." 31 U.S.C. § 3729(a)(1)(A)-(B).

Plaintiffs must prove every element of an FCA cause of action by a "preponderance of the evidence," including such elements as falsity, knowledge, and damages. *See* 31 U.S.C. § 3731(d).

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HHS/DOJ Statistics

- HHS/DOJ Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2016
- 2016 - $3.35B in returned to CMS and US Treasury
  - $6.8B since 2009, $20B since 1986
- 2014-2016 Return on Investment
  - $5.00 returned for every $1.00 expended
- Medicare Fraud Strike Force – 2016
  - Los Angeles, Miami, Tampa, Chicago, Brooklyn, Detroit, Southern Louisiana, Dallas and Southern Texas
  - 246 indictments, 260 guilty pleas
  - 290 defendants sentenced to prison, averaging more than 48 months of incarceration

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Recent FCA Cases Against SNFs

- Typical allegations
  - All patients at the highest RUG level upon admission
  - HUG the RUG
  - Rounded v. Actual minutes
  - Increasing minutes through multiple modalities
  - Setting target rehab levels, including bonuses and comp.
  - Lack of documentation for medical necessity
  - Increasing "Failure of Care" or "Worthless Services"
  - During the period prior to Oct. 1, 2011, boosting the amount of reported therapy during "assessment reference periods," known as "ramping"
  - Inflating initial reimbursement levels by reporting time spent on initial evaluations as therapy time rather than evaluation time

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Litigation Updates

❖*U.S. v. Life Care Centers of America, Inc.*

- Based upon "ultra high" therapies
- FCA cases typically require individual "false claims" to be identified
- Here, no individual claims identified but rather through "sampling" and "extrapolation" (400 records sample applied to 54,396 admissions and 154,621 claims)
- Court refuses to dismiss FCA claims and will permit trial with sampling

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Litigation Updates

❖*U.S. v. Life Care Centers of America, Inc.*

- October 24, 2016 Department of Justice issues a press release announcing the terms of the settlement
  - $145 million to resolve false claims act allegations
    - Based on company's ability to pay
  - Life Care will enter into a five-year chain-wide Corporate Integrity Agreement
    - https://oig.hhs.gov/fraud/cia/agreements/Forrest_Preston_and_Life_Care_Centers_of_America_Inc_10212016.pdf

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Litigation Updates

❖*U.S. v. ManorCare, Inc.*

- December 2014: Government intervened in three consolidated qui tam, FCA lawsuits in Eastern District of Virginia
- April 2015: Government's consolidated complaint unsealed
- Allegations are that ManorCare knowingly and routinely submitted false claims for therapy services that were not medically reasonable and necessary
- Discovery phase completed, court is in process of evaluating various pending motions: (1) motion to exclude testimony of certain witnesses; (2) Manor Care's Motion for Summary Judgment

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Litigation Updates

- *U.S. v. ManorCare, Inc.*
  - ManorCare's motion for summary judgment argues facts demonstrate DOJ cannot establish elements of FCA liability, challenges use of statistical sampling to establish liability under the FCA
  - Potentially crucial development: magistrate judge assigned to case (Hon. Theresa Carroll Buchanan) held hearing on Oct 27 to address ManorCare's motion for sanctions regarding certain disclosures of DOJ's clinical expert
    - After berating DOJ counsel for over half an hour, Judge Buchanan granted ManorCare's sanctions motion and ruled that DOJ's clinical expert cannot testify at trial, which is scheduled to begin on January 22, 2018. Case could be dismissed unless DOJ has ruling overturned

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Litigation Updates

❖*U.S. v. SavaSenior Care, LLC*

- October 2015: Government intervened in three consolidated qui tam, FCA lawsuits in Middle District of Tennessee
- Allegations are that Sava knowingly and routinely submitted false claims for therapy services that were not medically reasonable and necessary
- Case recently had Motion to Dismiss denied, despite Government's failure to recognize and cite a violation of the Highest Practicable Level Standard required by statute and regulation
- Novel Motion to Dismiss filed in June 2017. Argument is that the court lacks subject matter jurisdiction by virtue of the administrative process established by Congress to review claims

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Litigation Updates

❖North American Health Care, Inc. settles with Department of Justice

- September 19, 2016 Department of Justice issues press release announcing terms of settlement
  - $30 million to resolve false claims act allegations
    - $28.5 million from company
    - $1 million from Chairman of the Board
    - $500 thousand from Senior Vice President of Reimbursement Analysis
- NAHC has also entered into a five-year Corporate Integrity Agreement. The CIA applies to all facilities managed by NAHC and requires an independent review organization to annually review therapy services billed to Medicare
  - https://oig.hhs.gov/fraud/cia/agreements/North_American_Health_Care_Inc_09162016.pdf

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Litigation Updates

- Rehabcare Group Inc. and Kindred Healthcare, Inc. paid $125 million to resolve claims that were not reasonable, necessary and skilled or were not provided at all
  - The government's complaint alleged that Rehabcare's policies and practices, including setting unrealistic financial goals and scheduling therapy to achieve the highest reimbursement level regardless of the clinical needs of its patients, resulted in Rehabcare providing unreasonable and unnecessary services to Medicare patients and led its SNF customers to submit artificially and improperly inflated bills to Medicare that included those services.

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Litigation Updates

- Catholic Health System, Inc. settles with the Department of Justice
  - On October 27, 2017, Department of Justice announced settlement with Catholic Health System, Inc. for $6 million to resolve government's claims for allegedly submitting false claims related to physical, speech and occupational therapy.
  - Covered conduct was services from 2007 – 2014
  - Allegations of providing unnecessary physical, speech and occupational therapy to nursing home residents
  - The allegations concerned 3 facilities within the health system
  - Organization enters into 5 year Corporate Integrity Agreement
  - Catholic Health Systems chose to issue its own press release
  - No indication of Yates approach

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Litigation Updates

- September 2016, US DOJ FCA suit against Vanguard Healthcare, LLC
  - Patients harmed between 2010-2015 as a result of "grossly substandard" or "worthless" care.
    - Staffing shortages, lack of infection control, improper medication administration, inadequate pain management
  - Names corporate entities and company director of operations
  - Company was in the process of bankruptcy - Chapter 11
  - Court is allowing the FCA case to proceed in spite of bankruptcy

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Litigation Updates

- U.S. ex rel. Ruckh v. Genoa Healthcare, LLC,
  - On February 15, 2017, in U.S. ex rel. Ruckh v. Genoa Healthcare, LLC, a case in which both the United States and the state of Florida declined to intervene
  - Jury returned a verdict finding that the operators of 53 SNFs had committed FCA violations resulting in more than $115 million in damages. The FCA violations resulted from the submission of false claims to Medicare and Medicaid stemming from the inflation and upcoding of RUG levels for patients and false certifications that the SNFs had created timely and adequate patient care plans.

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Litigation Updates

- U.S. ex rel. Ruckh v. Genoa Healthcare, LLC,
  - The jury's verdict represented only actual damages. On March 1, 2017, the district court assessed a statutory penalty of $5,500 per claim to 446 false claims and trebled the jury's damages number, the result being almost $348 million. This dwarfs even the largest of the long-term care settlements that have preceded it
  - Two additional aspects of the case are noteworthy. First, the relator—a former employee at two facilities—utilized statistical sampling to prove her case. The relator proactively filed a motion in limine seeking permission to introduce statistical sampling evidence to prove both the number of false claims and the corresponding damages.
  - Though it did not intervene, the United States filed a motion in support of relator's request.

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Litigation Updates

- Relying in part on U.S. ex rel. Martin v. Life Care Centers of America, the district court granted relator's motion, explaining that "it would be impracticable for the Court to review each claim individually" and this "would consume an unacceptable portion of the Court's limited resources."
- The district court held there was no universal ban on expert testimony based on statistical sampling in qui tam actions, but it left open the possibility of a *Daubert* attack on such testimony. District court allowed the relator to introduce statistical sampling evidence at trial, and it was enough to convince the jury of FCA liability as to the universe of claims at issue.

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Litigation Updates

- District court excluded some 31,000 pages of medical records that defendants had claimed supported their defense. Despite producing over one million pages of medical records, defendants inadvertently failed to produce thousands of MDS assessments during discovery. They produced these documents, along with some additional records from patient files, after discovery had closed and in conjunction with their rebuttal expert reports. (The documents were produced almost a year before trial.) The district court excluded the documents, finding the late production, even if not willful, showed a "careless disregard for the discovery process."

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Litigation Updates

- Reliant Care Group and Reliant Affiliated Entities reach $8.3 million civil settlement
  - DOJ alleges from January of 2008 through April of 2014, Reliant provided unnecessary physical, speech and occupational therapy to nursing home residents who had a relatively high level of independence and who were residing in a SNF primarily because of a psychiatric condition. The United States alleged that Reliant provided the unnecessary therapy and then sought the inflated reimbursement from Medicare influenced by its own financial considerations. The United States further alleged that some Reliant Care Rehabilitative Services management pressured therapists to provide therapy to residents even when the therapists believed that the therapy was not medically necessary

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Litigation Updates

- Reliant Care Group and Reliant Affiliated Entities reach $8.3 million civil settlement
  - Reliant manages 23 facilities, it appears only 11 were part of the settlement agreement
  - Reliant agrees to a 5-year CIA with the OIG
  - No Yates approach

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Litigation Updates

- Genesis Healthcare settles six federal lawsuits and investigations alleging that companies and facilities acquired by Genesis violated the False Claims Act by causing the submission of false claims to government health care programs for medically unnecessary therapy and hospice services, and grossly substandard nursing care.
- $53,639,288.04 in total settlement
  - DOJ did not quantify the amounts attributed to each of the cases comprising the settlement

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U.S. ex rel. Paradies et al. v. AseraCare Inc.

- On March 30, the District Court for the Northern District of Alabama issued an order granting summary judgment to AseraCare in a hospice False Claims Act (FCA) case worth $200 million. This case stemmed from whistleblower allegations that AseraCare provided hospice services to Medicare beneficiaries that were not clinically eligible for the hospice benefit.
- From the very outset of its Memorandum Opinion, the court made clear its conclusion that FCA claims cannot be won on the conflicting clinical judgment of one medical expert.

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U.S. ex rel. Paradies et al. v. AseraCare Inc.

- AseraCare's motion to bifurcate the trial into two phases:
  - one phase on the 'falsity'
  - second phase on the other elements of the United States' FCA claims and all other claims."
- The court took this unprecedented step because the court found that review of evidence of AseraCare's corporate patterns and practices, before assessing whether claims submitted by AseraCare were actually false, would unduly prejudice AseraCare. As such, the issue of "falsity" was solely at issue in the first phase of this trial rather than considering the knowledge and falsity elements of the FCA claims simultaneously.

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Post-AseraCare

- *U.S. ex rel. Polukoff v. St. Mark's Hospital*
  - January 19, 2017 - District Court ruled that a claim cannot be false if reasonable minds can differ over the medical necessity of the services. This decision, along with AseraCare and others, should bolster the defense of skilled nursing facilities defending FCA cases involving therapy claims and other services
- *United States of America v. Harold Persaud*
  - June 13, 2017 – 6th Circuit Court of Appeal decision that was certified for publication and brought to the attention of the 11th Circuit by DOJ in the pending AseraCare appeal involving the ongoing dispute over the impact of competing medical judgments on the issue of medical necessity in healthcare fraud cases. Court seems to leave such disputes to the jury to decide rather than negating objective falsity of a claim.

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Universal Health Services v. Escobar

- On June 16, 2016, The U.S. Supreme Court issued its opinion in *Universal Health Services v. Escobar*.
  - The Court unanimously upheld the theory of "implied certification," in which a government contractor can be held liable under the False Claims Act for failing to disclose non-compliance with "material" statutory regulatory or contractual requirements.
  - However, the Court set forth rigorous parameters for determining "materiality"
  - The Court stated its disagreement "with the Government's and First Circuit's views of materiality: that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation."

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Universal Health Services v. Escobar

- False Claims Act does not adopt such an extraordinarily expansive view of liability" and emphasized that the Act "is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations."
- The Court vacated and remanded the decision of the First Circuit for reconsideration of whether a False Claims Act violation exists in light of the High Court's new materiality standard.

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Post-*Escobar*

- *McBride v. Halliburton Company* – 03/02/2017
- *U.S. ex rel. Se. Carpenters Counc. v. Fulton County* – 08/05/2016
- *U.S. ex rel. George v. Fresenius* – 09/26/2016
- *U.S. ex rel. Lee v. N. Adult Day Health Care Ctr.* – 09/07/2016
- United States ex rel. Swoben v. United Health Group
- USA ex rel. Prather v. Brookdale Senior Living Communities, Inc. No. 3:12-cv-00764 [June 22, 2017]
- Unites States ex rel. Harman v. Trinity Indus., Inc. No. 15-41172 [5th Cir Sept. 29, 2017]

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Jimmo v. Sebelius

- 02/01/2017 – District Court ruling ordering CMS to implement a Corrective Action Plan ("CAP") to improve education related to the coverage of skilled therapy and nursing services needed to maintain health and function or "Maintenance Coverage"
- The judge ruled that the CAP, which must be certified as compliant by September 4, 2017, include the following:
  - 1. CMS publish a new web page dedicated to the *Jimmo* settlement agreement.
  2. CMS publish a Corrective Statement disavowing an "Improvement Standard".
  3. CMS post Frequently Asked Questions.

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Jimmo v. Sebelius

- 4. CMS develop and implement training for Medicare Contractors and Medicare Advantage plans making coverage decisions.
  5. CMS conduct a new National Call to explain the correct "Maintenance Coverage" policy."

- Additionally, since the plaintiff and CMS could not agree on the language to be included in the "Corrective Statement", the court mandated specific language based mostly on language from the plaintiff.

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Qui Tam lawsuit brought under the False Claims Act
  - *Relators*: laboratory corporate officers who submitted a proposal to defendants to provide pre-transplant histocompatibility testing for kidney transplant patients
  - *Defendants*: Kidney transplant center (USC) and its histocompatibility testing contractor (Metic)

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Allegations: overbilled Medicare in connection with their provision of histocompatibility testing
  - Relator's Expert's Testimony:
    - Defendants' protocol was inconsistent with industry standard and resulted in unnecessary testing
    - ". . . kidney protocol which I saw last year was not optimal. Depending upon the lab's prices, it ***might be possible*** to lower costs while obtaining higher quality data."

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Procedural posture:
    - Multiple motions to dismiss
    - Only remaining claim was centered on Defendants' alleged redundant and unnecessary testing
    - Defendants filed motion for summary judgment, contending there are no triable issues of fact on multiple issues, including FCA elements of "falsity" and scienter

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Court granted Motion for Summary Judgment
  - *Rationale*: relators have not established triable issues of fact as to "falsity" and "scienter
    - "Conundrum of the 'Objectively Verifiable Fact' and Scienter in Medical FCA Cases": "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false"
    - FCA implied false certification theory "does not fit comfortably into the health care context because the [FCA] was not designed for use as a blunt instrument to enforce compliance with all medical regulations"

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Rationale (cont.):
    - "Interests of federalism counsel that 'the regulation of health and safety matters is primarily, and historically, a matter of local concern"
    - Permitting "qui tam plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the qui tam relator would replace the aggrieved patient as plaintiff"
    - "State, local or private medical agencies, boards and societies are better suited to monitor quality of care issues"

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Rationale (cont.):
    - Defendants can only be deemed to have submitted claims to Medicare seeking reimbursement for laboratory tests performed that are "knowingly false" by proving the providers, in their medical opinion, knew (or acted in deliberate ignorance or reckless disregard of the truth) that their selection of such tests was not "medically necessary"

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U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc

- *U.S. ex rel. Dooley v. Metic Transplantation Lab, Inc.*, 3:07-cv-00604-M (N.D. Tex. June 20, 2016)
  - Rationale (cont.):
    - At best, the evidence showed defendants were negligent in failing to take timely notice of advances in histocompabilitiy testing technology and methods
    - This may have created less than optimal circumstances where defendants were incurring higher costs while obtaining lesser quality data, but does not give rise to liability under the FCA

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Yates Memorandum

- 09/09/2015 – New DOJ Approach to hold individuals responsible for corporate wrongdoings
  - Mortgage crisis
- Six principles
  - 1. To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.
  - 2. Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.
  - 3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.

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Yates Memorandum

- 4. Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- 5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.
- 6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suite against an individual based on considerations beyond that individual's ability to pay.

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Developments in the Use of Statistical Sampling and Extrapolation

- Elements of FCA Case:
  - (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . ." 31 U.S.C. § 3729(a)(1)(A)-(B).
- Plaintiffs must prove every element of an FCA cause of action by a "preponderance of the evidence," including such elements as falsity, knowledge, and damages. *See* 31 U.S.C. § 3731(d).

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Developments in the Use of Statistical Sampling and Extrapolation

❖How is statistical sampling used in FCA litigation and why is it controversial?

- In recognition of the highly fact-dependent analysis and per-claim liability under the FCA, plaintiffs must allege fraud with particularity in FCA actions.
- However, some district courts have shown an increased willingness to endorse plaintiffs' controversial use of statistical sampling and extrapolation of such samples to establish *liability* in FCA actions involving a large number of alleged false claims.
- Damages calculation v. liability

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Sampling and Extrapolation of Findings

- What is statistical sampling and extrapolation?
  - Statistical sampling provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample
  - It is merely a confident inference: statisticians account for any discrepancies by calculating a margin of error

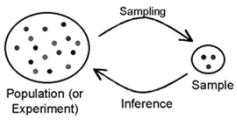

Image Source: Mr. Adams' Blog (https://mradamsblog.blogspot.com)

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Sampling and Extrapolation of Findings

- Extrapolation can turn a molehill into a mountain
  - $100,000 overpayment becomes $10 million overpayment
  - $400,000 overpayment becomes $40 million overpayment
- Focus of dispute may turn to extrapolation issues
- Still important to argue medical necessity of sample claims
  - Two-way street: victories in the sample are also extrapolated to larger victories in the universe

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Sampling and Extrapolation of Findings

- Permissible in ZPIC audits under certain circumstances
  - The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires (a) a determination of sustained or high level of payment error, or (b) documentation that educational intervention has failed to correct the payment error
  - CMS contends the determination that a sustained or high level of payment error exists is not subject to administrative or judicial review
  - See Medicare Program Integrity Manual, Chapter 8 – Administrative Actions and Statistical Sampling for Overpayment Estimates (available at www.cms.gov)

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Sampling and Extrapolation of Findings

- Is it appropriate in FCA context?
  - Government's Position:
    - *See United States ex rel. Martin v. Life Care Centers of America, Inc.*, Nos. 1:08-cv-251, 1:12-cv-64, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014) – Order on Motion to Exclude Expert Testimony
    - HEAT initiative analyzing medical necessity of therapy services rendered at 82 facilities, 54,396 admissions, 154,621 total claims
    - Extrapolation used for (1) estimating number of claims submitted for non-covered services and (2) estimating amount of loss associated with claims – has been used in litigation for decades
    - Recognized as "an acceptable due process ***solution***"
    - Extrapolation deemed admissible, i.e., motion denied
    - Settled for $145 million

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Sampling and Extrapolation of Findings

- Is it appropriate in FCA context? (cont.)
  - Provider's Position
    - *See U.S. ex rel. Michaels v. Agape Senior Community, Inc.*, No. 0:12-3466-JFA, 2015 WL 3903675 (D.S.C. June 25, 2015) (certified for interlocutory appeal to Fourth Circuit)
    - Statistical sampling not allowed to prove damages
    - Different diagnoses, different comorbidities, different physicians – extrapolation inappropriate
    - ". . . highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each patient . . ."
    - Medical records intact – not a case where rendering direct proof of damages is impossible
    - Appeal provided no definitive resolution

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Sampling and Extrapolation of Findings

- Is it appropriate in FCA context? (cont.)
  - Provider's Position
    - *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016)
    - Cited and agreed with rationale in *Agape Senior Community*
    - Extrapolating in hospice case is especially problematic, because it requires "examination of the subjective clinical judgment of a number of certifying physicians applying the uncertain, changeable, and inexact science involved in predicting an individual's life expectancy"
    - Technical problems with extrapolation
    - Methodology unreliable because expert failed to select a random sample or to account for relevant variables

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Sampling and Extrapolation of Findings

- ❖Retain counsel
- ❖Retain statistician (Ph.D. level)
  - ❖Experience with extrapolation of Medicare claims (e.g., participation in FCA litigation, ZPIC audits) is essential
- ❖Exchange your own claims data for comparison
- ❖Often technical and substantive problems with methodology
  - ❖Valid selection of frame?
    - ❖ What was the overall universe? Why?
    - ❖ Who selected it? How?
    - ❖ Definition of terms in the universe.
    - ❖ Claims within audited period and/or relevant time period?

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Sampling and Extrapolation of Findings

- ❖Technical issues with extrapolation methodology (cont.)
  - ❖Valid selection of sample?
    - ❖ What methods were used to ensure stratification?
    - ❖ Software utilized?
    - ❖ How does the sample ensure representativeness?
    - ❖ Is the sample large enough?
  - ❖Valid results?
    - ❖ What is the confidence level?
    - ❖ Margin of error?
    - ❖ How was the error rate calculated?
    - ❖ What does error rate represent (e.g., overpayments, errors in coding, lack of documentation, claims with errors, etc.)?
    - ❖ Can it be replicated?

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Government investigations and Qui Tam cases

- DHHS-Office of the Inspector General continues to issue broad based subpoenas to skilled nursing providers seeking information regarding therapy utilization
  - Subpoenas seek broad range of documents sometimes for periods of 7 years
  - Subpoenas seek:
    - patient medical records;
    - therapy policies and procedures;
    - financial bonus plans tied to Medicare utilization;
    - organizational charts;
    - lists of current and former employees;
    - documents related to marketing, advertising and promotion
    - training materials related to RAI, OBRA, PPS, RUGs, MDS, ADL,

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Government investigations and Qui Tam cases- Cont.

- Subpoenas seek:
  - audits completed by provider or consultant relating to provision of therapy services
  - agendas and minutes from Stand Up meetings
  - And ALL COMMUNICATIONS RELATED TO THE ABOVE, INCLUDING EMAIL AND TEXTS

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Key Areas of Risk

❖ Medical Necessity
- RUGs
- Census, LOS and Utilization Goals
- Local and National Coverage Determinations v. Physician Judgment

❖ Referrals/Kickbacks
- Financial Arrangements with Physicians
- Bonus Programs
- Marketing Activities

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Self-Audits

❖Self-audit of elements of program, such as billing and/or quality of care issues
- Effectiveness – When issues are identified through auditing, does the compliance program address the issues?
- Does the compliance committee meet to review?
- Employee training?
- Updating of the program by compliance officer

❖Evaluate self audits for appropriate RUG levels

❖Trends in comparison to other comparable Providers

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Compliance Program

- Elements of Effective Compliance Program
  - Implementing written policies, procedures and standards of conduct
  - Designating a compliance officer and compliance committee
  - Conducting effective training and education
  - Developing effective lines of communication
  - Conducting internal monitoring and auditing
  - Responding promptly to detected offenses and developing corrective action

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