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Numbers Never Lie . . . Or Do They? The Use of Statistical Sampling in False Claims Act Cases

By Kelly A. Carroll and James F. Segroves

As those in the health care industry are well aware, the federal False Claims Act (FCA) imposes stiff penalties for each false claim submitted to the federal government, resulting in recoveries of over $2 billion in fiscal year 2014 relating to federal healthcare programs alone. In recognition of the highly fact-dependent analysis and per-claim liability, plaintiffs must allege fraud with particularity in FCA actions. However, while the FCA continues to attach liability at a claim-by-claim level, 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.

In an issue of first impression for the federal appellate courts, the United States Court of Appeals for the Fourth Circuit recently agreed to decide whether statistical sampling may be used to prove liability or damages under the FCA, in *United States ex rel. Michaels v. Agape Senior Community Inc.,* No. 15-2145.

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). 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).

Historically, some courts have recognized the use of statistical sampling in other types of litigation, such as antitrust, complex employment litigation, and toxic tort and mass tort cases. Statistical sampling involves the use of mathematical and statistical methods to estimate characteristics of a large population by extrapolating results from a small sample of that population.

In This Issue

While courts have accepted analyzing samples of evidence as a method of proving liability about a significantly larger universe of evidence in other kinds of litigation, the courts that have allowed the use of statistical sampling in FCA actions generally have limited its use to determining damages. *See United States v. Cabrera-Diaz,* 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (discussing cases endorsing the use of statistical sampling to establish damages).

In *United States ex rel. Martin v. Life Care Centers of America, Inc.*, however, the United States District Court for the Eastern District of Tennessee sided with the government's request to employ statistical sampling to establish both FCA damages and liability by extrapolating from a random sample of 400 patient admissions to a universe of 54,396 patient admissions, totaling more than 154,000 claims. *See Life Care,* No. 1:08-cv-251, 2014 U.S. Dist. LEXIS 142660, at *20 (E.D. Tenn. Sept. 29, 2014). The government alleged that Life Care, as owner of more than 200 skilled nursing facilities nationwide, engaged in a corporate scheme whereby it submitted fraudulent claims to Medicare for unnecessary therapy services. Life Care moved for partial summary judgment on the unidentified claims that the government sought to prove as false exclusively through the use of extrapolation. Life Care argued that the government's use of statistical extrapolation would inappropriately shift the burden of proof to Life Care, would violate Life Care's due process rights, and would not provide evidence to satisfy the elements of proof in an FCA action, including falsity, knowledge, and materiality.

After reviewing FCA cases addressing the use of statistical sampling and finding them non-determinative, the court found that neither the plain language of the FCA nor its legislative history reflects a prohibition or disinclination toward the use of statistical sampling in FCA cases. *Id.* at *43, 62. Ultimately, the court concluded that the government could employ statistical sampling to prove its FCA causes of action, focusing its holding on the impracticability of a claim-by-claim review in complex FCA actions and noting that to require such claim-by-claim review "would open the door to more fraudulent activity because the deterrent effect of the threat of prosecution would be circumscribed." *Id.* at *63.

The *Life Care* court emphasized that, while its holding permits plaintiffs to use statistical sampling to prove FCA causes of action involving Medicare overpayment, the burden of weighing the extrapolated evidence lies with the ultimate fact finder. *Id.* at *64. The court noted that defendants may challenge the statistical sample through a variety of methods, including cross-examination of plaintiffs' experts and presentation of competing witnesses, experts, and evidence. The *Life Care* court subsequently denied the defendant's request for permission to appeal its ruling.

Unlike the court in *Life Care*, the United States District Court for the District of South Carolina recently rejected the use of statistical sampling and extrapolation as a method of proving liability or damages in an FCA case involving the submission of more than 50,000 allegedly false claims for hospice services. *See United States ex rel. Michaels v. Agape Senior Cmty. Inc.,* No. 12-3466, 2015 WL 3903675 (D.S.C. June 25, 2015). Though it declined to intervene, the government objected to a settlement reached by the parties on the basis of the government's extrapolation to a potential recovery amount significantly greater than the agreed-upon settlement. Interestingly, prior to the government's objection, the court had ruled during discovery that it would not allow the plaintiffs-whistleblowers to use statistical sampling to determine damages. Faced with the government's use of statistical sampling, the court set forth its rationale for disallowing statistical sampling as a method of proving liability or damages, noting at the outset that this case is not one where direct proof of damages has dissipated or been destroyed. Acknowledging numerous cases on either side of the issue, the court found the case not suited to statistical sampling, as each payment claim presented a question of medical necessity requiring review of the detailed medical chart of each patient. *Agape*, 2015 WL 3903675, at *8.

The *Agape* court implored the parties to seek permission from the Fourth Circuit to review two questions: (1) whether the government has unreviewable veto power to reject a settlement in a case in which it has declined to intervene and (2) whether statistical sampling and extrapolation can be used to prove damages or liability in an FCA case. On September 29, 2015, the Fourth Circuit agreed to review both questions, opening the door to the first appellate ruling on the statistical-sampling issue. Briefing on the merits of that issue will take place later this year. Those interested in submitting their views via a friend-of-the-court brief will also have an opportunity to do so. A decision is not expected until late 2016.

In the meantime, health care providers have a number of available strategies for challenging the use of statistical sampling in FCA cases, including the following:

Challenge the Need for Statistical Sampling: Consider whether other reasonable options exist for analyzing the claims at issue that would eliminate the need for statistical sampling.

Challenge the Validity of the Sampling Technique: Highlight defects in the sampling methodology, including small sample sizes, unrepresentative samples, sample selection biases and randomness of the sample.

Challenge the Extrapolation Method and Conclusions: Scrutinize the estimation method employed and extrapolation conclusions reached, paying close attention to the confidence (degree of certainty) and precision (range of accuracy) levels.

Challenge the Admission of Statistical Sampling Evidence: Procedurally, providers may challenge the admission of statistical extrapolation evidence or testimony through so-called *"Daubert* motions." In *Daubert* proceedings, a court determines the admissibility of expert testimony or scientific evidence under Federal Rule of Evidence 702 by analyzing whether the evidence is both relevant and reliable.

Challenge the Findings: Closely review the factual findings and examination processes used regarding the sample claims, conducting an independent examination of the sample claims as appropriate. This is a critical step, as allowing incorrect or questionable determinations about sample claims to go unchallenged has significant ramifications when multiplied exponentially as a result of extrapolation. Providers may also demonstrate uncertainty by challenging the credentials or the findings of the reviewers or by providing evidence of the subjectivity of the medical decisions underlying the submitted payment claims.

The Fourth Circuit's eventual ruling could have a significant impact on FCA cases in the healthcare sector. Should the Fourth Circuit agree with the lower court's disapproval of the use of statistical sampling, providers' ability to negotiate reasonable settlements likely will increase, as plaintiffs would need to expend additional resources to prove FCA liability. Conversely, judicial approval of the use of statistical sampling for determining liability under the FCA would significantly improve the government's bargaining position

HLB Briefs

Attorneys Felicia Sze, Kelly Carroll, and David Vernon recently published an article in CSHA's California Health Law News titled California Medicaid Rate Challenges.

HLB Attorney Jasmin Niku recently published an alert for AHLA on the House v. Burwell decision.

during settlement discussions and would arguably lower the bar for proving liability under the FCA. Faced with complex and widespread fraudulent schemes in which claim-by-claim review is impractical, the government would argue that refusing to allow statistical sampling and extrapolation would perversely incentivize large-scale fraud. However, while the availability of statistical extrapolation would lower the costs of prosecuting FCA actions, defendants will face higher costs as a result of increasing damages estimates and defending claims involving significantly larger universes of claims.

Whether at settlement or trial, providers should discuss available strategies for challenging the use of statistical sampling in FCA cases with knowledgeable counsel as early in the process as possible.

For additional information, please contact Kelly Carroll or James Segroves in Washington, D.C. at 202.580.7700; Patric Hooper in Los Angeles at 310.551.8111; Mark Reagan in San Francisco at 415.875.8500; or Mark Johnson in San Diego at 619.744.7300.

Developments In The Rush of Class Action Suits Attacking Hospital Charges

by Amanda L. Hayes-Kibreab and Glenn E. Solomon

Several hospitals throughout California have been hit with putative class action lawsuits brought by counsel for uninsured patients alleging that the hospitals' charges for emergency services are unreasonably high and that the financial agreements signed by the patients requiring payment of charges are improper and not enforceable. The suits further allege that the hospitals' charges are unreasonably high and a surprise to patients. These cases are shaping up to be an important battleground over hospital chargemasters.

California's charity/discount laws already require hospitals to offer discounts to certain low income patients when they receive emergency services — specifically patients making less than 350% of the federal poverty level. *See generally* Health & Saf. Code § 127405(a)(1)(A). The lawsuits by uninsured patients and their counsel are asking courts to upend the balance struck by the California Legislature in the charity/discount law, and replace hospital charges with arbitrarily suggested figures by plaintiff's counsel, or other figures to be determined by the courts. A significant difficulty presented by these lawsuits is that courts simply are not in the best position to set what should be paid for emergency services delivered in a hospital needed to save a person's life. *See Desert Healthcare Dist. v. PacifiCare, FHP, Inc.* (2001) 94 Cal.App.4th 781, 795 (describing as a "perfect example of when a court of equity should abstain" a lawsuit where fashioning an appropriate remedy would have required the court to determine the appropriate level of capitation and exercise oversight in the arena of health care services plans which a state agency was responsible for regulating).

Plaintiffs argue that courts should determine what a "reasonable person" would expect to pay for emergency services, by using government and contracted rates. However, plaintiffs ignore that a "reasonable person" does not expect to receive the same discounts as those who choose to participate in large discount networks, such as commercial or government insurance products. A "reasonable person" typically would expect to pay more than those who take the time and effort to procure coverage. Plaintiffs also ignore that the discounts extended by hospitals to network payors come with a cost that the uninsured do not incur. For example, Medicare beneficiaries typically worked for many years, during which they and their employers were taxed, in order to create a government trust fund and later qualify to participate. Likewise, those with private insurance pay

premiums themselves, and/or share the burden with employers, who may have paid the employee more if they were not paying for healthcare benefits.

Moreover, the charity/discount laws means that these lawsuits only are seeking only to establish discounts for patients who are more financially well-off than 350% of the poverty level. Only a person at 100% of the poverty level is considered to be in poverty. Thus, 350% of the poverty level is 3.5 times better off than those in poverty; and these lawsuits only would benefit those uninsured who have even higher incomes. Simply put, these lawsuits seek to place the well-off uninsured in a better position than those who choose to procure health care coverage, by getting the benefits of coverage without incurring the burdens, like premiums, taxes, or years of work to qualify.

These lawsuits also ignore that the more well-off uninsured who would benefit from the relief sought all have the option to obtain insurance. Even before the Affordable Care Act created the Covered California exchange products, there were California government programs that provided insurance coverage options for people who could not qualify to buy insurance through the commercial market. This included California's Major Risk Medical Insurance Program (MRMIP), which for many years offered insurance through private companies that contracted with the state to administer this program; and the Pre-Existing Condition Insurance Plan (PCIP), which came into effect in 2010 with funding from the federal government. More recently, effective January 1, 2014, anyone who has wanted to procure health care coverage also may purchase it on the Covered California exchange, and with government premium subsidies for anyone who makes less than 400% of the FPL. The existence of these programs means that anyone in the putative class of uninsured who these lawsuits purport to represent already made a conscious choice to remain uninsured rather than procuring the benefits of getting coverage.

These lawsuits also argue that hospitals' charges are higher than the costs of providing the actual treatment/services. However, California courts have rejected the notion that "costs" have any relevance to determining the "reasonable" value of hospital services. *Children's Hosp. Central Cal. v. Blue Cross of Cal.* (2014) 226 Cal. App.4th 1260, 1278. This makes sense because value does not depend on cost, and pretending that it does would reward inefficiency and punish efficiency. Like any business, a service provider in health care might be able to provide more value at less cost than another service provider.

California law also requires hospitals to file their chargemaster rates with OSHPD, which inherently requires that chargemasters will exist. Health & Saf. Code § 1339.55(a). Ultimately, plaintiffs seek to supplant prior legislative and judicial approval of billing chargemaster rates. These lawsuits generally allege that the specific reference to "chargemaster rates," "regular rates" or "hospital rates" in a hospital's Conditions of Admission contract results in an imprecise price term. However, the California Legislature has expressly referenced hospital charges and chargemasters and their use in setting charges. See Health & Saf. Code § 1339.51.

In a recent decision, the California Court of Appeals enforced a standard hospital Conditions of Admissions contract against a similar class action suit alleging unfair competition, upholding the trial court's decision to grant the hospital's demurrer without leave to amend. *Nolte v. Cedars Sinai Medical Center* (May 21, 2015) 236 Cal.App.4th 1401. In Nolte the lead plaintiff signed a standard Conditions of Admission form requiring him "to pay the account of the Hospital in accordance with the regular rates and terms of the Hospital." *Id.* at 740. In sustaining the hospital's demurrer, the trial court held that "[a]s a matter of law, Mr. Nolte consented to pay the facility fee to defendant and his pleading does not show that the contract was unconscionable or otherwise unenforceable." *Id*. at 741.

The Court of Appeals reasoned that "California Health and Safety Code § 1339.51 requires the hospital to make a written or electronic copy of its charge description master (schedule of charges) available online or at the hospital loca-

tion, with notices posted in the emergency department, admissions office and billing office." *Id.* at 742. Ultimately, the Court of Appeals held that the contract was enforceable, explaining that the law does not give Nolte the right to have every individual charge specifically disclosed prior to the hospital issuing a bill. *Id.* at 744.

In an action brought against Pomona Valley Hospital Medical Center, the trial court recently granted the hospital's demurrer to the plaintiff's declaratory relief complaint, reasoning that the plaintiff was seeking an advisory opinion that would likely serve to invite future litigation. The Court questioned who would determine what charges are reasonable and how such a declaration would be administered assuming that the plaintiff were successful.*Doster v. Pomona Valley Hospital Medical Center* (Los Angeles County Superior Court, Case No. BC570211).[1]

In another recent ruling, the California Court of Appeals upheld the trial court's decertification of an uninsured alleged class in a similar action. The court held that a class should not be certified in such a case where the administrative cost of identification and processing of claims outweigh the likely benefits to the proposed class. *Hale v. Sharp Healthcare* (2014) 232 Cal.App.4th 50, 66-67 (individual class issues predominate and the almost infinite number of possible fact patterns rendered class treatment highly unmanaged).

Courts outside of California have faced similar questions and found that there was no unconscionability when a hospital pursues regular chargemaster rates absent a discount agreement, particularly when those rates are set and published in accordance with state law and the patient was billed the regular rates. *Banner Health v. Medical Sav. Ins. Co.* (Ariz.Ct.App. 2007) 216 Ariz. 146, 153. The Banner court explained that the patients "fail to take into account the public filing of the rates and [the hospital's] compliance with the legislatively-created process for setting and filing the rates and charges." *Id.*

Despite recent rulings which suggest courts may be unwilling to accept plaintiffs' invitation to intervene, hospitals are likely to continue to face legal challenges to rate setting.

Hooper, Lundy & Bookman, P.C. has represented a number of hospitals on these and related disputes by patients and others about hospital charges. For more information please call Amanda Hayes-Kibreab or Glenn Solomon in Los Angeles at 310-551-8111, or Jennifer Hansen or Joseph LaMagna in San Diego at 619-744-7300.

[1]The author of this article worked on the Pomona Valley Hospital case, drafting and arguing the demurrer that was sustained by the trial court.

	Summary of Selected California Bills Signed by the Governor
Alcohol & Drug Treatment Facilities	AB 848 (Stone – D) Authorizes alcoholism and drug treatment facilities to allow a licensed physician, or other healthcare practitioner, to provide incidental medical services to a resident of the facility and requires the Department of Health Care Services to conduct an evaluation of the program on or before July 1, 2018.
ASCs/Surgical Clinics	SB 396 (Hill – D) Adds new regulatory requirements to ASCs, including a requirement for Medicare providers for reports on any provider seeking privileges, as to whether the provider has had privileges denied, restricted or removed previously.
Billing/Rates	SB 546 (Leno – D) Establishes weighted average rate increase disclosure requirements for a health plan's or insurer's aggregated large group market products and requires the Department of Managed Health Care and the California Department of Insurance to conduct a public meeting regarding large group rate changes for each plan or insurer that offers coverage in the large group market between November 1, 2016, and March 1, 2017, and annually thereafter.
	AB 658 (Wilk – R) Inmate Health Care: This bill would authorize, for claims that have not previously been paid or otherwise determined by local law enforcement, those costs to be calculated according to the most recent approved cost-to-charge ratio from the Medicare Program. The bill would authorize the hospital, with the approval of the county sheriff, police chief, or other public agency responsible for providing healthcare services to local law enforcement patients, to choose which cost-to-charge ratio is most appropriate, and would require the hospital to give notice of any change.
Data Breach Notification	AB 964 (Chau – D) Requires any agency that owns or licenses computerized data that includes personal information to disclose any breach of the security of the system following discovery or notification of the breach in the security of the data to any resident of California whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person. SB 570 (Jackson – D) Requires specific information to be included in data breach notifications and specific structure of notification of Data Breaches.
End of Life Options	SB X2 15 (Eggman – D) Until January 1, 2026, enacts the End of Life Option Act authorizing an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease, as defined, to make a request for a drug prescribed pursuant to these provisions for the purpose of ending his or her life. The bill establishes the procedures for making these requests. Note: Enactment of this bill will happen 90 days after the end of the special session; however, developing challenges, including a proposed ballot initiative may provide challenges to enactment at that time.

Managed Care- Drugs	AB 374 (Nazarian – D) Creates a process for prescribers to request an override of a health plan or health insurer's step therapy requirement.
Medical Marijuana	SB 643 (McGuire – D) Establishes a regulatory framework for the cultivation, sale, and transport of medical cannabis by the Bureau of Medical Marijuana Regulation, the Department of Food and Agriculture, and other state entities. AB 266 (Bonta – D) Establishes a licensing framework for the cultivation, manufacture, transportation, storage, distribution, and sale of medical marijuana to be administered by the Department of Consumer Affairs, Department of Food and Agriculture, and Department of Public Health. AB 243 (Wood – D) Requires the Department of Fish & Wildlife to adopt regulations to enhance the fees on any entity cultivating marijuana that impacts a bed, channel or bank of any river, stream or lake, pursuant to Fish and Game regulations.
Medi-Cal	SB 4 (Lara – D) Requires individuals under 19 years of age enrolled in restricted-scope Medi-Cal to be enrolled in the full scope of Medi-Cal benefits, if otherwise eligible, beginning in May, 2016.
Mental Health	AB 1194 (Eggman – D) Requires, when an individual is determining if a person is a danger as a result of a mental health disorder (for the purposes of deciding whether the person meets criteria for a "5150" involuntary hold), the individual to consider available relevant information about the historical course of the person's mental disorder, if the individual concludes that the information has a reasonable bearing on the determination. It also specifies danger is not limited to danger of imminent harm.
Physician Assistants	SB 337 (Payley – D) Provides additional mechanisms for supervising physicians to ensure adequate supervision of physician assistants.
Public Health	SB 277 (Pan – D) Eliminates the personal belief exemption from the requirement that children receive vaccines for certain infectious diseases prior to being admitted to any public or private elementary or secondary school or day care center.

CALENDAR

October 1

LACBA 12th Annual Healthcare Law Compliance Symposium, Los Angeles, CA
Amy Joseph co-presents *Responding toData Breaches;*
Ben Durie co-presents *Self-Disclosure and the 60-day Repayment Rule.*

October 22, 23

Baker Healthcare Consulting 2015 Conference on Health Reform, Daytona Beach, FL
John Hellow presents *IPPS and OPPS Update;* Precious Murchison Gittens co-presents *Overpayments—The 60-Day VultureComes Home to Roost;* Charles Oppenheim co-presents *Tax Matters;* Robert Roth co-presents *Litigation & Appeals Update;* Charles Oppenheim co-presents *The Purpose Driven Deal.*

October 29

Healthcare Financial Management Association Regulatory Conference, Minneapolis, MN
Robert Roth presents *Hospital FFY 2016 IPPS Legislative and Regulatory Policy Update.*

November 6

CCLA Annual Meeting, Newport Beach, CA
Patric Hooper provides *Health Law Update.*

November 6

2015 CSHA Fall Program, San Francisco, CA
Charles Oppenheim presents *New Alliances.*

December 8

CHA Behavioral Health Care Symposium, Riverside, CA
Steve Lipton presents *Navigating from the Non-Designated World to the Designated World and 24-Hour Holds - Why, When and How to Use in the ED.*

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