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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, *ex rel* KARIN BERNTSEN,

Plaintiffs,

v.

PRIME HEALTHCARE SERVICES, INC.; PRIME HEALTHCARE SERVICES ALVARADO, LLC; PRIME HEALTHCARE SERVICES GARDEN GROVE, LLC; PRIME HEALTHCARE HUNTINGTON BEACH, LLC; PRIME HEALTHCARE LA PALMA, LLC; DESERT VALLEY HOSPITAL, INC.;

Case No.: CV 11-08214 PJW (MG)

RELATOR KARIN BERNTSEN'S OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE STATISTICAL SAMPLING EVIDENCE

PRIME HEALTHCARE SERVICES FOUNDATION, INC.; PRIME HEALTHCARE SERVICES ENCINO, LLC; VERITAS HEALTH SERVICES, INC.; PRIME HEALTHCARE SERVICES MONTCLAIR LLC; PRIME HEALTHCARE PARADISE VALLEY, LLC; PRIME HEALTHCARE SERVICES SAN DIMAS, LLC; PRIME HEALTHCARE SERVICES SHASTA, LLC; PRIME HEALTHCARE SERVICES II, LLC; PRIME HEALTHCARE ANAHEIM, LLC; and DR. PREM REDDY,

Defendants.

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INTRODUCTION

As shown in the Relator's Fourth Amended Complaint ("Complaint" or "FAC"), the Prime Defendants[1] have implemented a top-down, corporate-wide scheme to defraud Medicare through: (1) medically unnecessary inpatient admissions; and (2) upcoding by falsifying patient diagnoses. In their Motion to Exclude Statistical Sampling to Prove Falsity of Claims Under the FCA Based on Medically Unnecessary Admissions or Clinically Unsupported Diagnoses ("Motion to Exclude"), the Prime Defendants assert that the False Claims Act requires individualized proof of false claims when those claims result from the clinical decision-making of independent physicians, and thus, the Plaintiffs are precluded as a matter of law from using statistical extrapolation to prove liability. Defendants' Motion not only is premature, but also should be denied because courts have approved of statistical sampling to establish falsity in FCA cases. Furthermore, Prime's system-wide directives directly influenced and caused the fraudulent admission, coding, and diagnosis practices at issue, as opposed to the independent judgments of physicians.

The Prime Defendants seek an extraordinary remedy, particularly at this stage of the litigation. Statistical sampling is a widely-recognized evidentiary tool for proving disputed facts in many areas of complex litigation, including liability and damages. It is a mathematically and scientifically proven technique by which accurate estimates of a characteristic of a population can be made based on a sample of that population. Extrapolation is particularly well-suited for complex litigation, such as False Claims Act ("FCA") cases, because it allows voluminous amounts of data to be distilled in a simpler—though still reliable and accurate—format for the jury. Courts have routinely approved the use of statistical sampling evidence in FCA cases for these very reasons.

[1] The Defendants identified in both the Relator's Fourth Amended Complaint and the United States' Complaint in Intervention will collectively be referred to as the "Prime Defendants," "Defendants," or "Prime."

In this case, the extrapolation results will constitute direct evidence of the number of false claims the Prime Defendants submitted, or cause to be submitted, to Medicare.

Paradoxically, the Prime Defendants argue that precluding extrapolation at the beginning of the litigation is in the best interest of judicial economy. But as the Prime Defendants know, nothing could be further from the truth. The relief sought would create, not avoid, inefficiencies. Indeed, granting the requested relief would cause an unnecessary exhaustion of time and resources for both the Court and the parties.

Prime concedes that "FCA liability could still arise based on objective and verifiable facts establishing that the physicians' admission decisions were false because the patients did not have the medical condition diagnosed as the principal reason for admission . . . ." (Doc. 140 at p.25). This admission alone—that evidence of falsified diagnoses can form the basis for FCA liability—should warrant denial of the Motion to Exclude. As a result, it is not surprising that the Motion to Exclude barely addresses Relator's upcoding claims, which allege that Prime directed physicians to falsely diagnose certain higher paying complications and comorbidities ("CCs" and "MCCs").

As a fundamental matter, Relator's allegations here are not about clinical disagreements with physician judgments. They are about a corporate-wide scheme designed to remove physician judgment from the treatment process and to substitute the practice of medicine with the boosting of profits. The Prime Defendants improperly altered medical records, threatened physicians, falsified criteria to mislead physicians, and retaliated against those who did not acquiesce to their scheme. The Motion to Exclude ignores these material facts. Now, after spending years corrupting and interfering with the judgment of treating physicians, the Prime Defendants are attempting to use physician judgment as a contrived shield to escape liability.

Among other flaws, the Motion to Exclude is premature. There is no authority to grant such extraordinary relief at so early a stage in the litigation. The Motion to Exclude is simply a poorly disguised *Daubert* motion, and under Federal Rule 702 and the *Daubert* analysis, the Court must examine and consider a number of factors that are

not yet before it. Without a well-developed record that includes deposition and hearing testimony, sample size, and methodology, the Court cannot properly decide or even objectively assess the merits of this premature *Daubert* motion.

In addition, there is clear authority for the use of statistical sampling evidence to establish FCA liability. In a recent FCA case involving allegations similar to Relator's, the court denied a corporate defendant's motion to exclude statistical sampling evidence. In *United States, ex rel. Martin v. Life Care Centers of America, Inc*., 114 F. Supp. 3d 549 (E.D. Tenn. 2014), the court allowed the Government's use of extrapolation to establish falsity, noting that "as long as the statistical sample is a valid sample that is representative of the universe of claims, the natural disparity between the claims does not preclude using sampling and extrapolation as evidence of the total number of claims…." *Id*. at 567. Critically, the court gave great weight to considerations of practicality and efficiency, but correctly observed the public policy justification for refusing to categorically exclude extrapolation in cases involving widespread Medicare fraud: "Armed with the knowledge that the government could not possibly pursue each individual false claim, large-scale perpetrators of fraud would reap the benefits of such a system. Put another way, limiting FCA enforcement to an individual claim-by-claim review would open the door to more fraudulent activity because the deterrent effect of the threat of prosecution would be circumscribed. The Court is unable to conclude that such a result is consistent with the purpose and history of the FCA." *Id*. at 571.

The nationwide scope of Prime's fraudulent scheme and the sheer volume of false claims support the need and efficiency of statistical sampling evidence. This case involves tens of thousands of claims tainted by Prime's fraud. Prime's ill-conceived request would require this Court to individually review tens of thousands of patient files and records. That process would unnecessarily exhaust judicial resources. This case presents exactly the type of factual scenario where courts have routinely used statistical sampling to determine FCA damages and liability.

RELATOR'S ALLEGATIONS

MS-DRGs under the Medicare Inpatient Prospective Payment System

Relator's complaint alleges that Defendants have systemically and fraudulently increased the MS-DRG payments it receives from Medicare through upcoding by falsifying diagnoses on inpatient claims. Medicare reimburses hospital inpatient claims under a prospective payment system (PPS) based on Medical Severity - Diagnostic Related Groups (MS-DRGs). (FAC ¶ 21). The intent of the MS-DRG categorization is to group clinically similar cases and pay the facility a single rate for each claim in that group, which is considered payment in full for the services provided. While there are variables that may impact this rate, such as demographic data, the base payment is driven by the MS-DRG assigned to the case. (FAC ¶ 21). The grouper software program assigns one of 745 unique MS-DRGs to each inpatient claim.

MS-DRGs are calculated based on the diagnoses and procedure codes on the claim. During the relevant time period, the principal and secondary diagnoses for patients were reported by the hospital using codes from the International Classification of Diseases, Clinical Modification Version 9 (ICD-9-CM codes). The ICD-9-CM codes submitted then mapped to a specific MS-DRG which determined the amount of reimbursement that the hospital received from Medicare. (FAC ¶ 21-22). An MS-DRG classification includes an indication as to whether it is: with major complications and comorbidities (MCC); with complications and comorbidities (CC); or without complications and comorbidities (without CC/MCC). (FAC ¶ 21). Prime's upcoding scheme is primarily based on the fact that an MS-DRG with an MCC or a CC has a higher reimbursement rate than the same MS-DRG with no MCC or CC. Further, an MCC increases the reimbursement rate more than a CC. Thus, patients' diagnoses including the presence of complications and comorbidities must be accurately recorded in order to ensure that the facility is appropriately reimbursed by Medicare. (FAC ¶ 22). Prime's introduction of corporate pressures to upcode and its use of false records to increase reimbursement caused the Government to pay Prime millions of dollars as a

result of Prime's false claims. If the Government had known that these claims were tainted with fraud, it would not have paid the Medicare reimbursements to Prime.

Defendants' fraudulent inpatient admission and upcoding practices were both integral parts of the same system-wide scheme and in many instances resulted in overlapping false claims

The Government's inpatient admission claims in the Complaint in Intervention ("CI") coupled with Relator's upcoding claims in the FAC paint a clear and uniform picture of Defendants' overall scheme to fraudulently increase reimbursement from Medicare. Defendants' prohibition on the use of observation status and upcoding of diagnoses were both integral parts of the fraudulent scheme that Defendant Reddy implemented at all of the Prime hospitals. Many of the same facts and corporate practices that give rise to the inpatient admission claims also give rise to the upcoding claims. For example, each time Prime would acquire a new hospital, Reddy would begin conducting meetings with the physicians in which he would issue system-wide instructions to engage in fraudulent practices which resulted not only in the upcoding of diagnoses, but also medically unnecessary inpatient admissions. (FAC ¶ 50-58). Defendants knew that both of these practices would lead to greater Medicare payments to Prime.

In fact, in many instances there is an overlap between the medically unnecessary inpatient admission claims and the upcoding claims. Specifically, several of the same diagnoses that Reddy directed the physicians to upcode were also the same diagnoses used by Prime to make its inpatient admissions appear justified. For example, diagnoses such as acute respiratory failure, pneumonia, acute renal failure, and acute congestive heart failure were falsified by Prime to meet inpatient admission criteria and to increase the MS-DRG reimbursement category for that inpatient admission. Indeed, the diagnoses most routinely targeted and abused by Prime were the same diagnoses that CMS classifies as MCCs, and therefore resulted in Prime's fraudulent receipt of the highest of the three reimbursement categories.

Because of the way Defendants' scheme to defraud Medicare was designed, some Medicare patients were victimized twice when treated at Prime hospitals. First, when they were admitted without medical need, and then again when they were labeled with false diagnoses to ensure that their unnecessary inpatient admissions would result in higher MS-DRG payments to Prime. As a result, a portion of the inpatient admission claims correlate with and overlap with a portion of the upcoding claims.

Defendants' fraudulent practices have been implemented on a system-wide basis.

As pled in Relator's complaint, "Reddy has created a corporate-wide culture of fraudulent behavior which permeates all of the Defendant PHS hospitals at all levels." (FAC ¶ 64). "Reddy has pressured and trained individuals, including corporate administrators, ER physicians, hospitalist physicians, case managers, and CDIs to engage in fraud in order to increase the payments PHS receives from Medicare." (FAC ¶ 64). At a December 13, 2013 meeting conducted by Reddy, Reddy stated, "We have in every hospital the same thing . . . We have now twenty-five hospitals testing it . . . that's what the advantage of having that kind of information from various hospitals so somebody's not in silo in one hospital." (FAC ¶ 52). This Court previously noted in this case in its Order Denying Defendants' Motion to Dismiss Relator's Fourth Amended Complaint that "[t]he FAC describes a standardized system of meetings, procedures, hospital forms, and training sessions by all Prime hospitals to perpetrate Medicare fraud and provides sufficient detail regarding why relator Berntsen believes these practices are common to all Defendants." (Doc. 102 at p.8-9). This "standardized system" of fraud tainted tens of thousands of claims submitted by Prime.

When discussing coding, billing, and other hospital procedures in the context of inpatient admissions and/or increased DRG payments, Reddy has made numerous comments indicating that the practices are system-wide including: "This is the way we do things at Prime" and "We don't do observation . . . you can always find a reason to make the patient an inpatient." Reddy has also instructed coders to improperly code at

the highest paying DRG and has told physicians that there needs to be an MCC or CC included in all Medicare patients' diagnoses. (FAC ¶¶ 32, 41-42). Almost every time Reddy has issued these instructions or addressed these issues, he has spoken in terms of the entire Prime healthcare system. (FAC ¶ 50). Furthermore, the data reflect and confirm the use of consistent fraudulent practices throughout the Prime hospitals. For example, the Program for Evaluating Payment Patterns Electronic Reports (PEPPER reports) demonstrate similar patterns of increases in inpatient admissions, decreases in the use of observation status, and increases in certain higher paying diagnoses each time Prime acquires a new hospital. (FAC ¶ 56). The use of statistical sampling is efficient, time-tested, and necessary in this case which involves a massive FCA fraud at multiple Prime hospitals across the United States.

LEGAL ARGUMENT

The use of statistical sampling and extrapolation is widely recognized. Its purpose is to permit reasonable inferences about a universe of claims from a sample of that universe. *See In re Countrywide Fin. Corp. Sec. Litig.*, 984 F. Supp.2d 1021, 1038 (C.D. Cal. 2013) ("[T]he purpose of using a sample is to extrapolate results from a small sample to a large population."). As the Supreme Court recently observed, "[i]n many cases, a representative sample is 'the only practicable means to collect and present relevant data' establishing a defendant's liability." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1046 (2016) (quoting Manual of Complex Litigation § 11.493, p. 102 (4th ed. 2004)). This is particularly true in complex litigations where the quantity of relevant data can overwhelm and possibly confuse a jury. *See In re Estate of Marcos Human Rights Litigation*, 910 F.Supp. 1460, 1467 (D.Haw.1995) ("[i]nferential statistics with random sampling produces an acceptable due process solution to the troublesome area of mass tort litigation."). As a result, courts have approved the use of statistical sampling in FCA cases (as discussed below) and in cases ranging from class actions[2],

[2] *Hilao v. Estate of Marcos*, 103 F.3d 767 (9th Cir.1996).

securities litigation[3], trademark infringement[4], mass torts[5], and employment discrimination[6].

The Motion to Exclude should be denied for three reasons. First, it is premature. The Court is without a proper, well-developed record from which to make an evaluation of whether the statistical sampling evidence in this case is admissible under Federal Rule of Evidence 702. Second, the Motion to Exclude ignores that the Prime Defendants, with Reddy as the architect of the fraudulent schemes, constructed a system-wide fraudulent culture which corrupted the independent judgment of treating physicians. Third, statistical sampling and extrapolation is a court-approved evidentiary tool for proving falsity in FCA cases. In this case, extrapolation will constitute direct evidence of false claims, and like all evidence, a jury will be entitled to accept or reject it.

I. The Motion to Exclude seeks an extraordinary remedy which is premature at this juncture.

Substantively, the Motion to Exclude is a contorted *Daubert*[7] challenge made prior to any expert opinions having been identified in discovery. Prime raises a *Daubert* challenge but does so without the benefit to the Court (or the plaintiffs) of having any experts or their opinions to attack. The Motion to Exclude invokes arguments and language that are almost universally reserved for *Daubert* hearings, but does so without the experts and opinions to which to apply them.

This court reviews motions to exclude statistical sampling under Federal Rule 702 and the factors articulated in *Daubert*. *See In re Countrywide Fin. Corp. Mortgage–Backed Sec. Litig.*, 984 F.Supp.2d 1021, 1036 (C.D. Cal. 2013); *see also O' Connor v.*

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[3] *In re Countrywide Fin. Corp. Mortgage–Backed Sec. Litig.*, 984 F.Supp.2d 1021, 1036 (C.D. Cal. 2013)

[4] *Exxon Corp. v. Texas Motor Exchange, Inc.*, 628 F.2d 500 (5th Cir.1980)

[5] *In re Chevron U.S.A., Inc.*, 109 F.3d 1016 (5th Cir. 1997).

[6] *Castaneda v. Partida*, 430 U.S. 482 (1977)

[7] *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

Boeing North American, Inc., 2004 WL 5532395, at *8 (C.D. Cal. 2004) (determining defendants' arguments concerning expert opinion to be "premature at this juncture" and stating "*Daubert* challenges and summary judgment motions are principally the arena in which the quality and strength of the expert's testimony is tested.").

A *Daubert* analysis comprises five factors which should guide judges in this determination: (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; (4) the existence of standards controlling the technique's operation; and (5) the level of the theory's or technique's acceptance within the relevant discipline. *Daubert*, 509 U.S. at 593–94, 113 S.Ct. 2786. Relator respectfully submits that the Court cannot properly consider the Motion to Exclude at this juncture when there has been limited document production, no depositions taken, and no reports issued by the parties' designated experts[8]. As such, the requested relief is premature and the Motion should be denied.

A recent FCA case, *U.S. ex rel Ruckh v. Genoa Healthcare LLC*, Case No. 8:11-cv-1303, 2015 WL 1926417, (M.D. Fla. April 28, 2015), is instructive here. In *Ruckh*, the court considered a motion in limine regarding the admissibility of expert testimony based on statistical sampling. However, the motion was filed before any statistical sampling had even occurred. *Id*. at *1. The court determined that the matter could only be resolved with a *Daubert* hearing, but essential information, such as the methodology and error rate, were not yet before the court, and as such, a *Daubert* hearing conducted with an incomplete record was improper. *Id*. at *4. The Court correctly noted that "no universal ban on expert testimony based on statistical sampling applies in a qui tam action," and found the requested relief to be premature, and denied the motion. *Id*.

Even the cases that the Defendants cite support Relator's argument that the Motion to Exclude is premature. For example, the court in *U.S. ex rel Wall v. Vista*

[8] Expert reports are not due until January 13, 2018. (Doc. 133).

Hospice Care, Inc., 2016 WL 3449233, No. 3:07-cv-604 (N.D. Tex. 2016) reviewed the expert's methodology in arriving at its statistical sampling determination. *Id*. at *13 (Citing *Daubert* to support the finding that "Dr. Kriegler's sample was not randomly selected from the entire Population, and he did not control for variables even Dr. Steinberg identified as important."). The court also noted that the expert "misclassified approximately 1,100 patients when he stratified the Population, placing patients from the Odyssey period in the Gentiva period." *Id*. Finally, in concluding that the expert's errors were "fatal to his conclusions," the court stated that the expert's unreliable methodology deprived the parties and the court from being able to properly challenge his findings. *Id*. The Court here is unable to conduct a similar analysis because, unlike in *Vista*, there is no evidentiary record to support any findings.

Similarly, in *United States ex rel. Martin v. Life Care Centers of America, Inc*., 114 F.Supp. 3d 549 (E.D. Tenn. Sept. 29, 2014), the court approved the government's use of statistical sampling to establish falsity **after** a *Daubert* hearing in which it analyzed the expert witness's methodology and sampling plan. Other False Claims Act cases support the use of sampling and further demonstrate that a final determination as to the admissibility of specific statistical sampling is subject to a *Daubert* analysis, and thus requires a record complete with an expert and an expert opinion. *See United States ex. rel. Loughren v. UnumProvident Corp.*, 604 F.Supp.2d 259, 261 (D.Mass.2009) (finding that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate.") *see also United States ex rel. Barron v. Deloitte & Touche, LLP*, No. SA-99-CA-1093-FB, 2008 WL 7136869, at *2 (W.D. Tex. Sept. 26, 2008) ("underlying focus continues to be the Supreme Court's ruling in *Daubert* which permits the use of statistical methods of scientific research and proof pursuant to Rule 702 of the Federal Rules of Evidence provided the evidence is based upon sufficient facts or data, the product of reliable principles and methods, and the expert applied the principles and methods reliably to the facts of the case.").

Without extensive expert discovery and a well-developed evidentiary record, the Court will be unable to adequately consider whether statistical sampling is permissible for establishing liability. *See John v. Equine Services, PSC*, 233 F.3d 382, 393 (6th Cir. 2000) ("a district court should not make a *Daubert* ruling prematurely, but should only do so when the record is complete enough to measure the proffered testimony against the proper standard of reliability and relevance." Granting the requested relief in the embryonic stages of this litigation—without a proper record—would be inconsistent with the Court's role as "gatekeeper." *Id*. (reversing district court and finding abuse of discretion in excluding expert testimony without sufficient evidentiary record).

In short, the relief sought here is extraordinary, premature, and without any authoritative support. No experts have yet been identified in this litigation, much less experts who have produced reports that disclose their qualifications, methodologies, findings and conclusions. The parties have not had the opportunity to either challenge or support the validity of any statistical extrapolation in accordance with Federal Rule of Evidence 702. Accordingly, the Motion to Exclude is premature and should be denied.

II. Defendants' fraudulent directives and retaliatory practices have interfered with the independent judgment of Prime physicians and have influenced admission, diagnosis, and coding decisions on a system-wide basis

In addition to being premature, Defendants' Motion should also be denied because the use of statistical sampling is proper and necessary in the instant case. Defendants argue that the claims must be analyzed on a case-by-case basis as opposed to using statistical sampling because Prime physicians have allegedly exercised independent judgment. This argument is false because Prime, through Defendant Reddy, has issued corporate directives that have influenced medical decision-making at Prime hospitals in a consistent, top-down, system-wide manner with regard to inpatient admissions and the upcoding of certain diagnoses. This system-wide fraud has corrupted the independent judgment of Prime physicians and has impacted tens of thousands of claims in multiple hospitals. Almost immediately after Prime acquires a hospital, sharp increases in

upcoding, inpatient admissions, and Government reimbursement are apparent. These increases are a direct result of Prime's fraudulent practices.

Defendants correctly state that the "prohibition on the corporate practice of medicine is meant 'to protect the professional independence of physicians . . . .'" (Doc. 141 at p.27) (citing *California Physicians' Service v. Aoki Diabetes Research Institute*, 163 Cal.App.4th 1506, 1514 (2008)). When a hospital system corrupts the professional independence of its physicians, patient safety is threatened and the safeguards against decision-making based on financial considerations, as opposed to medical necessity, are compromised. This fraudulent and dangerous practice of interfering with the judgment of physicians is exactly what Prime has engaged in and continues to engage in at all of its hospitals at Government financial expense. As the court stated in *California Physicians' Service*, "the principal evils attendant upon corporate practice of medicine spring from the conflict between the professional standards and obligations of the doctors and the profit motive of the corporation employer." *Id*. at 1515-1516. Prime's profit motive has driven it to corrupt and even subvert with falsified documentation the professional standards and obligations of its doctors. By giving its physicians clear and consistent directives illegally prohibiting the use of observation status for treating patients and mandating the diagnosis of certain higher paying complications and comorbidities (CCs and MCCs), Prime has constructively engaged in the "corporate practice of medicine" for the sole purpose of increasing Medicare reimbursements. Furthermore, these improper practices can be verified by using statistical sampling of the Prime hospitals. The patterns of fraud are consistent and can be proven using statistically valid samples from each Prime hospital.

Ironically, despite the fact that Prime actively impedes physicians from exercising independent decision-making, Defendants attempt to escape liability by hiding behind the false assertion that its physicians have exercised independent judgment with regard to diagnosis and admission decisions. Defendants cannot claim that it is the independent and subjective nature of those decisions that precludes liability, when Prime has

successfully implemented a system-wide scheme to corrupt the very process which protects a physician's independent judgment.

Defendants erroneously argue that the "admission and diagnosis decisions are not made by the Prime Defendants, but by independent physicians who cannot be employed by Prime Defendants due to California's ban on the corporate practice of medicine." (Doc. 141 at p.27). As a preliminary matter, pressuring physicians was only one component of Prime's fraudulent scheme, as alleged by Relator and the United States. Prime pressured corporate administrators, ER physicians, hospitalist physicians, case manages, CDIs, and coders, which effectively removed the checks and balances normally present in hospitals to prevent upcoding and unnecessary admissions. (FAC ¶ 64). In addition, simply because California law does not allow Prime to employ physicians directly does not prevent Prime from exercising control over its physicians in a calculated manner. The FAC and CI are replete with the specific means Prime used to control physicians it did not directly employ. Even though Prime does not directly employ physicians, it retaliates against physicians who do not comply with its directives by threatening to terminate the employing physician groups' valuable contracts with Prime; by pressuring the physician groups to terminate noncompliant individual physicians; by pressuring the contracted group to transfer noncompliant physicians to other hospitals; and by refusing to call on noncompliant physicians to treat patients.

Contrary to Defendants' assertions, the facts demonstrate that physicians at Prime were not free to exercise independent judgment on a case-by-case basis. Prime has been extremely effective at influencing its physicians' conduct through pervasive, consistent, and unrelenting pressure – including financial pressure - placed on its employees as well as contract physicians. Moreover, Prime's retaliation effectively prevents physicians who do not acquiesce to Prime's directives from being able to treat patients at Prime hospitals. Prime's practices are designed to ensure that those physicians who remain at Prime hospitals are those who agree to follow the Prime directives and goals regarding upcoding and inpatient admissions. *See U.S. ex rel Hayward v. Savaseniorcare, LLC,*

2016 WL 5395949 n. 14 (M.D. Tenn. September 27, 2016) (noting that "even under the objectively false standard a claim can be false, notwithstanding a clinician's prescription. For example, a clinician who prescribes therapy because he or she has mandated goals and not because it is in the patient's best interest is not prescribing objectively reasonable or necessary care.").

As noted above, Reddy is the mastermind of Prime's fraudulent scheme and the common thread throughout the Prime Healthcare system. He is the President, Chairman of the Board, and CEO of Prime. Reddy's plan to increase Medicare reimbursements immediately with each Prime hospital acquisition by micromanaging the Prime facilities has created a commonality amongst those facilities with regard to admission and upcoding decisions, which are controlled by Defendants as opposed to independent physicians. Contrary to Defendants' assertions, the facts demonstrate that Prime physicians were not free to exercise independent judgment on a case-by-case basis. Rather, Defendants issued clear directives regarding the use of observation status and certain higher paying diagnoses, and used retaliation and financial pressure to ensure that physicians at Prime conformed to those system-wide directives.

III. Statistical sampling evidence is a court-approved method for establishing False Claims Act liability.

The Prime Defendants assert that, as a matter of law, statistical extrapolation cannot be used to establish liability here. This assertion is erroneous for several reasons. First, it is well-settled that statistical sampling is a reliable methodology for use in complex litigation, including False Claims Act cases. Indeed, extrapolation is often the ideal method for assisting juries in their role as fact-finder when the cases involve voluminous evidence or claims. Second, statistical sampling evidence has been used to prove falsity in False Claims Act Cases where medical necessity determinations resulted in tens of thousands of false claims submitted to government healthcare programs, most recently in *United States, ex rel. Martin, v. Life Care Centers of America, Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014). Third, the Motion to Exclude primarily relies on

inapposite cases in which there are experts and expert reports on which the required *Daubert* analysis was conducted and in which Medicare coverage decisions were based on different factors than those at issue here. Finally, the Motion to Exclude raises arguments which go to the weight the jury should give to the expert's methodology, not whether extrapolation should be precluded as a matter of law. The Prime Defendants will have several mechanisms for challenging the statistical sampling evidence, including depositions and cross-examination at trial, as well as designating its own expert to produce their own sample size and opine as to the reliability and accuracy of any extrapolation evidence.

A. The Use of Statistical Sampling Evidence in Complex Litigation Cases, Including False Claims Act Cases, is Firmly Established

Because healthcare fraud cases, in particular, inherently involve voluminous claims submitted to government healthcare programs, statistical sampling is the most practical and efficient method for assisting the jury in understanding how many false claims the Prime Defendants submitted for payment, and why those claims were false. This is precisely why courts have repeatedly upheld the use of statistical sampling in Medicare and Medicaid overpayment cases as a valid means by which the Department of Health and Human Services (HHS) may determine the amount of overpayment by Medicare and Medicaid to health care providers. *See Balko & Assocs. v. Sec'y*, 555 Fed. Appx 188, 194 (3d Cir. 2014) (upholding use of extrapolation in review of Medicare overpayments); *Ratanasen v. State of Cal., Dep't of Health Servs.*, 11 F.3d 1467, 1471 (9th Cir. 1993) (joining other circuits in "approving the use of sampling and extrapolation as part of [Medicare] audits . . . provided the aggrieved party has an opportunity to rebut such evidence"); *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 89-90 (2d Cir. 1991) (approving the use of sampling and statistical evidence to determine Medicaid overpayment); *Illinois Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) ("The use of statistical samples to audit claims and arrive at a rebuttable initial decision was reasonable where the number of claims rendered a claim-

by-claim review a practical impossibility."); *Miniet v. Sebelius*, No. 10-24127-CIV, 2012 WL 2930746, at *6 (S.D. Fla. July 18, 2012) (in medical necessity case, propriety of statistical extrapolation to determine the amount of overpayment is "undisputed," and "the sampling utilized need not be based on the most precise methodology, just a valid methodology"); *Pruchniewski v. Leavitt*, No. 8:04-CV-2200-T-23TMB, 2006 WL 2331071 at *7 & n.9 (M.D. Fla. Aug. 10, 2006); *Webb v. Shalala*, 49 F. Supp. 2d 1114, 1123 (W.D. Ark. 1999); *Georgia v. Califano*, 446 F. Supp. 404, 409 (N.D. Ga. 1977); *see also Mile High Therapy v. Bowen*, 735 F. Supp. 984, 986 (D. Colo. 1988) (rejecting speech and physical therapy provider's challenge to HHS' use of sampling in Medicare overpayment case).

Allowing the use of statistical sampling evidence is not only reasonable and routine in complex litigation cases, but is essential in False Claims Act cases where the defendants' conduct caused the submission of more false claims and records than could reasonably be tried before a court on a claim-by-claim basis. In fact, a primary reason courts authorize 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." *Illinois Physicians Union v. Miller*, 675 F.2d 151, 157 (7th Cir.1982).

In addition, the use of statistical sampling in False Claims Act cases involving Medicare overpayments is permissible "provided the evidence is based upon sufficient facts or data, the product of reliable principles and methods, and the expert applied the principles and methods reliably to the facts of the case." *United States ex rel. Barron v. Deloitte & Touche, LLP*, No. SA-99-CA-1093-FB, 2008 WL 7136869, at *2 (W.D. Tex. Sept. 26, 2008) (applying *Daubert* analysis to expert conclusions based on statistical sampling and extrapolation). *See also United States v. Fadul*, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) ("Courts have routinely endorsed sampling and extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical") (citing *Illinois*

Physicians Union, at 155; *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 89-90 n.7 (2d Cir. 1991)).

B. Statistical Sampling Is Direct Evidence That Can Be Used To Establish Falsity In False Claims Act Cases.

While extrapolation is an evidentiary tool often used to establish damages, the Ninth Circuit expressly allows extrapolation to be used to establish liability. *Jimenez v. Allstate Ins. Co*., 765 F.3d 1161, 1167 (9th Cir. 2014) ("statistical sampling and representative testimony are acceptable ways to determine liability"). The *Life Care* court recently authorized the Government's use of statistical sampling and extrapolation in a False Claims Act case involving allegations against a skilled nursing facility chain. 114 F.Supp. 3d 549 (E.D. Tenn. 2014). In *Life Care*, the United States alleges that the defendant, which owns over 200 skilled nursing facilities, knowingly caused the submission of claims to Medicare and TriCare for inpatient services at its nursing facilities that were medically unnecessary and unreasonable in violation of the False Claims Act. *Id*. at 551. The United States disclosed a statistical expert who selected a statistically valid random sample of patient admissions from a population of the defendant's patients within certain facilities during a certain time frame. *Id*. at 556-564. The United States also disclosed that its statistical expert will extrapolate the number of false claims which defendant caused to be submitted for patients in the population and the amount Medicare and TriCare overpaid defendant for patients in the population based on the results of expert review of the medical records for patients within the sample. *Id*. In denying defendant's motion for partial summary judgment to bar the United States' use of statistical sampling with respect to its False Claims Act allegations, the *Life Care* court observed that "a claim-by-claim review is often impractical" in cases involving numerous potential false claims and that the exclusion of statistical sampling and extrapolation in False Claims Act cases "would open the door to more fraudulent activity because the deterrent effect of the threat of prosecution would be circumscribed." *Id*. at 571. Finding that "[t]he language and the history of the FCA do

not suggest that statistical sampling is an improper vehicle by which to litigate FCA claims," the Life Care court held that "statistical sampling may be used to prove claims brought under the FCA involving Medicare overpayment." *Id*.

Other False Claims Act cases have also concluded that a claim-by-claim review is both unnecessary and not feasible. In *United States ex rel. Loughren v. Unumprovident*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009), the relator alleged that the defendant insurance company caused its insureds to file disability applications with the Social Security Administration that falsely stated that the claimants were unable to work. *Id*. at 260. There were 468,641 applications at issue. *Id*. at 263. The relator sought to introduce expert testimony regarding the use of "statistical techniques to extrapolate the number of false claims within a sample of claims to an estimation of the total number of false claims filed." *Id*. at 260. The defendant challenged the reliability of the extrapolation. *Id*. While excluding relator's statistical expert based on a determination that the sampling methodology was flawed, the *Loughren* court held that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate." *Id*. at 261, 269 (citations omitted).

The Motion to Exclude seeks to distinguish *Life Care* from the instant case by observing that payment rates for skilled nursing facilities are created through the use of Research Utilization Groups ("RUG"). (Doc. 141 at 31). This is a classic distinction without a difference. The *Life Care* court's decision allowing the use of extrapolation evidence to establish falsity **did not turn on how reimbursement rates were classified**. To the contrary, the court's conclusions were based on considerations of practicality and efficiency, noting that statistical sampling is a well-recognized evidentiary tool in complicated cases, and that the defendants remained free "to challenge the weight a fact finder may attribute to the extrapolation" including designating its own statistician who can offer competing models. *Id*. at 566-567.

In reality, there is substantial similarity between the allegations in *Life Care* and the instant matter. For example, as noted above, Relator's upcoding allegations assert

that the Prime Defendants pressured providers to falsify diagnoses in order to qualify for a higher reimbursement amount under the DRG classification system, just as Life Care pressured its providers to falsify information in order to qualify for higher reimbursement under the RUG system. DRGs and RUGs both group clinically similar cases together and both are designed to capture the resource intensity of a case.

But more importantly, *Life Care* demonstrates that expert testimony can establish objective falsity in cases involving medical judgments based on criteria applied on a patient-by-patient basis. The facts and criteria underlying the medical necessity judgments in this case are no more complex or subjective than the considerations for the skilled nursing facilities[9] at issue in *Life Care*.

Rejecting the exact argument that Prime makes here, the *Life Care* court found that the fact-intensive and subjective nature of differing physicians treating individualized patients was not a proper basis for excluding extrapolation evidence as a means for proving falsity. *Id*. at 565-568. Crucially, the Court acknowledged that while there are numerous factors that "are likely unique to each patient," this only "highlights the very nature of statistical sampling: that a smaller portion of claims will be used to draw an inference about a larger, not entirely identical, population of claims." *Id*. at 566. Therefore, whether it is RUGs or DRGs, or medical unnecessary inpatient admissions or increased lengths of stay at skilled nursing facilities, both *Life Care* and the instant case involve medical necessity determinations and unique patients, and in neither case is the nature of that medical judgment so inherently subjective as to preclude the use of statistical sampling to establish liability.

[9] The consideration for skilled nursing determinations include "age; gender; pre-hospital condition/prior level of function; reason for hospitalization; condition upon admission to skilled nursing facility; visual defects; whether the patient received nursing assistance at home prior to hospitalization; incontinence; mental status; whether the medical history was extensive; whether the patient was terminally ill; whether the patient's strength was impaired; degree of the patient's dependency on others; whether the patient exhibited nausea, pain and fatigue, and endurance, among many others." *Id*. at 566.

C. Defendants' Rely on Inapposite Cases From Other Circuits

In their Motion, Defendants unsuccessfully try to squeeze the instant case into the confines of a few cases that did not permit statistical sampling on their facts. These cases are easily distinguishable from the instant case. Defendants rely primarily on *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D. Tex. 2016) and *U.S. ex rel Michaels v. Agape Senior Community, Inc.*, 2015 WL 3903675 (D. S.C. 2015).

Unlike the Motion to Exclude, *Vista Hospice Care* involved challenges to the reliability and admissibility of ***actual experts' reports and testimony***. 2016 WL 3449833, at *4, *10–*11. Contrary to decisions by courts in this Circuit and elsewhere, the district court concluded that sampling and extrapolation was impermissible. *Id*. at *11. The district court did ***not*** hold, however, that extrapolation was inappropriate in all cases involving fact-specific inquiry, or even in all cases involving hospice care. *See id*. at *12 n.100 (noting that certain "evidence" may "mak[e] the sample a reasonable basis for extrapolation to the whole"); *id*. at *14 (criticizing expert's failure to control for variables like individual clinical judgment but noting that he "could have"). And even if *Vista Hospice Care* had been decided at the pleadings stage and involved the same standards at issue here, the decision should be rejected as inconsistent with the FCA and the cases decided under it by courts in this Circuit.

Agape Senior Community should likewise be rejected as a non-controlling district court decision involving a different procedural posture and coverage standard. Moreover, the district court's analysis of the sampling question was conclusory, equivocal, secondary to a separate legal question, and *dicta*. The primary question in *Agape Senior Community* (currently on appeal in the Fourth Circuit) was whether the United States was entitled to object to the settlement of a *qui tam* action in which it had not intervened. 2015 WL 3903675, at *3–*8. The district court held that it was, denied the provider's motion to enforce the settlement over the Government's objection, and *sua sponte* certified the question for interlocutory appeal. *Id*. Then, in *dicta*, the district court offered an advisory opinion on sampling and extrapolation. *Id*. It suggested that if

its denial of the provider's motion to enforce the settlement was overturned, it would find the Government's objection to the settlement "unreasonable" because it was based on "some form of statistical sampling," which the district court had earlier "rejected for purposes of trial." *Id*. Instead of expounding on that earlier summary prohibition,[10] the district court surveyed cases "on each side of the issue;" found that although "some cases are suited for statistical sampling, this "is not such a case;" and certified that question, too, for interlocutory appeal. *Id*.

Finally, Defendants fail to tell the Court about a recent decision that declined to prohibit sampling in a hospice case (like *Agape* and *Vista Hospice)*, s*ee Cretney-Tsosie v. Creekside Hospice II, LLC*, 2016 WL 1257867, at *6 (D. Nev. Mar. 30, 2016). Nor do they address the fact that although the court in *U.S. v. Aseracare, Inc.* reversed itself after the jury verdict, it had permitted sampling in that hospice case as well. See *United States v. AseraCare, Inc.*, 2014 WL 687254, at *10 (N.D. Ala. Dec. 4, 2014).

In any event, this is not a hospice case and the falsity of the claims at issue turns on completely different criteria. For these reasons, the Court should reject *Vista Hospice Care* and *Agape Senior Community* as procedurally and substantively distinguishable, and representative of the minority approach to statistical evidence in a subset of FCA cases unlike the present.

D. <u>Case-by-case Uniqueness of Patients Does Not Preclude the Use of Statistical Sampling</u>

Again, the Prime Defendants contend that statistical sampling evidence is inappropriate because this case involves physician judgments made about individual patients with unique symptoms and conditions. (Doc. 141, pp. 26,27). Because medical necessity determinations are fact-intensive, so the argument goes, extrapolation evidence should be categorically excluded as a method for establishing liability in cases involving

[10] The portion of the order explaining the Court's reasoning prohibiting statistical evidence was one sentence: "After additional consideration and research on statistical sampling, the Court believes that based on the facts of this case, statistical sampling would be improper." *Agape Senior Community*, No. 0:12-cv-034666, Docket No. 255 (Mar. 16, 2015).

physician judgment. This argument overlooks that **all medical determinations**—whether in an emergency room, skilled nursing facility, or hospice center—are based on unique factors for each patient. Additionally, this assertion ignores the purpose of statistical sampling, which is to allow reasonable inferences about a universe of claims from a sample of that universe. *See Tyson Foods, Inc*., 136 S.Ct. at 1046 (stating "categorical exclusion" of extrapolation evidence in class action cases "would make little sense. A representative or statistical sample, like all evidence, is a means to establish or defend against liability."). For this reason, courts have rejected the argument that statistical sampling evidence and extrapolation cannot be relied on in a False Claims Act case because of the need for "individual proof." *See Life Care*, at 565 (rejecting that argument because "the purpose of statistical sampling is precisely for these types of instances in which the number of claims makes it impracticable to identify and review each claim and statement"); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (rejecting the argument that "the district judge had to address each of the 1,812 claim forms" at issue and holding that "[s]tatistical analysis should suffice"); *see also Yorktown Med. Lab*., 948 F.2d at 89 (rejecting argument, in an overpayment case, that sampling improperly prevented doctor from contesting "unidentified unacceptable practices"). To conclude otherwise would encourage providers to commit fraud on a large-scale basis to escape liability.

E. The Prime Defendants' Arguments Go to the Weight, not Admissibility of, Statistical Sampling Evidence

The Court must keep in mind the Supreme Court's admonition that, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596, 113 S.Ct. 2786. If an expert's testimony is within "the range where experts might reasonably differ," the jury, not the trial court, should be the one to "decide among the conflicting views of different experts...." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

Statistical sampling is an established method for proving liability. *See Tyson Foods, Inc.*, 136 S.Ct. at 1046 ("A representative or statistical sample, like all evidence, is a means to establish or defend against liability."). The Prime Defendants will have numerous tools at their disposal for challenging the validity and accuracy of any statistical sampling evidence, including depositions, cross-examination, designating their own statisticians, and providing their own sample size. The Motion to Exclude seeks to sidestep these aspects of the litigation by having the Court remove this evidence from the jury's consideration. Such a ruling invades the province of the jury and distorts the purpose of a *Daubert* inquiry.

As the First Circuit stated:

> ("*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's scientific testimony rests upon "good grounds, based on what is known," it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies. In short, *Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion".)

Ruiz–Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir.1998) (quoting *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786). As such, the Motion to Exclude offers arguments that go to the weight, not admissibility of, the sampling evidence, and the Prime Defendants will remain free to challenge, contradict and rebut that evidence before the trier of fact.

CONCLUSION

For the reasons set forth above, this Court should deny Defendants' motion to exclude statistical sampling to prove falsity of claims under the FCA based on medically unnecessary admissions or clinically unsupported diagnoses.

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