UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
at CHATTANOOGA

UNITED STATES OF AMERICA *ex rel.* GLENDA MARTIN and STATE OF TENNESSEE *ex rel.* GLENDA MARTIN,	)	
Plaintiffs / Relator,	)	Case No. 1:08-cv-251
v.	)	Judge Mattice
LIFE CARE CENTERS OF AMERICA, INC.,	)	
Defendant.	)	

UNITED STATES OF AMERICA *ex rel.* TAMMIE JOHNSON TAYLOR,	)	
Plaintiff / Relator,	)	Case No. 1:12-cv-64
v.	)	Judge Mattice
LIFE CARE CENTERS OF AMERICA, INC.,	)	
Defendant.	)	

ORDER

Before the Court is Defendant's Motion for Partial Summary Judgment (Doc. 140). For the reasons stated hereafter, Defendant's Motion will be **DENIED**.

I. BACKGROUND

As a preliminary matter, the Court notes that Defendant is only seeking summary judgment as to the Government's use of statistical sampling for Counts I and II of its Consolidated Complaint in Intervention. *See* Doc. 152 at 7. Thus, the Court will not address the merits of the Government's identified false claims under the False Claims

Act ("FCA") or its claims for unjust enrichment, payment by mistake, and conversion. Additionally, as Defendant is seeking a legal determination solely regarding the use of statistical sampling in cases brought under the FCA, the parties do not dispute the material facts relevant to this determination. The Court will provide a brief background of the allegations stated in the Complaint, and then address the merits of Defendant's arguments.

The Court summarized the procedural posture of this action as well as the allegations set forth in the Government's Complaint in its March 26, 2014 Order on Defendant's Motion to Dismiss:

> This consolidated *qui tam* action was filed separately by relators Glenda Martin and Tammie Taylor. (Doc. 69 at 5). Glenda Martin is a registered nurse and former staff development coordinator of Defendant Life Care Center ("Life Care") in Morristown, Tennessee, and she filed her claim on October 16, 2008. (*Id.*). Tammie Taylor is a former occupational therapist at Life Care in Lauderhill, Florida, and she filed her claim on February 23, 2012. (*Id.*). The Government moved to intervene as Plaintiff in this case on October 1, 2012, and the Court granted the Government's Motion on November 15, 2012. (Docs. 60, 67). In the same Order, the Court also ordered that Martin and Taylor's cases be consolidated. (Doc. 67). . . .
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> Life Care is a corporation that owns over 200 skilled nursing facilities and is headquartered in Cleveland, Tennessee. (*Id.* at 5). Life Care receives funds from Medicare, a health insurance program established and administered by the United States Government. Between the period of January 2006 through December 2011, Medicare paid Life Care over $4.2 billion for its services, including "inpatient services at its nursing facilities." (*Id.* at 5).
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> Each Life Care facility has a Rehab Manager who manages rehabilitation therapy staff and therapy services. (Doc. 69 at 17). The Rehab Manager reports to that facility's Executive Director, who in turn reports to the Regional Vice President and Divisional Vice President. (*Id.*). Each facility has therapy staff, including physical therapists, physical therapy assistants, occupational therapists, certified occupational therapy assistants, and speech-language and pathology therapists. (*Id.* at 18). Each facility also has a Minimum Data Set (MDS) coordinator who is

responsible for collecting information needed for the MDS and determining the assessment reference date for Medicare purposes. (*Id.*).

Medicare, Medicaid, and TRICARE

People of any age can qualify for Medicare in certain circumstances, but Medicare is commonly known as "our country's health insurance program for people who are 65 or older." *Medicare*, SSA.Gov, http://www.ssa.gov/pgm/medicare.htm (last visited Feb. 3, 2014)("Medicare Overview"). Medicare is financed in part by taxes and in part by "monthly premiums deducted from social security checks." Medicare Overview. Medicare is broken up into four parts: (1) hospital insurance ("Part A"); (2) medical insurance ("Part B"); (3) Medicare advantage ("Part C"), which combines the health care services provided in Part A and Part B; and (4) prescription drug coverage ("Part D"). Medicare Overview. Each part of Medicare has a list of requirements, which determine whether a person will be eligible to receive Medicare benefits. Medicare Overview.

Part A includes coverage for "post-hospital extended care services for up to 100 days during any spell of illness." 42 U.S.C. § 1395d(a)(2)(A). A physician, nurse practitioner, clinical nurse specialist, or a physician assistant must certify that: (1) services are required because the person needs skilled nursing care or other "skilled rehabilitation services" on a daily basis; (2) services "can only be provided in a skilled nursing facility on an inpatient basis;" and (3) services are provided to address the condition for which the patient was receiving care for when he was an inpatient. 42 U.S.C. § 1395f(a)(2)(B); 42 C.F.R. § 409.31(b). Additionally, Medicare does not cover services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). A "skilled service" is defined as a service that is "so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel" such as a physician, registered nurse, physical therapist, occupational therapist, or speech pathologist.[1] 42 C.F.R. § 409.32(a); 42 C.F.R. § 409.31(a)(1-3).

Skilled nursing facilities such as Life Care are paid by Medicare through a prospective payment system ("PPS") based on provisions of the Balanced Budget Act of 1997 ("BBA"). *Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities*, 63 Fed. Reg. 26252-01 (May 12, 1998). The BBA "sets forth the formula for establishing [per diem Federal payment] rates as well as the data on which they are based. *Id.* The rates are created using the classifications of Resource Utilization Groups ("RUG"), which "uses measures of staff time

[1] Many examples of skilled services and "personal care services," which are distinguished from skilled services, are listed in 42 C.F.R. § 409.33.

and service frequency, variety, and duration" to classify patients as different levels. *Id*; *Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for Fiscal Year 2006*, 70 Fed. Reg. 45026-01 (Aug. 4, 2005). In calculating RUG levels, there are three types of therapy disciplines: occupational therapy, physical therapy, and speech pathology. 63 Fed. Reg. 26252-01. The structure of RUG groups and the daily PPS rate is adjusted from time to time; the RUG-III classification system was in place from January 1, 2006 until October 1, 2010, and the RUG-IV classification system has been in effect from October 1, 2010 until the present.[2] 70 Fed. Reg. 45026-01.

There are seven RUG-III categories: rehabilitation, extensive services, special services, clinically complex, impaired cognition, behavior, and physical. 63 Fed. Reg. 26252-01. The rehabilitation category is divided into five general sub-levels: (1) Rehab Ultra, which requires 720 minutes of treatment per week, two out of three rehabilitation therapy disciplines being used, and one discipline providing services 5 days of the week or more; (2) Rehab Very High, which requires 500 minutes of treatment per week and one discipline providing services 5 days of the week or more; (3) Rehab High, which requires 325 minutes of treatment a week with one discipline providing services 5 days of the week or more; (4) Rehab Medium, which requires 150 minutes of treatment from any of the 3 disciplines for at least 5 days of the week; and (5) Rehab Low, which requires 45 minutes of treatment a week from any of the 3 disciplines for at least 3 days of the week. *Id*. The higher the RUG level, the more money a skilled nursing facility will receive from Medicare for providing the services. *See id*. ("The Ultra High Rehabilitation sub-category is intended to apply only to the most complex cases requiring rehabilitative therapy well above the average amount of service time. This translates into higher charges for therapy services, both because treatment is more frequent and complex, and because length of stay is longer than for other skilled rehabilitation groups.").

RUG levels also consider a person's capacity to perform activities of daily living ("ADL") such as "bed mobility, toilet use, transfer from bed to chair, and eating." *Id*. ADL scores are broken into 5 different scores based on a person's capabilities ranging from categories of A, B, and C, which are for rehabilitation without extensive services, to categories L and X, which are rehabilitation with extensive services. Of these categories, the most capable patient in terms of ADL scores is an "A" patient, whereas the patient that will need the most assistance is an "X" patient. 74 Fed. Reg. 40288-01.

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[2] *Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for Fiscal Year 2010*, 74 Fed. Reg. 40288-01 (Aug. 11, 2009); *see* Doc. 69 at 11 ("CMS added new clinical RUG categories, modified the timeframe in which each assessment must be performed, required that nursing facilities assess changes in the level of therapy every 7 days, and revised certain rules pertaining to group therapy, among other changes").

A skilled nursing facility assesses a patient's RUG level and completes a MDS on the 5th, 14th, 30th, 60th, and 90th days of the patient's stay at that facility. 42 C.F.R. § 413.343(b). These periodic assessments are significant because, as noted above, they determine the daily rate that Medicare will pay for the facilities' services during that period. 63 Fed. Reg. 26252-01; 70 Fed. Reg. 45026-01. Skilled nursing facilities submit a MDS and the accompanying forms to Medicare payment processors. From January 2009 through August 2009, BlueCross BlueShield of Tennessee was the processor for Life Care. (Doc. 69 at 13). From August 2009 through the present, Cahaba Government Benefit Administrators has been the processor for Life Care. (*Id.*).

In addition to Medicare, there is also the federal program TRICARE and the state program Medicaid, through which people can get medical benefits. TRICARE is another federal program that provides medical benefits to veterans, service members, and military families. 10 U.S.C. § 1071. TRICARE uses "Medicare's PPS and RUGs methodology and assessment schedule," and provides reimbursement to skilled nursing facilities in accordance with the rules that apply to Medicare. Doc. 69 at 14; 10 U.S.C. §1079(j)(2). Each state also has a Medicaid program for residents with low-income. *Medicaid*, Medicaid.Gov., http://www.medicaid.gov/index.html (last visited Feb. 3, 2014). The individual states set the eligibility requirements for Medicaid within the federal guidelines, and "Medicaid . . . provide[s] health coverage to nearly 60 million Americans, including children, pregnant women, parents, seniors and individuals with disabilities." *Eligibility*, Medicaid.Gov.,http://www.medicaid.gov/ Medicaid -CHIP- Program-Information/By-Topics/Eligibility/Eligibility.html (last visited Feb. 3, 2014).

Complaint Allegations

In its Consolidated Complaint, the Government first claims that Life Care pressured its therapists to target Ultra High RUG levels and longer average length of stay periods for patients in order to maximize its Medicare revenue and exhaust "all 100 days of [a patient's] Medicare [skilled nursing facility] benefit." (Doc. 69 at 15). The Government asserts that Life Care provided therapy "that was not medically reasonable or necessary" by pressuring therapists to assign higher RUG levels. (*Id.* at 16).

In support of its claim, the Government asserts that Life Care: (1) generated reports that tracked Ultra High RUG percentages, average length of stay levels, and productivity levels; (2) set targets at the corporate level for the amount of Medicare rehabilitation days it would bill at the Ultra High RUG level without knowledge of individual patient needs; (3) had its Chief Operating Officer "push for increased Medicare

revenue;" (4) had at least one Regional Rehab Director contact Rehab Managers that did not have Ultra High RUG percentages above 61% to create an action plan to create higher RUG levels; (5) set a 2 hour minimum level of therapy per day "unless proven otherwise;" (6) had Rehab Managers submit their RUG level information to a Resource Utilization Specialist ("RUS") to "question facility employees" about failures to meet higher RUG levels; (7) created and used its Rehabilitation Opportunity Committee ("ROC") to identify and pressure "focus" facilities to meet corporate RUG targets; (8) had Life Care management create "action plans" based on ROC visits that focused on increasing the length of stay of patients at higher RUG levels; (9) had Regional Rehab Directors visit facilities in their region and push facilities to increase Ultra High RUG levels; (10) had certain divisions set targets to "double the Ultra High percentage of certain patients;" (11) had certain divisions establish a "$400 club" for employees who booked daily Medicare rates of $400; (12) measured the performance of employees, including Regional Rehabilitation Directors, Rehab Managers, and therapists, in part, on "their ability to achieve Ultra High targets;" (13) had its Rehab Managers set therapy minutes based on meeting higher RUG levels; and (14) rewarded employees that met higher RUG levels. (Doc. 69 at 18-32). In support of these allegations, the Government provides examples of specific Life Care divisions, managerial employees, and/or time frames during which the alleged actions took place. (*Id.*).

The Government next claims that Life Care billed Medicare for services that were "medically unreasonable, unnecessary, and unskilled." (Doc. 69 at 33). Specifically, the Government claims that the patients' therapy plans were not individualized to their needs, but rather consisted of "rote exercises that provided little clinical benefit." (*Id.*). As part of this allegation, the Government has attached to its Complaint a list of allegedly false claims and false statements, which identifies specific patients and therapy amounts. (*Id.* at 52-53).

In support of this claim, the Government provides several examples of patients who allegedly received unreasonable and unnecessary services, including: (1) Patient A, a 78-year-old "frail and rehabilitated" male who received 1,298 therapy minutes during his first week of treatment, received Ultra High levels of therapy for several weeks, was readmitted to the hospital and returned to the nursing home (where he received 269 minutes of therapy), and ultimately died several days after returning to the nursing home; (2) Patient B, a 85-year-old non-ambulatory female with "significant heart problems and functional deficits due to long-term obesity and blindness" who received Ultra High levels of therapy for 77 days and had "unrealistic long-term goals;" and (3) Patient D, a 92-year-old patient who was "dying" of metastatic cancer and received Ultra High levels of therapy for the two weeks leading up to his death. (Doc. 69 at 33-35).

In further support of its claim that Life Care billed Medicare for "unnecessary" services, the Government alleges that Life Care increased therapy for patients without clinical justification. (Doc. 69 at 35). The Government asserts that Life Care "ramped up" the amount of therapy provided to patients during the Medicare assessment periods in order to receive the maximum Medicare payment. (*Id.*). The Government points to several examples in support of this allegation, including: (1) Patient E, whose occupational therapy was "nearly double" during the assessment period and whose physical therapy was increased by 15 minutes a day during his assessment period, both of which contributed to his classification as an Ultra High RUG level; and (2) Patient F, a 92-year-old patient who was provided more than 300 minutes of therapy on a single day during his assessment period, despite a physical condition that would have made him "unable to participate in or. . . harmed by such an excessive amount of therapy in a single day." For both Patient E and Patient F, their medical records did not reflect a clinical need that supported increased therapy. (*Id.*).

The Government's final factual allegations that Life Care billed for unnecessary therapy are that (1) Life Care used unnecessary modalities, such as heat, cold, and electrical treatments, to increase the patient's number of therapy minutes; (2) Life Care billed Medicare for patients who should have been discharged; (3) Life Care improperly placed patients in group therapy that was unrelated to their plans of care; and (4) Life Care billed Medicare for services that did not require a rehabilitation therapist. (Doc. 69 at 38-40). In support of these allegations, the Government provides several examples, including: (1) Patient G, an 88-year-old patient with colon cancer who was provided with "an excessive level of electrical stimulation;" (2) Patient H, an 73-year-old patient who reached his maximum potential on day 59, but for whom Life Care continued his therapy until his 100-day Medicare benefit was exhausted; (3) Patient I, a 62-year-old male who did not walk and was totally dependent for many ADLs and for whom Life Care billed Medicare for therapy focused on standing exercises; and (4) Patient J, a 82-year-old female whose "physical therapy documentation show that her treatment largely consisted of unskilled services," but for whom Life Care billed Medicare at the Ultra High RUG level for 90 out of 100 days that she stayed at Life Care. (Doc. 69 at 38-40).

Finally, the Government claims that Life Care knew that it was billing medically unreasonable, unnecessary, and unskilled services. (Doc. 69 at 41). The Government alleges that Life Care knew that it was billing unnecessary services based on: (1) the numerous complaints filed by its employees about corporate targets and pressure; and (2) the fact that Life Care ignored and/or minimized complaints and retaliated against employees who complained. (*Id.* at 41-46). The complaints were sent to

> Life Care's compliance office (the Integrity Services Division) and Life Care's corporate Rehabilitation Services offices, and the complaining parties stated that the therapists provided medically unnecessary therapy, the supervisors directed employees to increase RUG levels, and the patients were not discharged from Life Care until they exhausted their 100-day Medicare skilled nursing benefit. (Doc. 69 at 43). Life Care also received a complaint from an outside contractor regarding Life Care's "unnecessary rehab therapy designed primarily to increase Life Care's revenue rather than meet patient needs." (*Id.*).
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> Life Care often responded to these complaints by having the Vice President of Rehabilitation Practice Standards and other corporate rehabilitation staff conduct investigations. (*Id.*). The Government alleges that, in investigating these complaints, Life Care sought to "root[] out the complainant" rather than "addressing the problem." In an "informal study" done by Integrity Services, Life Care terminated 57% of employees who gave their name when filing their complaint within 3 weeks. (*Id.* at 46).

(Doc. 153 at 2-12).

The Court ultimately denied Defendant's Motion to Dismiss in its March 26, 2014 Order. (Doc. 153). On February 18, 2014, the Government filed a Motion to Partially Exclude the Testimony of Stefan Boedeker (Doc. 135); Defendant filed a Motion to Exclude the Expert Testimony of Constantin T. Yiannoutsos (Doc. 137) on February 18, 2014. Also on February 18, 2014, Defendant filed the instant Motion for Partial Summary Judgment (Doc. 140). On June 18, 2014, the Court held a hearing on Defendant's Motion for Partial Summary Judgment, and the parties presented argument in support of their positions. (Docs. 172, 176).

The parties agree that the Government will not undertake a claim-by-claim review of every claim filed within the relevant time frame. Rather, the Government seeks to use a random sample of 400 admissions from 82 Life Care facilities "from January 1, 2006, until October 31, 2012, where Medicare was the primary payer [and] more than 65% of those facilities' rehabilitation therapy days were at the Ultra-High

Resource Utilization Group . . . level of reimbursement." (Doc. 141-3 at 3). The Government intends to extrapolate from this sample to make "estimates on the total number of claims which were submitted for non-covered services and the total amount of overpayments made by Medicare." (*Id.*). From these facilities during this time period, the entire sample universe to which the sample would be extrapolated is 54,396 patient admissions, comprising 154,621 total claims. (*Id.*). As there are no disputes as to material facts relevant to the issue of whether statistical sampling may be used to prove the number of claims in a FCA action and the loss associated with those claims, the Court can resolve this issue on summary judgment.

II. STANDARD OF LAW

Federal Rule of Civil Procedure 56 instructs the Court to grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A party asserting the presence or absence of genuine issues of material facts must support its position either by "citing to particular parts of materials in the record," including depositions, documents, affidavits or declarations, stipulations, or other materials, or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). As previously noted, when ruling on a motion for summary judgment, the Court must view the facts contained in the record and all inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita*, 475 U.S. at 587 (1986); *Nat'l Satellite Sports, Inc. v. Eliadis Inc.*, 253 F.3d 900, 907 (6th Cir. 2001). The Court cannot weigh the evidence,

judge the credibility of witnesses, or determine the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

The moving party bears the initial burden of demonstrating that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The moving party may discharge this burden either by producing evidence that demonstrates the absence of a genuine issue of material fact or simply "by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325. Where the movant has satisfied this burden, the nonmoving party cannot "rest upon its . . . pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009) (citing *Matsushita*, 475 U.S. at 586; Fed. R. Civ. P. 56). The nonmoving party must present sufficient probative evidence supporting its claim that disputes over material facts remain and must be resolved by a judge or jury at trial. *Anderson*, 477 U.S. at 248-49 (citing *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253 (1968)); *see also White v. Wyndham Vacation Ownership, Inc.*, 617 F.3d 472, 475-76 (6th Cir. 2010). A mere scintilla of evidence is not enough; there must be evidence from which a jury could reasonably find in favor of the nonmoving party. *Anderson*, 477 U.S. at 252; *Moldowan*, 578 F.3d at 374. If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to summary judgment. *Celotex*, 477 U.S. at 323.

III. ANALYSIS

In its Motion for Partial Summary Judgment, Defendant argues that the Government cannot satisfy its burden of proof through evidence based on statistical sampling and extrapolation. In Response, the Government asserts that statistical

sampling is used in a number of evidentiary contexts, "including both criminal and civil fraud cases" and is "essential" to the instant case due to the large number of claims. (Doc. 152 at 7). For the Court to make a determination regarding whether statistical sampling is appropriate in the instant case, it must first review the history of the FCA and principles of statistical sampling.

A. The FCA

1. History

The FCA was originally adopted by Congress in order to stop "the massive frauds perpetrated by large contractors during the Civil War." *United States v. Bornstein*, 423 U.S. 303, 309 (1976). Contractors looted the federal treasury and created a "windfall profit" through fraudulent interactions with the government. *See United States ex rel. Newsham v. Lockheed Missiles & Space Co., Inc.*, 722 F. Supp. 607, 609 (N.D. Cal. 1989) ("For sugar [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors, or the refuse of shops and foreign armories")(quoting Tomes, *Fortunes of War*, 29 Harper's Monthly Mag. 228 (1864)). On account of these transactions, the government faced "rampant fraud in Civil War defense contracts," and, in 1863, Congress adopted the FCA and President Abraham Lincoln signed it into law. S. REP. NO. 99-345, at 8, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273 ("Senate Report").

The version of the FCA adopted in 1863 provided that the government would receive payment for double the damages suffered by the false claim, as well as a $2,000 forfeiture per submitted claim. The FCA was amended in 1943 and 1986 to better suit the needs of the growing economy. *See* Patricia Meador & Elizabeth S. Warren, *The*

False Claims Act: A Civil War Relic Evolves into A Modern Weapon, 65 Tenn. L. Rev. 455, 459-60 (1998). Since the FCA was adopted, many courts have had the opportunity to interpret the meaning of its language. In determining how FCA claims may be litigated, these interpretations have accorded significant weight to the legislative history and the purpose of the FCA. *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 547-48, 63 (1943) ("The very fact that Congress passed this statute shows that it concluded that other considerations of policy outweighed those now emphasized by the government . . . [u]nder the circumstances here, we could not, without materially detracting from its clear scope, decline to recognize [a private party's] right to sue under the Act."); *United States v. Griswold*, 24 F. 361, 366 (D. Or. 1885) ("It is intended to protect the treasury against the hungry and unscrupulous host that encompasses it on every side, and should be construed accordingly. It was passed upon the theory, based on experience as old as modern civilization, that one of the least expensive and most effective means of preventing frauds on the treasury is to make the perpetrators of them liable to actions by private persons acting, if you please, under the strong stimulus of personal ill will or the hope of gain.")

The FCA has evolved over time, both through these amendments and the developing body of case law, and the current version permits the government to recover treble damages as prescribed by statute and civil penalties ranging from $5,000 to $11,000 per false claim. *United States ex rel. Hobbs v. MedQuest Associates, Inc.*, 711 F.3d 707, 714 (6th Cir. 2013); 28 C.F.R. § 85.3(a)(9). While the end penalty remains similar to the original text, the legislative history of the FCA is clear that the FCA has evolved with the ever-changing landscape of technology and new methods and mechanisms for committing fraud. For example, the FCA was amended in 1986 because

the "growing pervasiveness of fraud necessitate[d] modernization of the Government's primary litigative tool for combatting fraud." Senate Report at 2. Congress found the amendment to be necessary on account of the increase in fraud against the government, which was indicated by (1) the increase in fraud investigations; (2) the number of defense contractors under investigation for fraud offenses; (3) the amount of public money estimated to be lost to fraud; and (4) the failure of employees to report fraudulent activity. The amendments to the FCA represent "a long history of repeated congressional efforts to walk a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 876 (6th Cir. 2006) (quoting *United States ex rel. Karvelas v. Melrose–Wakefield Hospital*, 360 F.3d 220, 225 (1st Cir. 2004)).

Despite the recent amendments to the FCA and its increased use as a litigative tool, fraud remains a serious issue for government programs, including the Medicare program. The United States Government Accountability Office ("GAO") reported that for 2012, "the Medicare program covered more than 49 million elderly and disabled beneficiaries at an estimated cost of $555 billion, and reported improper payments estimated to be more than $44 billion." U.S Gov't Accountability Office, GAO-13-283, *High Risk Series: An Update* (2013). The Senate Report recommending the 1986 Amendments discussed the ongoing problem of fraud by describing it as "pervasive" and "costly to the Government due to a lack of deterrence." Senate Report at 3. Specifically, the Report cited the GAO's conclusion that "most fraud goes undetected due to the failure of Governmental agencies to effectively ensure accountability on the part of program recipients and Government contractors." *Id*.

2. Elements

The FCA imposes liability on any person who, among other things, knowingly presents the United States with a false or fraudulent claim for payment. *See* 31 U.S.C. § 3729. It also enables private individuals to bring suits for violations of § 3729 in the Government's name. 31 U.S.C. § 3730(b). As the Medicare program has grown, one of the primary uses of FCA actions has been "to combat fraud in the healthcare field." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011).

In the instant case, the government brings two counts under the FCA, one for making a false statement or record that is material to a false or fraudulent claim and one for making a false or fraudulent claim. For a person to be civilly liable for making a false statement or record, he must (1) knowingly make, use, or cause to be used a false record or statement; (2) with actual knowledge, deliberate indifference, or reckless disregard of the information; and (3) the record or statement must be material (having a tendency or being capable of influencing the payment or receipt of money or property) to a false or fraudulent claim.[3] 31 U.S.C. 3729(a)(1)(B). For a person to be civilly liable for submitting a false or fraudulent claim, he must (1) submit a claim for payment to the federal government; (2) the claim must be false or fraudulent; and (3) the person must have either actual knowledge of the claim's falsity or have acted in reckless disregard of the claim's validity. 31 U.S.C. 3729(a)(1)(A).

[3] The Court notes that, while the Government brings two counts under the FCA, one for making a false statement or record that is material to a false or fraudulent claim and one for making a false or fraudulent claim, the parties frequently do not differentiate between the two claims. The Court recognizes the symbiotic nature of the two claims and will distinguish between the individual claims only when it is appropriate to do so.

B. Principles of Statistical Sampling

The general purpose of statistical sampling is to "provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample." *United States v. Rosin*, 263 F. App'x 16, 29 (11th Cir. 2008) (citing Laurens Walker & John Monahan, *Sampling Evidence at the Crossroads*, 80 S. Cal. L. Rev. 969, 973–74 (2007)). In order "to draw reliable conclusions" about the sample universe, the statistical sample must be of a sufficient size to support the conclusions. *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*, 984 F. Supp. 2d 1021, 1033 (C.D. Cal. 2013). Given that the nature of a statistical sample is to draw an inference from the sample to the larger population, statisticians account for any discrepancies by calculating a margin of error. Generally, when a sample method "defines an appropriate population, uses a probability method for selecting the sample, has a high response rate, and gathers accurate information on the sample units, . . . the sample tends to be representative of the population." David H. Kaye and David A. Freedman, Reference Guide on Statistics, *in Reference Manual on Scientific Evidence* 211, 226 (3d ed. 2011) ("Reference Guide on Statistics").

Litigants have attempted to use evidence in the form of sampling as early as the 1920s. *Elgin Nat. Watch Co. v. Elgin Clock Co.*, 26 F.2d 376, 377 (D. Del. 1928). Over time, statistical sampling has become commonplace in certain types of litigation. *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1020 (5th Cir. 1997) ("The applicability of inferential statistics have long been recognized by the courts."). In fact, courts now consider "mathematical and statistical methods [to be] well recognized as reliable and acceptable evidence in determining adjudicative facts." *State of Ga., Dep't of Human Res. v. Califano*, 446 F. Supp. 404, 409 (N.D. Ga. 1977); *see United States v. Lahey*

Clinic Hosp., Inc., 399 F.3d 1, 18 n.19 (1st Cir. 2005) ("sampling of similar claims and extrapolation from the sample is a recognized method of proof."). Statistical reasoning and analysis is often used in "antitrust, employment discrimination, toxic torts, and voting rights cases." Reference Guide on Statistics. In recent years, "courts have routinely permitted the use of statistical sampling to determine whether there has been a pattern of overpayments spanning a large number of claims where case-by-case review would be too costly." *Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 919 (D.C. Cir. 1991).

In the context of the FCA, as will be discussed more thoroughly *infra*, statistical sampling has been generally limited to determine damages, rather than liability. *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (providing an overview of federal circuit courts that have permitted statistical sampling in this context). One of the reasons that courts permit parties to use 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); *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").

When statistical sampling has been permitted, courts have placed the burden of evaluating the weight of a statistical sample on the fact finder. *State of Ga., Dep't of Human Res.*, 446 F. Supp. at 410. While the proponent of sampling may argue that the sample permits the fact finder to draw an inference regarding the sample universe, the

opposing party can challenge the sample through cross-examination of the proponent's expert, presentation of its own expert, as well as other competing witnesses and evidence. *See Michigan Dep't of Educ. v. U.S. Dep't of Educ.*, 875 F.2d 1196, 1206 (6th Cir. 1989). The fact finder must then consider the evidence, including the risk of uncertainty and the size of the sample, in determining its weight.

C. Interaction between the FCA and Statistical Sampling as Relevant to the Instant Case

To this point, the use of statistical sampling in FCA cases has been limited. However, as the Medicare program grows and the FCA is used to combat fraud within the program, the government has sought to use statistical sampling as a means to use the FCA with respect to ever-larger quantities of claims. In their briefs, the parties have highlighted several of the cases in which a court has permitted or declined to use statistical sampling to prove claims brought under the FCA.

1. Cases in which Courts Declined to Use Statistical Sampling

In support of its position–that statistical sampling cannot be employed to establish liability for FCA claims–Defendant first relies on a District of Massachusetts case, *United States v. Friedman*, No. 86-610-MA, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993). Similar to the instant case, the government alleged that the Defendant in *Friedman* violated the FCA by submitting claims to Medicare for overpayment by billing for more expensive services than were provided. The parties proceeded to a nonjury trial, and the court ultimately found that the Defendant violated the FCA. In a footnote in its Opinion, the court acknowledged that the government offered evidence at trial in the form of statistical sampling. However, the judge noted that, "[w]hile I recognize the validity of the mathematical and statistical projections

based on a review of the smaller number of claims I have declined to extrapolate in the manner urged by the government." Rather, the court elected to review each claim in order to reach its conclusion. As the court in *Friedman* was faced with the review of only 676 claims, it was presented with a distinctly different factual scenario than is presented in the instant case. Additionally, the court in *Friedman* recognized the validity of statistical sampling even though it was not applied in that case, indicating that the case does not stand for the proposition that statistical sampling cannot be used in large-scale FCA cases. Regardless, the opinion is not binding on this Court and provides little analysis regarding the propriety of statistical sampling in a FCA case. Thus, the Court does not find *Friedman* to be determinative as to the outcome of the instant case.

Defendant also argues that a Western District of Oklahoma case, *United States ex rel. Trim v. J.D. McKean*, is analogous to the instant case. (Doc. 141 at 21). In *Trim*, Midwest City Hospital ("MCH") used a coding system named Emergency Physicians Billing Services ("EPBS") to bill for services provided to patients. 31 F. Supp. 2d 1308, 1312 (W.D. Okla. 1998). EPBS was established by J.D. McKean, the director of the Emergency Medicine Department at MCH, to bill and collect for physicians' claims. The system relied on the good faith of the physicians providing the medical services as well as the coders assisting with reimbursement. *Id.* A *qui tam* suit was brought under the FCA against EPBS and J.D. McKean alleging that unnecessarily higher billing codes were used and justified by physicians' charts. After the suit was commenced, audits were performed by Pennsylvania Medicare, Medicaid in Oregon and Arizona, and other benefit programs. The court considered whether to use the audits as a statistical sample

of the universe of fraudulent claims, but found the audits to be "insufficient." *Id.* at 1314. The audits were deemed insufficient for the following reasons:

> The Oregon audit was tainted by the request, which invited a recovery in a pending action if fraudulent claims were found, and the Pennsylvania charts were not typical of any other program. Without any testimony as to the reliability of the auditor or circumstances under which the audit was undertaken in the remaining three, the Court is unwilling to extrapolate those findings to all other claims. Moreover, in light of the admittedly subjective nature of coding, the relatively small sample size, and the variation in years covered, given the evolution of more consistent and predictable coding definitions and practices over time, the audits are not a reliable or accurate representation of all EPBS claims.

Id. The Court also noted that many of the charts were "completely illegible and, in some cases, [did not] appear to be written in English." *Id.* Despite the insufficiency in the nature of the audits, the Court ultimately found that the audits contained "persuasive" evidence of false claims, and that the "documentation which supports the audits, combined with the multitude of improper billing practices . . . require[d] the conclusion that inflated codes found in the audited charts represent[ed] false claims." *Id.* Considering these distinct factual circumstances, the Court finds the statistical sample in the instant case to be devoid of the issues identified in *Trim*, leaving the Court to conclude that *Trim* is distinguishable and of little assistance in deciding Defendant's Motion. As the court in *Trim* was faced with a very different factual landscape, the Court does not find it to be analogous to the instant case.

2. Cases Supporting the Use of Statistical Sampling

As part of its Response to Defendant's Motion–to show that statistical sampling *is* proper in the instant case–the Government has cited to the following types of cases: (1) appeals from administrative agency decisions; and (2) cases in which statistical

sampling has been used to establish the amount of damages. The Court will discuss in turn why each of these types of cases are distinguishable from the instant case.

Appeals from administrative agency decisions are distinguishable from the instant case because they are considered by an appellate court under a different standard of review. Specifically, under the Administrative Procedure Act, a reviewing court will only set aside an agency's action if "it finds that the actions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Dressman v. Costle*, 759 F.2d 548, 555 (6th Cir. 1985) (quoting 5 U.S.C. § 706(2)(A)). The United States Court of Appeals for the Sixth Circuit has characterized this review as a "narrow one," and has observed that the reviewing court "is not empowered to substitute its judgment for that of the agency." *State of Mich. v. Thomas*, 805 F.2d 176, 182 (6th Cir. 1986) (quoting *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971)); *Am. Fed'n of State, Cnty. & Mun. Emp., AFL-CIO, Greater Cleveland Dist. Council 78 v. City of Cleveland*, 484 F.2d 339, 348 (6th Cir. 1973) ("To suggest that other methods might have been better employed to achieve the results sought by the limitation is to substitute the judgment of the reviewing court for that of the administrator of the Act. This is not permitted."). Given the level of review and the discretion granted to the agency action, the Court does not find the use of statistical sampling as addressed in these cases to be persuasive regarding the propriety of the use of statistical sampling in a claim brought under the FCA.

Unlike the standard of review in an appeal from an administrative agency decision, in order to sustain a claim under the FCA, a plaintiff must prove the elements of a false claim by a preponderance of the evidence. 31 U.S.C. § 3731(d); *United States. ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) *aff'd*, 302 F.3d

637 (6th Cir. 2002). This standard of review has been defined as "such evidence as, when considered and compared with that opposed to it, has more convincing force and produces in [one's] mind[] belief that what is sought to be proved is more likely true than not true." *Williams v. Eau Claire Pub. Sch.*, 397 F.3d 441, 444 (6th Cir. 2005). The Court considers the administrative agency appeals cases as narrowly instructive as to how statistical sampling can be used in a similar context. However, while these cases provide insight on the possible uses of statistical sampling, the Court can only view the holdings of the cases themselves within the context of the knowledge that they were considered under a quite different standard of review.

Administrative agency decision appeals are also distinguishable because using statistical sampling to determine overpayment amounts is explicitly authorized by statute. 42 U.S.C. § 1395ddd(f)(3). Under the statute, statistical sampling and extrapolation is permitted when "there is a sustained high level of payment error" or "documented educational intervention has failed to correct the payment error." 42 U.S.C. § 1395ddd(f)(3)(A-B). With respect to the instant case, this consideration could be interpreted to be in favor of either party.

From the Government's standpoint, this serves as an example that statistical sampling has been authorized as an evidentiary tool in the administrative context. However, from Defendant's perspective, the legislature has not included such a provision in the FCA, leaving the issue of whether statistical sampling is appropriate under the FCA open to interpretation. Under either interpretation, it is clear that these cases are decided under a distinctly different standard than the instant case. *Chillicothe Chiropractic & Wellness Ctr. v. Sibelius*, 2014 WL 1382478, at *5-6 (S.D. Ohio Apr. 8, 2014). Therefore, considering the disparate nature of administrative agency decision

appeals as compared to the instant case, the Court will only consider them as an example of how extrapolation *can* be used rather than a conclusive determination of how statistical sampling *should* be used in FCA actions.

The Government also heavily relies on FCA cases and criminal cases in which statistical sampling and extrapolation was permitted to establish loss or damages. *See United States v. Jones*, 641 F.3d 706, 712 (6th Cir. 2011) ("A statistical estimate may provide a sufficient basis for calculating the amount of loss caused by a defendant"); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (finding that "[s]tatistical analysis should suffice" rather than an individual review of claims); *Fadul*, 2013 WL 781614, at *14 (entering judgment against the defendant in an amount calculated through statistical sampling and extrapolation). The Court agrees with the courts in *Rogan* and *Fadul* that "[c]ourts 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." *Fadul*, 2013 WL 781614, at *14. However, using extrapolation to establish damages when liability has been proven is different than using extrapolation to establish liability. Specifically, as will be considered *infra*, to use statistical sampling to find liability for extrapolated claims could be in conflict with the Government's evidentiary burden to establish the elements of a FCA claim.

Aside from the categories of cases discussed above, the Government also relies on *United States v. Cabrera-Diaz*, a case in which statistical sampling was used to establish liability for claims under the FCA. 106 F. Supp. 2d at 234. In *Cabrera-Diaz*, a physician billed a Medicare Part B carrier for his anesthesia services. When the Medicare Part B carrier audited his claims for anesthesia services for a certain period of time, it used a

statistically valid random sample, which revealed that the physician had "overstated, falsely reported, unsupported or undocumented the anesthesia time in all but six of the 461 sampled claims." *Id.* at 237. Based on this sample, the government extrapolated the sample to the entire universe of claims to determine the total amount of payment. *Id.* at 240. The issue of whether the extrapolation was proper came before the court when the physician did not appear and the government moved for default judgment. The court found that the government's use of statistical sampling was proper and, without objection from the defendant, granted the government's motion for default. *Id.* at 240-43.

The Court agrees with the similarities between *Cabrera-Diaz* and the instant case that were identified by the Government. However, as Defendant argues in its Reply brief, the case is distinguishable because "the defendants defaulted and never appeared to challenge or litigate the matter, and liability was therefore established as a consequence of the default." (Doc. 159 at 11). Without evidence and argument opposing the government's position, the Court cannot view the result in *Cabrera-Diaz* as anything other than an unopposed remedy suggested by the government, which was granted through a procedural mechanism to obtain judgment from unresponsive parties. Here, the Court must determine whether the Government may be permitted to use sampling and extrapolation in the face of contested allegations.

The final noteworthy case upon which the Government relies in its Response is *United States ex. rel. Loughren v. UnumProvident Corp.*, 604 F. Supp.2d 259 (D. Mass. 2009). In *Loughren*, plaintiff brought a *qui tam* action against the defendants alleging violations of the FCA because defendants allegedly caused their insured to file applications for disability benefits even though they did not meet the qualifying

statutory definition of disability. *Id*. at 260. Similar to the instant case, "[g]iven the enormous number of claims and the significant time and resources it would take to determine if a single claim were false," plaintiff submitted a statistical sample to the court, which he sought to extrapolate to the universe of possible claims. *Id*. Defendants challenged the reliability of the extrapolation, and the Court held a bellwether trial. *Id*. From the evidence presented by plaintiff at trial, the Court found that plaintiff presented sufficient evidence from which a jury could reasonably find that defendants "had a policy and practice of coercing its insureds to file for SSA benefits as soon as they were disabled for six months." *Id*. at 261. Based on this evidence, the Court concluded that "extrapolation is a reasonable method for determining the number of false claims," as long as the statistical methodology was appropriate. *Id*.

Defendant argues that *Loughren* is "inapposite" from the instant case because the court held an "extensive bellwether jury trial," the parties consented to statistical sampling, and the defendant had a policy of seeking benefits for each patient rather than individually evaluating whether each patient should seek benefits. (Doc. 159 at 12). The Court does not find *Loughren* to be an inappropriate case with which to draw a comparison because it provides an instance of complex *qui tam* litigation under the FCA where the issue of whether statistical sampling was appropriate was considered by the court. However, similar to the cases discussed above, *Loughran* is not precisely on point with the instant case given the several distinguishing factors that Defendant has identified in its arguments. Thus, the principles that the Court can draw from *Loughren* are limited due to the distinguishing factors between the instant case and *Loughren*. The Court has now reviewed the noteworthy cases cited by the parties as analogous to the instant case and found each of them to be non-determinative regarding the issue of

using statistical sampling in an FCA action involving Medicare overpayment. As the parties have not identified–and the Court's research has not revealed–any cases which are determinative regarding the use of statistical sampling in FCA cases involving Medicare overpayment, the Court will consider the collection of cases relating to this issue, the facts and procedural posture of the instant case, and the language of the FCA to determine whether statistical sampling and extrapolation is appropriate. Before making a final determination regarding statistical sampling and extrapolation in this action, however, the Court will address the elements of a claim brought under the FCA to identify whether statistical sampling and extrapolation may be used to establish each element.

D. Proving Elements of the FCA with Statistical Sampling

In its brief, Defendant addresses the elements of a FCA claim and argues why the Government is unable to establish each element through statistical sampling. In response, the Government argues that (1) "the results of statistical sampling and extrapolation constitute direct evidence of the number of claims associated with overpayments"; and (2) it is not required to produce every document to support each individual claim because statistical sampling can be used to prove the number of claims that were overpaid. (Doc. 152 at 19). The Court will address Defendant's arguments regarding each element in turn.

1. Identification of Specific Claims Submitted or Statements Made

In its brief, Defendant argues that statistical extrapolation does not provide individualized proof of specific claims or statements made. (Doc. 141 at 14). In response, the Government argues that this element, proof of a false claim, does not necessarily preclude statistical sampling. (Doc. 152 at 19).

The Court takes issue with Defendant's categorical position that the Government could not "comply with an order . . . requiring the Government to specify with detail all of the Unidentified Claims for which it seeks to impose liability and damages." (Doc. 141 at 14). Considering the evidence and argument before it, the Court finds that the Government *could* specify in detail the specific claims for which it alleges are false, but in order to do so, it would require the devotion of more time and resources than would be practicable for any single case. However, as the Government has identified in its Response, 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. *See Fadul*, 2013 WL 781614, at *14. Thus, given the set of circumstances before the Court, the Court does not find Defendant's argument that the Government cannot "specify with detail" all of the individual claims to be a compelling one.

In support of its argument, Defendant relies on *Friedman*. 1993 U.S. Dist. LEXIS 21496. However, as the Court has discussed above, *Friedman* is distinct from the instant case because there was a sufficiently limited universe of claims for the court to review each one individually rather than relying on extrapolation. Considering the large universe of allegedly false claims in the instant case, it would be impracticable for the Court to review each claim individually, as the court did in *Friedman*. Indeed, if the Court were to individually review each allegedly false claim or statement in this action, it would consume an unacceptable portion of the Court's limited resources. Additionally, the court in *Friedman* cited no case law in support of its position, nor did it explain its reasoning for declining to use statistical extrapolation in detail. As Defendant has not identified other reasons that the Government cannot use statistical sampling and

extrapolation regarding this element, the Court will turn to the next element of a FCA claim.

2. Falsity

Throughout this litigation and throughout its Motion, Defendant has made the argument that statistical sampling cannot be used in this context because of the "fact-intensive, subjective determinations by scores of different physicians, therapists, and other professionals as to whether individualized therapy treatments" were medically necessary. (Doc. 141 at 15). Thus, in attacking the falsity element of the Government's case, Defendant argues that it would be inappropriate for the Government to prove liability for its FCA claims through statistical sampling because "the determination of whether therapy is medically necessary for a particular patient requires an 'individual assessment of the patient's clinical condition.'" (Doc. 141 at 17); *see United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 777 (S.D. Tex. 2010) ("The decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients."). More specifically, Defendant argues that, as the Government will only rely on statistical sampling and will not present evidence concerning patients' actual conditions, diagnoses, clinical needs, the nature of therapy, or the extent of therapy, the Government cannot establish that the therapy provided to each patient was medically unnecessary. (Doc. 141 at 18). The Government responds by asserting that statistical sampling is "routinely used in the medical necessity context" and the plan it has set up, including a medical review before extrapolation, sufficiently accounts for the medical necessity determination. (Doc. 152 at 23-24).

The Sixth Circuit has interpreted the FCA's use of "fraud" or falsity to encompass situations in which a defendant has aimed "to extract from the government money the government otherwise would not have paid." *Chesbrough*, 655 F.3d at 467. To establish falsity, the plaintiff must establish that, "in at least one instance," the defendant has submitted a false claim. *United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 856 (7th Cir. 2006). More generally, the falsehood that plaintiff establishes must be objective. "Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." *Roby*, 100 F. Supp. 2d at 625.

Defendant particularly takes issue with the use of statistical sampling in establishing liability because of the individualized factors that affect an analysis of each patient's care such as:

> 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.

(Doc. 141 at 21).

The Court agrees that some of these factors will determine the type and amount of therapy a patient receives. However, the fact that these factors exist and are likely unique to each patient does not necessarily preclude the use of statistical sampling. Statistical sampling has been used in litigation for decades, and Defendant's argument regarding the individuality of each claim in the sample is not unique to this litigation. *See State of Ga., Dep't of Human Res.*, 446 F. Supp. at 409. In fact, Defendant's

argument 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. *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*, 984 F. Supp. 2d at 1033. If all of the claims were exactly the same in every respect, there would be no need for statistical sampling and extrapolation in litigation because each individual unit would be identical, and it would be relatively simple to formulate a mathematical calculation for a large number of claims.

Accordingly, the Court finds Defendant's argument to be unpersuasive. The large number of allegedly false claims at issue in this action leads to the natural effect that the claims are unique to one another in some respects. If Defendant wishes to challenge the weight that a fact finder may attribute to the extrapolation, it can employ cross-examination and competing witnesses and testimony to highlight the disparity between claims. However, 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 for non-covered services.

3. Knowledge

Similar to the other elements, the Government does not argue that it will present evidence as to whether each claim was knowingly submitted as false. Rather, the Government argues that statistical sampling is sufficient to meet this element of a FCA claim. In its Motion, Defendant argues that the Government is unable to satisfy the knowledge element of the FCA through statistical sampling because the statute requires the Government to show that "a particular employee or agent acted knowingly with respect to the alleged false claims." (Doc. 141 at 24)(internal quotation omitted).

The FCA does not require an individual to have proof of specific intent to defraud, but rather defines the term knowing or knowingly as having (1) actual knowledge of the information; (2) acting in deliberate ignorance of the truth or falsity of the information; or (3) acting in reckless disregard of the truth or falsity of the information. 31 U.S.C. 3729(b)(1). In order to avoid displaying reckless disregard of the truth or falsity of information, a person is obligated "to make such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim." Senate Report at 20. This specific provision was included "to target that defendant who has buried his head in the sand and failed to make some inquiry into the claim's validity." *U.S. ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (internal quotation omitted). Consistent with the purpose of the FCA, negligent actions or innocent mistakes do not satisfy the knowledge element of a FCA claim. *Hindo v. Univ. of Health Sciences/The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995). In sum, interpretation of the knowledge element of the FCA requires a balance between deterring fraud, but not punishing those who have accidentally submitted an incorrect claim. *See United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010).

As a general matter, federal courts have not permitted a "collective knowledge" theory to be applied in an FCA case. *Id.* at 1275 *(*"We know of no circuit that has applied the 'collective knowledge' theory to the FCA."); *Fadul*, 2013 WL 781614, at *9 ("When the Government seeks to hold an entity liable under the False Claims Act, it cannot rely on the collective knowledge of the entity's agents to establish scienter"); *United States v. Educ. Mgmt. Corp.*, 871 F. Supp. 2d 433, 452 (W.D. Pa. 2012) ("The Court does agree . . . that scienter may not be based on a collective knowledge theory by piecing together

scraps of 'innocent' knowledge held by various corporate officials") (internal quotation omitted); *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 192 (D. Mass. 2004). Under the "collective knowledge" theory, a plaintiff in a fraud case "need not prove that any one individual employee of a corporate defendant also acted with scienter. Proof of a corporation's collective knowledge and intent is sufficient." *In re Nat'l Century Fin. Enterprises, Inc.*, 846 F. Supp. 2d 828, 874 (S.D. Ohio 2012). Courts have found this theory to be problematic in the context of FCA cases because it "would allow a plaintiff to prove scienter by piecing together scraps of "innocent" knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds." *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 n.9 (4th Cir. 2003).

Defendant has argued that the Government is presenting a "collective knowledge" argument, but that is a mischaracterization of the Government's claims. In its Response, the Government has represented that it intends to establish scienter by "proffering evidence of [Life Care's] corporate practices and pressure, and that Life Care knew those practices likely caused the submission of false claims given the complaints it received nationwide from its employees and others." (Doc. 152 at 28). Thus, the Government proposes to present evidence as to Defendant's scienter as to the claims identified within the sample. Regarding the specific evidence that will be used to prove scienter, while the parties have not specifically identified this evidence nor moved the Court to consider the merits of this issue, it appears that the Government has collected evidence regarding Defendant's scienter and intends to use it to establish this element. *See Renal Care Grp., Inc.*, 696 F.3d at 530.

This is not a collective knowledge theory as the Government will be attempting to meet the scienter element in each submitted claim and then extrapolate the total number of claims to the relevant universe. If Defendant's intent is to challenge the extrapolation portion of this process and characterize it as "collective knowledge," it entirely misrepresents the purpose and procedure behind using statistical sampling. *See In re Chevron U.S.A., Inc.*, 109 F.3d at 1019-20 ("The essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole."). The Court has already discussed the principles of sampling and extrapolation, and it will not further reiterate them here.

The determination of whether this evidence is sufficient to establish scienter depends on the evidence itself, but, given the lack of evidence submitted by either party, the Court is not persuaded at this juncture that the Government will be completely unable to establish that Defendant had knowledge of the alleged false claims. Defendant's argument has little to do with statistical sampling and extrapolation, but rather challenges the type of evidence the Government may use to prove scienter. Given the Government's representations about its intended method to prove scienter, the Court finds Defendant's argument in this regard to be inapposite to the issue presently before the Court. Indeed, the Government has stated that it does not intend to use statistical sampling to prove this element of the FCA. (Doc. 170 at 185). Thus, the Court finds that summary judgment in favor of Defendant would be unwarranted and without any support in the evidentiary record presently before it.

4. Materiality

Defendant also argues that the Government cannot use statistical sampling to establish that the purported false claims or statements are material. (Doc. 141 at 25).

The Government argues that the extrapolated claims would be material by definition because they represent "claims that the government would not pay." (Doc. 152 at 26).

Under the FCA, the term "material" is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money." 31 U.S.C. § 3729(b)(4). There are two standards by which materiality may be reviewed: the natural tendency test and the outcome materiality test. *See Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998) ("only those actions by the claimant which have the purpose and effect of causing the United States to pay out money it is not obligated to pay, or those actions which intentionally deprive the United States of money it is lawfully due, are properly considered 'claims' within the meaning of the FCA"); *United States ex rel. Berge v. Bd. of Trustees of the Univ. of Alabama*, 104 F.3d 1453, 1459 (4th Cir. 1997) ("the materiality of the false statement turns on 'whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action.'"). In the Sixth Circuit, as well as the Ninth and Fourth Circuits, the natural tendency test is the proper standard by which to determine materiality. *United States ex rel. Longhi v. United States*, 575 F.3d 458, 470 (5th Cir. 2009) (collecting cases); *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp., Inc.*, 400 F.3d 428, 445 (6th Cir. 2005) ("we conclude that the 'natural tendency' test is the appropriate standard by which materiality in the FCA civil context should be measured."). Thus, to determine whether the Government can prove the materiality element of a FCA claim through statistical sampling and extrapolation, the Court must focus on "the potential effect of the false statement when it is made, not on the actual effect of the false statement when it is discovered." *A+ Homecare, Inc.*, 400 F.3d at 445.

Defendant's argument regarding the inadequacy of statistical sampling targets the mathematical intricacies of the Medicare billing system. As discussed above, the Government's allegations revolve around a particular part of the Medicare billing system, the Ultra High RUG level. The Ultra High RUG level is most significant to the instant action because it is the billing category from which a skilled nursing facility would be paid the largest sum of money. However, in order to be classified at the Ultra High RUG level, a patient would need to require 720 minutes of treatment per week, using two out of three rehabilitation therapy disciplines. As Defendant highlights in its brief, a skilled nursing facility could arguably arrive at 720 minutes of medically necessary and reasonable therapy by a variety of numerical combinations. For instance, a patient could receive 800 minutes of therapy throughout a week with 80 of those minutes being either unskilled, unnecessary, or unreasonable, and he would still qualify for the Ultra High RUG level. Based on this theory, Defendant argues that a claim could only be deemed material under the FCA "if the patient would be re-classified into a lower RUG category (with a corresponding lower reimbursement rate) after subtracting the number of allegedly unnecessary therapy minutes from the total number of therapy minutes for the assessment period." (Doc. 141 at 26).

The Court finds Defendant's argument to be unpersuasive for several reasons. First, in this Circuit, the test for materiality focuses on "the *potential* effect of the false statement when it was made." *A+ Homecare, Inc.*, 400 F.3d at 445 (emphasis added). Because the standard hinges on the statement's potential rather than its actual effect, Defendant's arguments are misguided. Specifically, Defendant suggests that overbilling of therapy is not an issue, so long as a patient was already in the Ultra High RUG level. However, the fact that a patient was overbilled throughout an assessment period would

have the potential to affect any ultimate payment. Put another way, a patient accumulates therapy minutes throughout an assessment period, giving any overbilling the potential to affect the patient's ultimate RUG level as the minutes accumulate.

Second, Defendant's argument is solely speculative at this juncture in the litigation. To the extent that there are patients that fall into this category (of having so many therapy minutes that they could not have been affected by any overbilling), the Government claims that its "statistician will yield an estimate of the additional number of claims that contain overpayments that were not reimbursable." (Doc. 152 at 26). Thus, if Defendant's speculative argument materializes into a cognizable issue within the sample, the Government's methodology will take into account overpayments that would not be reimbursable.

Finally, similar to Defendant's argument regarding falsity, this would be an issue best left to the finder of fact. The fact finder will be able to consider this issue, if it arises, with Defendant's other evidence in determining how much weight should be attributed to the extrapolated evidence. Accordingly, the Court does not find this argument to preclude the Government from using statistical sampling and extrapolation.

E. Due Process Claims

Defendant's final argument asserts that, if the Court were to impose liability on Defendant for claims determined through statistical sampling, it would violate its right to due process and shift the burden of proof onto Defendant. (Doc. 141 at 27-31). Specifically, Defendant argues that its due process rights would be violated because the Government has not identified specific claims, thereby precluding Defendant "from investigating, developing and presenting factual and expert evidence related defenses to each of the essential FCA elements." (*Id.* at 28-29). Defendant also argues that the

Government's use of statistical sampling "improperly" shifts the burden of proof for the requisite elements of a FCA claim onto Defendant. (*Id.* at 30). The Government responds that courts have routinely rejected Defendant's argument and that Defendant will be provided with due process throughout these proceedings.

The Fifth Amendment to the United States Constitution provides that "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V. Under the Fifth Amendment, Defendant is not entitled to individually defend each claim brought against it under the FCA. Specifically, courts that have considered the issue of statistical extrapolation to calculate overpayment have found that it is an acceptable practice which does not violate a defendant's due process rights. *See Yorktown Med. Lab., Inc. v. Perales,* 948 F.2d 84, 90 (2d Cir. 1991) ("Given the low risk of error and the government interest in minimizing administrative burdens, the balance of interests favors [the government]"). Additionally, as the Government argues in its brief, Defendant will be afforded due process by having the opportunity to depose the Government's expert, challenge the qualifications of the Government's expert, retain its own expert, and to present all of this evidence at trial. (Doc. 152 at 30). Considering these factors, the Court finds that the use of statistical sampling and extrapolation in this action does not violate Defendant's due process rights.

F. Statistical Sampling and Extrapolation in the Instant Case

The Court has reviewed the language and the legislative history of the FCA as well as the relevant case law and concludes that the use of statistical sampling, to the extent described *infra*, is a legally viable mechanism which the Government may employ in attempting to prove the FCA claims in this action. The purpose of the FCA as well as the development and expansion of government programs as to which it may be employed

support the use of statistical sampling in complex FCA actions where a claim-by-claim review is impracticable. While Defendant may disagree with this conclusion, it is not without tools at its disposal to attack the weight to be accorded to any extrapolated evidence.

Over time, the Medicare program has grown, dramatically changing the breadth of the landscape from which false claims may arise. Unlike when the FCA was originally enacted in the 1800s, those who commit fraud today have the aid of tools of technology and a relative unlikelihood of detection deriving from the sheer scale of the Medicare program itself. *See* Laura B. Morgan, *The Independent Payment Advisory Board: Will It Effectively Curb the Medicare Growth Rate?*, 20 Annals Health L. Advance Directive 124, 124 (2011) (discussing the growth of the Medicare program). Given the large number of claims that can be submitted by a single entity to be reimbursed by Medicare, it is often not practicable to do a claim-by-claim review of each allegedly false claim in a complex FCA action.

The language and the history of the FCA do not suggest that statistical sampling is an improper vehicle by which to litigate FCA claims. The language of the statute is clear as to what is required to bring a claim under the FCA, and it is also clear that there is no explicit prohibition against the use of statistical sampling. *See* 31 U.S.C. 3729(a)(1)(A-B). If Congress intended to preclude statistical sampling from being used in this context, it has had ample opportunity to have that intention reflected in the language of the FCA. The FCA has been amended several times and Congress has declined to address the issue of statistical sampling, despite the fact that it was disputed in FCA cases as early as 1993. *See United States v. Friedman*, 1993 U.S. Dist. LEXIS 21496. Thus, as this issue has gone unaddressed by Congress for over twenty years, the

Court finds that neither the plain language or the legislative history reflects a legislative disinclination regarding the use of statistical sampling in FCA cases.

Defendant's position–that statistical sampling simply cannot be applied to an FCA case involving Medicare overpayment–is broad and potentially far-reaching. If accepted, it would materially limit the efficacy of the FCA as a tool to combat fraud against the government. The FCA is a remedial act, and it is intended "to protect the treasury from the hungry and unscrupulous host that encompasses it on every side." *Griswold*, 24 F. at 366. If the Court were to reach the conclusion urged by the Defendant–that a claim-by-claim review is required in every FCA action and that statistical sampling is never permissible–potential perpetrators of fraud would be emboldened by the fact that a claim-by-claim review is often impractical. 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.

While Defendant makes several compelling arguments regarding the inherent limitations associated with statistical sampling, these arguments are better considered by the fact finder rather than the Court. The Court's ruling today simply holds that statistical sampling may be used to prove claims brought under the FCA involving Medicare overpayment, but it does not and cannot control the weight that the fact finder may accord to the extrapolated evidence. Rather, the burden of determining the weight of the evidence lies with the fact finder. *See Califano*, 446 F. Supp. at 410. It has long

been the practice in our judicial system to leave weight of evidence determinations to the fact finder best equipped to make those determinations. *See Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 565 (1985); *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 394 (1948) ("The practice in equity prior to the present Rules of Civil Procedure was that the findings of the trial court, when dependent upon oral testimony where the candor and credibility of the witnesses would best be judged, had great weight with the appellate court"). Thus, Defendant's arguments addressing the intricacies of the Medicare system, the weight given to the sample, and the credibility of the Government's expert are best left for the jury to consider when determining the weight to be given to the extrapolated evidence. Defendant has many tools at its disposal to challenge the statistical sample, including cross-examination of the proponent's expert, presentation of its own expert, as well as presentation of other competing witnesses and evidence.

The Court's ruling today also does not decide the parties' pending motions regarding the admissibility of expert testimony. The motions regarding expert testimony and the reliability of the statistical sample will be decided separately and will take into consideration the standards set forth in the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

IV. CONCLUSION

For the reasons stated herein, Defendant's Motion for Partial Summary Judgment (Doc. 140) is hereby **DENIED**.

SO ORDERED this 29th day of September, 2014.

/s/ Harry S. Mattice, Jr.
HARRY S. MATTICE, JR.
UNITED STATES DISTRICT JUDGE