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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

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

Plaintiff,

v.

PRIME HEALTHCARE SERVICES, INC, et al.;

Defendants.

CASE NO.: cv 11-08214 PJW (MG)

DEFENDANTS' NOTICE OF MOTION AND MOTION TO EXCLUDE STATISTICAL SAMPLING TO PROVE FALSITY OF CLAIMS UNDER THE FCA BASED ON MEDICALLY UNNECESSARY ADMISSIONS OR CLINICALLY UNSUPPORTED DIAGNOSES; MEMORANDUM OF POINTS AND AUTHORITIES; DECLARATIONS OF MARK S. HARDIMAN AND AKILA PASUPULATI

Date: October 27, 2016
Time: 1:30 p.m.
Courtroom: 23, 3rd Floor
Action Filed: 06/23/2016
Trial Date: None Set

TO PLAINTIFF UNITED STATES, RELATOR, AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on October 27, 2016 at 1:30 p.m., before the Honorable Patrick J. Walsh, Chief Magistrate Judge, in Courtroom 23 on the 3rd Floor of the United States Courthouse, 312 North Spring Street, Los Angeles, California 90012, defendants Prime Healthcare Services, Inc., Prem Reddy, M.D., Alvarado Hospital, LLC, Prime Healthcare Services Garden Grove, LLC, Prime

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Healthcare Huntington Beach, LLC, Prime Healthcare La Palma, LLC, Desert Valley Hospital, Inc., Prime Healthcare Services Encino, LLC, Veritas Health Services, Inc., Prime Healthcare Services Montclair, LLC, Prime Healthcare Paradise Valley, LLC, Prime Healthcare San Dimas, LLC, Shasta Regional Medical Center, LLC, Prime Healthcare Anaheim, LLC, Prime Healthcare Centinela, LLC, and Prime Healthcare Services Sherman Oaks, LLC (collectively, "Prime" or "the Prime Defendants"), by and through their attorneys of record, will and hereby do move the Court for an order excluding the government's and relator Karin Berntsen's use of statistical sampling and extrapolation to prove the falsity of Prime claims under the False Claims Act, 31 U.S.C. §§ 3729 *et seq*., based on (a) allegedly medically unnecessary inpatient admissions, and (b) allegedly false diagnoses on the ground that such extrapolation is improper as a matter of law where the falsity of each claim at issue in this case requires an individualized in-depth medical review of each patient's presenting symptoms and clinical conditions as documented in his or her medical record by the treating physicians.

This motion is based on the accompanying memorandum of points and authorities and declarations of Mark S. Hardiman and Prasanna Weerakoon, the files and records in this case, and on such further evidence and argument as may be presented at any hearing of this motion.

Pursuant to Local Rule 7-3, this motion is made following telephonic discussions by counsel for the government, relator and the Prime Defendants on July 8, 2016 during which the government and relator informed Prime Defendants

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that they would be opposing the motion to exclude statistical sampling and extrapolation to prove the falsity of any Prime hospital claims.

DATED: September 1, 2016

Respectfully submitted,

NELSON HARDIMAN LLP

/S/ M.S. Hardiman

MARK S. HARDIMAN

Attorneys for Prime Defendants

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

By their instant motion, the Prime Defendants request an order excluding the government's and relator Karin Berntsen's use of statistical sampling and extrapolation to prove the falsity of Prime claims to the Medicare program in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. ("FCA"), based on the theories that (a) claims for "short stay" inpatient admissions were medically unnecessary and should have been billed on an outpatient basis as observation care, as alleged in the government's complaint in intervention, and (b) claims included diagnoses that were either not documented by treating physicians in the patient's medical record or were clinically unsupported, as alleged in relator's Fourth Amended Complaint, on the ground that statistical sampling is not legally permissible to prove the falsity of claims under the FCA where proof that a claim for medical services was false requires a highly fact-intensive inquiry involving medical testimony after a thorough review of a treating physician's decision-making as detailed in the medical chart of each individual patient.

In this case, under the government's and relator's theories of FCA liability, proof that any of the Prime Defendants' claims were false depend on Medicare coverage standards which recognize that a physician's determination that a patient should be admitted as an inpatient or has a particular diagnosis are medically complex decisions that rely on the physician's subjective medical judgment regarding each patient's unique clinical picture and require any medical review of such decisions to be conducted on a claim-by-claim basis because "coverage and liability determinations on Medicare claims are largely unique to the specific set of facts in a given case."

As a result, before the Prime Defendants are subject to the FCA's severe remedies of treble damages and up to an $11,000 per claim penalty in this case, the government and the relator must identify and directly prove the falsity of each

Medicare claim at issue and cannot sidestep their burden of proof by relying on statistical sampling and extrapolation to prove the falsity of claims involving different hospitals, physicians, patients and medical conditions that have never been reviewed for falsity by anyone. Requiring the government and relator to meet their burden of proving falsity in this case is particularly important because admission and diagnosis decisions are not made by the Prime hospitals, but by independent physicians who cannot be employed by the Prime Defendants due to California's ban on the corporate practice of medicine.

An early resolution by this Court of whether statistical sampling is legally permissible to prove the falsity of claims based on unnecessary admissions or unsupported diagnoses is also critical when literally hundreds of thousands of Prime claims to the Medicare program are potentially at issue during the relevant time period, including approximately over 35,000 inpatient claims less than or equal to two days and likely an even greater number of claims involving diagnoses questioned by relator. Since the essential facts are undisputed, this Court's ruling on whether statistical sampling is impermissible as a matter of law in an FCA case premised on unnecessary admissions and unsupported diagnoses is necessary to establish the scope of discovery regarding the claims at issue, clarify the government's and relator's burden of proof regarding the falsity element of their FCA claims, and promptly inform the Prime Defendants of which allegedly false claims are at issue so they can fairly defend themselves.

Absent this Court's ruling, the Prime Defendants are left in the untenable position of allowing the government and relator to define the universe of false claims through a sampling methodology that defendants believe is legally impermissible in this FCA action and then having to spend needless resources challenging that methodology with respect to both its statistical validity, any findings made as to the falsity of the sample claims themselves, and the reliability of extrapolating such findings to other claims involving different hospitals, patients

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and physicians. At the same time, Prime Defendants would also have to mount a claim by claim defense to allegedly false claims that have never actually been identified as such by the government or relator based on individual claim reviews. Thus, this Court's determination of whether statistical sampling and extrapolation can be used in this case to establish the falsity of the Prime Defendants' claims is not premature, but is instead essential to the orderly, efficient and fair litigation of this action.

II. STATEMENT OF FACTS

On August 8, 2016, Relator Karin Berntsen filed her Fourth Amended Complaint ("FAC") alleging that Prime Defendants, including 14 Prime acute care hospitals in California owned by defendant Prime Healthcare Services, Inc. ("Prime") or its affiliate, defendant Prime Healthcare Foundation, and defendant Prem Reddy, M.D., Prime's physician founder and Chairman, violated the FCA by submitting claims to the Medicare program that (a) were for medically unnecessary "short stay" inpatient admissions, and (b) contained false "information concerning the complications and comorbidities associated with patients' diagnoses." (CR 79; FAC ¶¶ 1-2, 10-13). On June 23, 2016, the government filed its complaint in intervention ("DOJC") regarding relator's allegations that Prime Defendants submitted false claims for unnecessary "short stay" inpatient admissions. (CR 127; DOJC ¶ 2). Relator is prosecuting the non-intervened FCA claims in her complaint based on allegedly false diagnoses on Prime claim forms.[1]

[1] In the parties' Rule 26(f) report, relator confirmed that she is only "pursuing the non-intervened upcoding claims against the PHS Defendants and Prime Healthcare Foundation . . . in Relator's Fourth Amended Complaint" alleging that these defendants violated the FCA "by wrongfully increasing the MS-DRG payments that Prime hospitals receive from Medicare through upcoding by falsifying information concerning the complications and comorbidities associated with patients' diagnoses." *See* 7/22/16 Rule 26(f), 1-2; CR 133.

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A. THE MEDICARE PROGRAM

The Medicare program is a federally funded health care program providing health insurance coverage to people who are aged 65 and over or who have certain physical disabilities. *See* 42 U.S.C. §§ 1395 *et seq*. Medicare Part A covers hospital inpatient services and Medicare Part B covers outpatient services, including emergency room services for patients that do not require a hospital admission. 42 U.S.C. §§ 1395c, 1395k. The program is administered by the U.S. Department of Health & Humans Services through its agency, the Center for Medicare & Medicaid Services ("CMS"). CMS in turn contracts with private organizations to act as Medicare Administrative Contractors ("MACs") to review and process Medicare claims submitted by hospitals for treatment of Medicare patients. *See* 42 U.S.C. §§ 1395ff(a)(1), 1395kk-1(a)(3)-(4).

1. Medicare Part A Hospital Inpatient Services

The Medicare program only reimburses health care services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). In the case of hospital services, an "inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services." Medicare Benefit Policy Manual, Pub. 100-02, Ch. 1("MBPM"), § 10. CMS has explained that, "[g]enerally, a patient is considered an inpatient if formally admitted as inpatient **with the expectation that he or she will remain at least overnight** and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight." MBPM, § 10 (emphasis added).[2]

CMS has also instructed physicians to order inpatient admission if a patient is expected to need more than 24 hours of hospital care, while also recognizing that

[2] CMS's Medicare manuals are available on the Internet at https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html.

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a physician's decision to admit an inpatient is a complex medical judgment which can only be made after consideration of numerous factors specific to the patient and hospital involved, including the patient's medical history and current medical needs, the severity of the patient's signs and symptoms, the medical predictability of something adverse happening to the patient, the types of facilities and diagnostic procedures available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. MBPM, Ch. 1, § 10.

According to CMS, "physicians should use a 24-hour period **and** the expectation of a beneficiary's need for an overnight stay in the hospital as inpatient admission benchmarks." 78 FR 27486, 27646 (May 10, 2013) (emphasis added). The decision to admit a Medicare patient must be made by the treating physician, not the hospital. MBPM, Ch. 1, § 10. In recognition of the subjective and complex nature of a physician's admission decision, CMS has expressly declined to issue clinical criteria that must be satisfied before a physician can admit a patient as an inpatient and has also refused to condition coverage of an inpatient admission on compliance with nationally accepted clinical guidelines, including the Milliman and InterQual screening tools.[3]

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[3] In particular, CMS explained that, "given the unique clinical circumstances of Medicare beneficiaries who require hospital care, it is difficult to adopt a set of clinical standards that are universally applicable based on diagnostic conditions and may be appropriately utilized on a retrospective basis." 80 FR 70298, 70547 (Nov. 13, 2015); *see also* CMS *Guidance on Hospital Inpatient Admission Decisions*, MLN Matters ® Number: SE1037 (July 31, 2012) (CMS does not endorse any particular screening guidelines nor automatically deny claims that do not meet the admission guidelines of any screening tool"), available at https://www.cms.gov /Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMatters Articles/ downloads/ se1037.pdf; 80 FR at 70541-70542 ("While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors.")

Under Medicare Part A's prospective payment system ("PPS"), reimbursement for hospital inpatient services is generally based on a set rate per patient discharge (regardless of the actual cost of care) that varies according to the Medicare Severity-Diagnosis Related Group ("MS-DRG") assigned to the patient's stay by the hospital on its claim form. Medicare Claims Processing Manual ("MCPM"), Pub. 100-04, Ch. 3, §§ 20, 20.2.2.[4] The MS-DRG is assigned based on the principal diagnosis and secondary diagnoses, principal and secondary procedure codes, and demographic data for the patient reported by the hospital. MCPM, Ch. 3, § 20.3.3. Both the principal and secondary diagnoses for the patient are reported by the hospital using standard codes from the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM"). MCPM, Ch. 3, § 20.3.3; 71 FR 47870, 47898 (Aug. 18, 2006).

Many MS-DRGs are split into three levels of severity depending on whether any one of the patient's secondary diagnoses has been categorized by CMS as a major complication or comorbidity ("MCC") or complication or comorbidity ("CC"). *See* 74 FR 24080, 24209 (May 22, 2009); 72 FR 47130, 47157, 47171 (Aug. 22, 2007).[5] Examples of an MCC include acute respiratory failure, acute on chronic systolic congestive heart failure, acute renal failure, and severe malnutrition.[6] CC examples include chronic systolic congestive heart failure,

[4] Each MS-DRG "represents the average resources required to care for a case in that particular MS-DRG relative to the national average of resources consumed per case," calculated by reference to the national average charges and geometric mean length of stay ("GMLOS") for each case. MCPM, Ch. 3, § 20.2.2; *see* CMS, *Details for title: FY 2013 Final Rule Tables* (listing MS-DRG GMLOS), Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ Acute InpatientPPS/FY-2013-IPPS-Final-Rule-Home-Page-Items/FY2013-Final-Rule-Tables.html.

[5] For example, the MS-DRGs for simple pneumonia & pleurisy include MS-DRGs 193 (with MCC), 194 (with CC) and 195 (without MCC or CC). *See* CMS FY 2013 Final Rule Tables, Table 5 (MS-DRGs), available at https://www.cms.gov/ Medicare/ Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2013-IPPS-Final-Rule-Home-Page-Items/FY2013-Final-Rule-Tables.html .

[6] *See* CMS FY 2013 Final Rule Tables, Table 6I (MCC List).

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chronic kidney disease (Stages 4 or 5), and chronic respiratory failure.[7] Because the presence of an MCC or CC has been identified by CMS as substantially increasing the hospital resources required to treat a patients, a MS-DRG with an MCC or a CC has a higher reimbursement rate that the same MS-DRG with no MCC or CC. *See* 72 FR at 47171, 47175. As of 2013, there were 751 MS-DRG codes, 1,622 MCC diagnosis codes, and over 3,529 CC diagnosis codes.[8]

2. <u>Medicare Part B Hospital Outpatient Services</u>

The Medicare program also covers necessary hospital outpatient services provided to diagnose and treat a patient who is not admitted as an inpatient to the hospital, but "is registered on the hospital records as an outpatient," including a patient who is treated and discharged from a hospital emergency room. MBPM, Ch. 6, §§ 20.2, 20. According to CMS, hospital outpatient services include "observation care" to determine whether an emergency room patient needs to be admitted as an inpatient:

> Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

MBPM, Ch. 6, § 20.6. Like an inpatient care, outpatient observation care must be ordered by the treating physician, not the hospital. MBPM, Ch. 6, § 20.6. Paradoxically, however, CMS defines the ordinary period of observation care to include the same 24-hour guideline to be used by a physician in determining whether an inpatient admission is necessary:

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[7] *See* CMS FY 2013 Final Rule Tables, Table 6J (CC List).

[8] *See* CMS FY 2013 Final Rule Tables, Tables 5 (MS-DRG list), 6I (MCC list) and 6J (CC list).

> In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours.

MBPM, Ch. 6, § 20.6. Thus, CMS's "time based admission framework" is a counter-intuitive instruction for physicians to use up to 48 hours of observation to determine whether a patient should be admitted as an inpatient based on an expectation that the patient will remain overnight or require 24 hours or more of hospital services. *See* 78 FR 50496, 50945 (Aug. 19, 2013).

B. THE GOVERNMENT'S COMPLAINT IN INTERVENTION

According to the government, Prime's business model is to buy and turn around financially distressed hospitals by investing tens of millions of dollars on capital improvements, maintaining emergency departments that are open and accessible to all members of the community, including the uninsured and indigent, and implementing, with the support and assistance of the independent medical staff, proven clinical protocols which improve the quality of care received by all patients. (DOJC ¶ 3).

However, between 2006 through September 30, 2013, the government alleges that the Prime Defendants executed an elaborate scheme to "induce" physicians at these 14 Prime hospitals to unnecessarily admit Medicare patients to the hospitals as inpatients when they could have been treated as outpatients, including through observation care. (DOJC ¶¶ 4-5). While the government dedicates almost half of its 52-page complaint to a description of the various ways that Prime allegedly "induced" physicians to unnecessarily admit Medicare patients, it makes little effort to tie such fraudulent inducement to any particular claims, other than by baldly asserting that the Prime Defendants "have claimed and received millions of dollars in inflated reimbursements for medically unnecessary inpatient admissions." (DOJC ¶¶ 14, 140). Nevertheless, the complaint does

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provide fourteen claim examples of Medicare patients that should allegedly have been discharged from the emergency room or treated through outpatient observation care rather than being admitted as inpatients to a Prime hospital. (DOJC ¶¶ 141-151). These examples confirm that proof of falsity for a claim based on an allegedly unnecessary admission necessarily involves a detailed medical review of each individual patient's presenting symptoms, diagnostic test results, and course of hospital treatment. (*Id.*)

Based on these allegations, the government's first, second and third causes of action charge the Prime Defendants with knowingly violating the FCA by (1) presenting false claims to the Medicare program, (2) making false records and statements to do so, and (3) avoiding the obligation to refund Medicare overpayments on false claims. (31 U.S.C. § 3729(a)(1)(A), (B), (G); DOJC ¶¶ 157-167). Its fourth and fifth causes of action charge the Prime Defendants with unjust enrichment and payment by mistake. (DOJC ¶¶ 168-173).

C. THE RELATOR'S FOURTH AMENDED COMPLAINT

According to relator's complaint, the Prime Defendants wrongfully increased Medicare reimbursement "by falsifying information concerning the complications and comorbidities associated with patients' diagnoses." (FAC ¶ 2). Similar to the government's allegations regarding inpatient admissions, relator alleges that the Prime Defendants instructed physicians to add various MCCs or CCs – such as encephalopathy, septicemia, malnutrition, acute heart failure, respiratory infections, aspiration pneumonia, renal failure, and autonomic nerve disorders – to patient diagnoses, and also had its clinical documentation specialists query physicians about whether such diagnoses existed and should be added as diagnoses. (FAC ¶¶ 30-31, 35, 39, 41-42, 75, 77-78).

While relator does not identify any particular Medicare claim where a false complication or comorbidity was supposedly added by a physician to the patient's diagnoses or by a Prime coder to a claim, she broadly alleges that the Prime

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Defendants submitted Medicare claims with false diagnoses without a "basis in the medical record to support the addition of a CC or MCC." (FAC ¶¶ 41, 48).

Based on these allegations, relator's Fourth Amended Complaint also charges the Prime Defendants with knowingly violating the FCA by (1) presenting false claims to the Medicare program, (2) making false records and statements to do so, and (3) avoiding the obligation to refund Medicare overpayments on false claims. (31 U.S.C. § 3729(a)(1)(A), (B), (G); FAC ¶¶ 102-104).

D. THE GOVERNMENT'S SAMPLE PATIENT CLAIMS

During its investigation, on June 12, 2012, the government served a subpoena on Prime requesting documents regarding Prime's Medicare coding practices, including with respect to 27 specific diagnoses relating to various CCs or MCCs. (Declaration of Mark Hardiman ("Hardiman Decl.") ¶¶ 2-3, Exhibit A).[9] This subpoena also requested medical and billing records for 600 Medicare patients treated on an inpatient basis at the 14 Prime hospitals with dates of service between October 2007 and December 2011. (*Id.*) From Prime's review, the government's patient sample focused on Medicare patients who were diagnosed with an MCC or CC of sepsis, acute respiratory failure, encephalopathy, malnutrition, acute renal failure, heart failure, acute pancreatitis and autonomic disorder. *Id.* Between 2006 and September 2013, the period alleged in the government's complaint, 13 of these Prime hospitals (excluding Alvarado Hospital Medical Center) treated approximately 228,000 Medicare patients, with their claims reflecting over 200,000 occurrences of these diagnoses listed as a primary

[9] These diagnoses were acute heart failure; acute renal failure; aspiration pneumonia; atrial fibrillation; atrial flutter; autonomic imbalance; autonomic nerve disorder; encephalopathy (any type); end stage renal disease; fecal impaction; hypercoagulable state; kwashiorkor; malignant hypertension; malnutrition; pathological fracture; pneumonia due to other specified bacteria; pneumonia due to other gram negative pneumonia; renal failure; respiratory failure; sepsis; septic shock; septicemia (any type); severe malnutrition; SIRS (systemic inflammatory response syndrome); syncope; unstable angina; and urinary tract infection (any type). Hardiman Decl. ¶ 2.

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diagnosis or secondary diagnosis, including MCCs or CCs. (Declaration of Akila Pasupulati ("Pasupulati Decl.") ¶ 5).

On December 23, 2013, the government served a separate subpoena requesting medical records for an additional 131 Medicare patients treated on an inpatient basis at the 14 Prime hospitals who had lengths of stay of less than 3 days with dates of services between January 2006 and June 2013. (Hardiman Decl. ¶ 3, Exhibit B).[10] Between 2006 and September 2013, the period alleged in the government's complaint, 13 of these hospitals (again excluding Alvarado) treated over 78,000 Medicare patients with lengths of stay of less than or equal to three days and over 35,000 Medicare patients with a lengths of stay of less than or equal to two days. (Pasupulati Decl. ¶ 5). The government's 131 sample of short stay claims therefore constituted 0.17% of the universe of 78,000 claims with lengths of stay less than or equal to three days, or a sampling of about one claim per 600. Notably, however, the Prime hospitals' emergency room inpatient admission rate of approximately 20% during the relevant time period is on par with the admission rates of peer hospitals in Southern California. (*Id.* at ¶ 7.)

III. ARGUMENT

UNDER THE FCA, STATISTICAL SAMPLING IS NOT PERMITTED TO PROVE FALSITY OF CLAIMS BASED ON MEDICALLY UNNECESSARY ADMISSIONS OR CLINICALLY UNSUPPORTED DIAGNOSES

The FCA imposes civil liability on any party who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States. 31 U.S.C. § 3729(a). Persons who do so are liable for civil penalties of up to $11,000 per claim and treble damages. *Id.* In order to establish a party's

[10] The government's sample therefore reviewed claims that were not actually short stay claims under the Medicare coverage standard for inpatient admissions because they involved overnight hospital stays and stays requiring more than 24 hours of hospital services. *See* Medicare Benefit Policy Manual, Pub. 100-02, Ch. 1 ("MBPM"), § 10.

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liability under Section 3729(a)(1), the government or relator "must prove three elements: (1) a 'false or fraudulent' claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with knowledge that the claim was false." *U.S. v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001). The FCA's knowledge requirement requires proof that the defendant, at a minimum, acted "in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(iii).

Unsurprisingly, the FCA focuses on actual claims that are alleged to be false. The statute "'attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.''" *Cafasso, U.S. ex rel. v. General Dynamics C4 Systems, Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *U.S. v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)); *U.S. ex rel. Aflatooni v. Kitsap Physicians Service*, 314 F.3d 995, 1002 (9th Cir. 2002) (FCA "focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme"). While the FCA does not define the meaning of a "false or fraudulent" claim, Medicare claims for unnecessary or "upcoded"[11] services can be false within the meaning of the statute. *See U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) ("claims for medically unnecessary treatment are actionable under the FCA"); *U.S. ex rel. Harris v. Bernad*, 275 F. Supp. 2d 1, 6(D.D.C. 2003) ("upcoding is actionable under the FCA").

The question of whether the government can use statistical sampling of claims to establish their falsity under the FCA is an issue of first impression in the Ninth Circuit. As a general matter, the science of statistical sampling or inferential statistics has long been recognized by the courts. *See In re Chevron U.S.A., Inc.,*

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[11] "Upcoding" typically "means mislabeling diagnoses or treatments on claim forms to increase the reported value of the claim." *U.S. ex rel. Obert-Hong v. Advocate Health Care.*, 211 F. Supp. 2d 1045, 1051 (S.D. Fl. 2012).

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109 F.3d 1016, 1019-1020 (5th Cir. 1997) ("essence of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole"); *U.S. ex rel. Martin v. Life Care Centers of America, Inc.*, 2014 WL 4816006, * 15 (E.D. Tenn. 2014) (citing cases). However, as recently explained by the Supreme Court, the permissibility of using sampling in a particular case turns on "the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016). In particular, the Supreme Court has made clear that where the nature of a particular cause of action requires an individualized determination of liability, that determination cannot be replaced by a "Trial by Formula." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367 (2011) (rejecting plaintiffs' attempt to establish liability by selecting a random sample of class members "as to whom liability for sex discrimination . . . would be determined" and applying the "percentage of claims determined to be valid . . . to the entire remaining class").

While no circuit has decided whether statistical sampling and extrapolation can be used in an FCA case to prove liability, a number of courts have allowed such extrapolation in FCA cases to prove damages, rather than liability. *See e.g.*, *U.S v. Fadul*, 2013 WL 781614, at *14 (D. Md. 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"); *U.S. v. Cabrera–Diaz*, 106 F. Supp.2d 234, 242 (D.P.R. 2000) (citing cases). However, there is a conflict amongst the district courts that have directly addressed the issue of whether statistical sampling of certain claims is legally permissible under the FCA to extrapolate the falsity of those claims to a universe of unreviewed claims.

Most recently, two district courts have ruled that sampling and extrapolation of the falsity of Medicare claims is legally impermissible in an FCA case where

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1 proof of such falsity depends on a determination of whether multiple physicians at
2 different locations properly exercised their individual and subjective clinical
3 judgment about whether specific patients were eligible for a particular Medicare
4 service. *See U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, *11
5 (N.D. Tex. 2016); *U.S. ex rel. Michaels v. Agape Senior Community, Inc.*, 2015
6 WL 3903675 (D.S.C. 2015); *see also U.S. v. Friedman*, 1993 U.S. Dist. LEXIS
7 21496, *9 n.1 (D. Mass. 1993) (refusing to extrapolate damages from random
8 sample of 350 claims to universe of 676 Medicare claims without subjecting
9 unreviewed claims to same analysis, discussion, and cross-examination as sample
10 claims offered at trial).

11 In *U.S. ex rel. Michaels v. Agape Senior Community, Inc.*, 2015 WL
12 3903675 (D.S.C. 2015), relators brought an FCA action against a network of 24
13 North Carolina nursing homes alleging that defendants had submitted between
14 50,000 and 60,000 potentially false claims for medically unnecessary hospice care
15 and "general inpatient services" provided to between involving between 10,000
16 and 20,000 nursing home patients to various federal health care programs. *Id.* at
17 *1, 5. Recognizing that sampling and extrapolation might be appropriate in a case
18 where this was the only way for a relator to prove damages, the district court ruled
19 that such extrapolation was legally impermissible in a FCA case where establishing
20 the falsity of claims based on alleged lack of medical necessity required a case-by-
21 case review of available medical records:

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> Distilled to its essence, each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary. Answering that question for each of the patients involved in this action is [a] highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient. As the Court has acknowledged, some cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages may be proved. This civil action, however, is not such a case.

Id. at *8. The district court certified the issue of whether sampling and extrapolation was legally impermissible in this FCA case for interlocutory appeal. *Id.* The issue is currently pending decision by the Fourth Circuit. *U.S. ex rel. Michaels v. Agape Senior Community*, Inc., No. 15-2145 (4th Cir. 2015).

Likewise, in *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D. Tex. 2016), the district court ruled that statistical sampling was legally impermissible to prove the falsity of claims in an FCA case in which the relator alleged that defendants submitted false claims for Medicare hospice services for almost 12,000 patients in 14 different states who supposedly were not terminally ill. *Id.* * 1, 10-11. Relator had a statistician select a sample of 291 patients from a universe of 12,000 hospice patients, and then had the sample patients reviewed by a medical expert who opined that more than 90% of them were not eligible for all of the claimed hospice services. *Id.* at 10-11.[12] In rejecting the extrapolation of such sampling results, the *Vista* court emphasized that Medicare eligibility for hospice services required physicians to certify that patients were terminally ill based on their clinical judgment that the patient's "life expectancy is 6 months or less if the illness runs its normal course." *Id.* at 2 (quoting 42 C.F.R. § 418.3). However, the district court noted that CMS had not issued any clinical benchmarks that needed to be satisfied before a physician could certify a patient as terminally ill and instead had recognized that a prognosis of a patient's life expectancy was "inexact" and not "an exact science." *Id.* at *3 (quoting CMS *Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article*, CMS-Pub. 60AB (Mar. 28, 2003)). Further, the district court

[12] Similar to this case, the relator also alleged that defendants had a discharge rate for live patients that was twice the national average and "a culture of admitting and maintaining patients who were ineligible for hospice," including by focusing on admission and census goals, bonusing employees for patient referrals, giving gifts to referral sources, admitting patients before determining eligibility and making it difficult to discharge them, and training employees to use charting practices or falsify records that made ineligible patients appear ineligible. *Id.* at 5-10.

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pointed out that CMS required a certifying physician to exercise his clinical judgment of the patient's life expectancy based on panoply of patient-specific medical factors, including "the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions . . . ." *Id.* (quoting 73 Fed. Reg. 32088, 32138 (June 5, 2008)).

Based on this Medicare eligibility standard for hospice services, the *Vista* court concluded that relator's statistical sampling "cannot establish liability for fraud in submitting claims for ineligible patients, as the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of the involved physicians." *Id.* at *11.[13] As a result, the district court found that "proof regarding one claim does not meet Relator's burden of proof regarding other claims involving different patients, different medical conditions, different caregivers, different facilities, different time periods, and different physicians." *Id.* at *13. Accordingly, the district court ruled that where "a relator alleges the falsity of [hospice] claims because various doctors improperly found patients were terminally ill, the relator cannot extrapolate based on an expert's after-the-fact examination of the medical charts of a sample of patients." *Id.*[14]

In this case, the *Vista* and *Agape* courts' reasons for rejecting sampling and

[13] The district court noted that relator's own medical expert "recognized, 'in the practice of hospice medicine, you have to look at the individual patient,' and 'certainly you can't extrapolate' from how one physician assessed a patient's eligibility to make conclusions about another physician." *Id.* at * 13.

[14] In addition, the district court rejected the relator's argument that a case-by-case review of the relevant 12,000 hospice claims was impractical on the ground that relator "was not required to pursue all potential false claims submitted in fourteen states over nearly a decade" and, in any event, her choice not to review all claims did "not reduce her burden to produce reliable evidence of liability" as to all of them. *Id.* at * 13.

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extrapolation as a legally permissible method of proving the falsity of claims in an FCA case involving physician judgment apply with equal force to the FCA theories of falsity asserted by the government and relator against the Prime Defendants. Here, as in *Vista*, the government's central theory of falsity does not question that the patients needed the hospital services provided by the Prime Defendants, but rather alleges that the claims were false because the Medicare beneficiaries should have received those services as outpatients, rather than inpatients. Like Medicare eligibility for hospice services, Medicare requires physicians to determine a patient's eligibility for inpatient care based on their subjective clinical judgment that a patient will remain overnight or will need more than 24 hours of hospital services. MBPM, Ch. 1, § 10. However, as previously noted, CMS has refused to cabin the physician's prognosis of how long a patient will stay in the hospital by issuing any clinical criteria that must be satisfied, including screening tools issued by third party organizations such as Milliman and InterQual.

Instead, CMS has consistently affirmed that a physician's "inpatient admission decision is a complex medical judgment that should take into consideration many factors, such as the patient's medical history and medical needs, the types of facilities available to inpatients and outpatients, the hospital's bylaws and admission policies, the relative appropriateness of treatment in the inpatient and outpatient settings, patient risk of an adverse event, and other factors described in the MBPM provisions." 78 FR 50496, 50907-50908 (Aug. 19, 2013); *see* 42 C.F.R. § 412.3. In particular, it "is up to the physician to make the complex medical decision of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or when the beneficiary may be discharged home." 78 FR at 50947.

Consistent with its view that a physician's admission decision involves a

subjective and complex medical judgment regarding a host of patient-specific risk factors, CMS also requires Medicare contractors to review the appropriateness of Part A hospital admissions on a case-by-case basis by considering whether the physician's order for inpatient admission and medical documentation regarding the "complex medical factors" informing an admission decision, including "beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event," support "a reasonable expectation of the needed duration of the stay . . . ." 73 FR at 50950-50951.[15] CMS also instructs Medicare contractors to use an inpatient's "medical record to determine whether . . . diagnoses were coded correctly," as "evidenced by the physician's entries in the beneficiary's medical record." MPIM, Ch. 6, §§ 6.5.2, 6.5.4; 42 C.F.R. § 412.46.

Similarly, under Medicare's five-level administrative appeals process, a beneficiary or hospital provider must appeal CMS's denial of Part A claims for allegedly unnecessary inpatient admissions or improper diagnosis coding on a claim-by-claim basis. *See* 42 U.S.C. § 1395ff; 42 C.F.R. §§ 405.900-405.1140.[16] CMS has also justified its refusal to "give precedential weight or require deference

[15] By way of specific example, CMS Quality Improvement Organizations ("QIO") must review the appropriateness of hospital admissions "on a case-by-case basis," and "consider only the medical evidence which was available to the physician at the time an admission decision had to be made," without taking "into account other information (e.g., test results) which became available only after admission, except in cases where considering the post-admission information would support a finding that an admission was medically necessary." MBPM, Ch. 1, § 10. Similarly, CMS elsewhere instructs Medicare contractors that a "clinical review judgment" requires the "synthesis of all submitted medical record information (e.g. progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient" and the "application of this clinical picture to the review criteria to make a reviewer determination on whether the clinical requirements in the relevant policy have been met." *See* Medicare Program Integrity Manual ("MPIM"), Pub. 100-08, Ch. 3, § 3.3.1.3.

[16] The five levels of administrative appeal are (1) redetermination by a Medicare MAC; (2) reconsideration by a Medicare Qualified Independent Contractor ("QIC"); (3) hearing by a Medicare Administrative Law Judge ("ALJ"); (4) appeal to the Medicare Appeals Council; and (5) judicial review. 42 C.F.R. §§ 405.900 - 405.1140.

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1 to appeals decisions on inpatient admissions even in situations where the
2 admissions involve a similar set of facts or issues" on the ground that "coverage
3 and liability determinations on Medicare claims are largely unique to the specific
4 set of facts in a given case" and "the decision to admit a patient as an inpatient
5 involves unique, complex issues that require clinical judgment of the treating
6 physician." 78 FR at 50929.

7 Based on Medicare's eligibility standard for inpatient care, the government's
8 use of statistical sampling to extrapolate the falsity of claims relating to the
9 appropriateness of inpatient admissions and associated diagnoses is legally
10 impermissible under the FCA in this case because such extrapolation is simply not
11 reliable. Such sampling cannot establish the Prime Defendants' liability for fraud
12 in submitting claims for patients who did not allegedly qualify for inpatient
13 admission or did not have particular CCs and MCCs because the physicians'
14 decisions that particular patients at 14 Prime hospitals were expected to remain
15 overnight or require more than 24 hours of hospital services, or had particular
16 diagnoses, are "inherently subjective, patient-specific, and dependent on the
17 judgment of the involved physicians." *Vista Hospice Care, Inc.*, 2016 WL
18 3449833, at *11. In particular, in a case involving more than 35,000 short
19 inpatient admissions of less than two days at 14 different Prime hospitals over a 7-
20 year period, proof that one inpatient claim did not satisfy Medicare's eligibility
21 standard for inpatient care or had a clinically unsupported diagnosis does not meet
22 the government's burden of proof regarding other claims involving different
23 patients, different medical conditions, different hospitals, different time periods,
24 and different physicians. Where CMS itself has recognized that the determination
25 of whether a patient admitted as an inpatient satisfies its coverage standard or had
26 an associated diagnosis requires a case-by-case review because a physician's
27 admission decision and associated diagnosis is medically complex and requires
28 application of clinical judgment to a host of risk factors and clinical symptoms that

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necessarily vary by individual patient, the government and relator cannot satisfy their burden under the FCA of proving that tens of thousands of inpatient claims submitted by the Prime Defendants were false by statistical extrapolation based on a medical expert's after-the-fact examination of the medical charts of a sample of such patients.

The conclusion that extrapolation of one physician's improper inpatient admission or diagnosis decision cannot be reliably extrapolated to another physician has particular force where FCA liability is premised on a challenge by the government to the medical judgment of thousands of different independent physicians practicing at various Prime hospitals. These 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. *See Rhodes v. Sutter Health*, 949 F.Supp.2d 997, 1000 n.1 (E.D. Cal 2013); *California Physicians' Service v. Aoki Diabetes Research Institute*, 163 Cal.App.4th 1506, 1514 (2008) (prohibition of corporate practice of medicine is meant "'to protect the professional independence of physicians and to avoid the divided loyalty inherent in the relationship of a physician employee to a lay employer.'"); Cal. Bus. & Prof. Code § 2400 ("Corporations and other artificial legal entities shall have no professional rights, privileges, or powers.") Moreover, while "clinical medical judgments are not automatically excluded from liability under the FCA," liability still "must be based on an objectively verifiable fact." *See U.S. ex rel. Landis v. Hospice Care of Kansas, LLC*, 2010 WL 5067614 at *4 (D. Kan. Dec. 7, 2010); *see also U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F.Supp.2d 709, 718 (N.D. Tex. 2011) ("FCA complaint about the exercise of [a physician's medical] judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment"). In particular, the government's or relator's proof that there was an objective falsity regarding a physician's inpatient admission decision

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1 or patient diagnosis – rather than a decision or diagnosis over which "reasonable
2 medical minds" could differ – necessarily requires an examination of the unique
3 medical facts underlying each specific physician's clinical decision-making. *See*
4 *U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F.Supp.2d 25, 65 n.
5 29 (D.C. Cir. 2007) ("question of whether a patient should be discharged becomes
6 one of medical opinion, and . . . where reasonable medical minds might differ over
7 the preferred course of treatment, FCA liability will be inappropriate"); *U.S. v.*
8 *AseraCare Inc.*, 2015 WL 8486874 at *11 (N.D. Ala. 2015) ("a difference of
9 opinion among physicians [is] insufficient to support a finding that a claim is
10 false"). In this specific context, extrapolation of one independent physician's
11 clinical decision-marking about a specific patient based on a unique set of medical
12 facts to a different physician's decision-making for a different patient is plainly
13 unreliable and therefore impermissible under the FCA as a matter of law.

14 Indeed, one need only look at the 14 examples of allegedly unnecessary
15 inpatient admissions described by the government in its complaint to confirm the
16 unreliability of extrapolating falsity in this case. The only factual commonality
17 between such examples is the government's allegation that the patient's short
18 inpatient stay was inappropriate and unnecessary based on its individualized and
19 patient-specific review of each patient's unique medical complaints, medical
20 history, comorbidities, diagnoses, diagnostic test results, and course of hospital
21 treatment. The notion that the alleged falsity of one inpatient based claim based on
22 this type of government medical review – requiring patient-specific analysis of a
23 particular physician's clinical decision-making – can be reliably extrapolated to
24 another inpatient claim for a different patient admitted by a different physician is
25 factually unsupportable and defies common sense. The same reasoning holds true
26 with respect to any extrapolation of a finding that one physician's diagnosis for a
27 specific patient was clinically unsupported to another physician's diagnosis of a
28 completely different patient.

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Under these circumstances, the government's and relator's predictable complaint that individual review of suspect inpatient admissions and diagnoses is impossible and impractical given the tens of thousands of Prime hospital claims at issue is of no legal moment. The short answer is that where Medicare's own coverage standards require an individualized case-by-case clinical review to determine whether a physician's clinical decision-making supports the falsity of a particular claim, the number of suspect claims does not reduce a plaintiff's "burden to produce reliable evidence of liability" as to all of them. *Vista Hospice Care*, Inc., 2016 WL 3449833, at *13. This is not a case where sampling and extrapolation of falsity is necessary because the records needed to prove the falsity of claims are missing. Here, the Prime Defendants are required to maintain the medical records for all Medicare patients treated by Prime hospitals and those records are generally available for any hospital claim that the government or relator chooses to review. Under these circumstances, subjecting the Prime Defendants to treble damages and civil per claim penalties of up to $11,000 based on an unreliable extrapolation of falsity from sample claims to a massive universe of unreviewed claims is a logistical shortcut and trial by formula that the FCA does not permit under the theories of falsity espoused by the government and relator.

The longer answer is that neither the government nor relator are required to pursue all potential false claims submitted by the Prime Defendants at 14 different hospitals over 7 years, especially when its identification of that universe is apparently based on a medical review of only 131 patients in the case of inpatient admissions and 600 patients in the case of MCC and CC diagnoses. Instead, the government and relator are perfectly capable of individually proving the falsity of a sufficient number of false claims to support its charge that Prime Defendants were allegedly engaged in a corporate scheme to unnecessarily admit Medicare patients and increase reimbursement through false diagnoses. This is no different than the burden imposed by CMS on the Prime Defendants by requiring them to

administratively appeal CMS denials of inpatient admission claims on a case-by-case basis based on the agency's determination that each "decision to admit a patient as an inpatient involves unique, complex issues that require clinical judgment of the treating physician." 78 FR at 50929. What is good for the goose should be good for the gander, especially when the Prime Defendants have been required to individually justify each physician's admission and diagnosis decisions on administrative appeal based on the unique clinical picture of each patient documented in the medical record.

Indeed, statistical sampling would appear to be entirely unnecessary in this case with respect to the government's inpatient claims because, since 2009, CMS (through its MAC and RAC contractors), the primary agency responsible for auditing hospital inpatient claims and the alleged victim in this case, has already audited the universe of short stay claims that it believes involve unnecessary admissions. To date, CMS has audited 13,326 Prime short stay claims and has approved the necessity of inpatient admissions for 7,197 audited claims, including 4,189 that were approved without appeal and 691 that were determined to have been underpayments. Pasupulati Decl. ¶ 6. Prime has also successfully appealed 2,168 of CMS's claim denials through the Medicare administrative appeals process, including 598 written decisions by Medicare administrative law judges or the Medicare appeals council finding that physicians at PHSI hospitals appropriately admitted the patients for inpatient care because their medical conditions could not be appropriately treated at a lower level of care, including through observation care. *Id.* Prime's success rate of appeal has been nearly 100% with 4,277 appeals pending at various stages. *Id.* In addition, during the same time period, CMS contractors have conducted 693 coding audits of inpatient claims, with 260 claims approved on audit or administrative appeal, and with Prime's appeals of approximately 357 claim denials currently pending at various levels. *Id.* Under these circumstances, there is no reason to allow the government

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to side-step the very process designated by CMS to identify unnecessary inpatient admissions and incorrect diagnoses by allowing the government to use unreliable statistical sampling to identify such admissions and diagnoses in an FCA action.

For these reasons, while *U.S. v. Life Care Centers of America, Inc.*, 114 F.Supp.3d 549, 565-567 (E.D. Tenn. 2014), and *U.S. v. Robinson*, 2015 WL 1479396, * 11 (E.D. Ky. 2015), both accepted sampling and extrapolation as a method of proving falsity of claims under the FCA, these two district court cases are distinguishable from the facts of this case. *Life Care Centers* did not involve falsity of claims based on a Medicare coverage standard requiring physician medical judgment to determine whether a patient should be admitted as an inpatient and what diagnoses should be made, but instead involved government allegations that the defendant nursing homes assigned false Resource Utilization Group ("RUG") codes that they were responsible for assessing by providing unnecessary therapy services. 114 F.Supp.3d at 552-555.[17] *Robinson* involved a single optometrist who conceded that the medical and time-keeping records supporting the sample claims were representative of his optometry visits, so extrapolation was not used in that case to make determinations about the clinical decision-making of numerous physicians at multiple hospitals. 2015 WL 1479396 at * 1-2.

In summary, where the government and relator have chosen to charge the Prime Defendants with FCA violations premised on improper clinical decision-making by independent physicians, the government cannot side-step the

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[17] In ruling that extrapolation of the falsity of unreviewed claims was permissible, the *Life Care* court recognized that there was no supporting authority precisely on point, *id*. at 560-565, but nevertheless concluded that such extrapolation could be used even though the numerous individualized factors relevant to the necessity of therapy would be unique to each patient because individual review of each claim "would consume an unacceptable portion of the Court's limited resources," and defendants could "employ cross-examination and competing witnesses and testimony to highlight the disparity between claims." *Id*. at 565-567.

individualized determination of falsity that Medicare's own coverage standards require through sampling and extrapolation of the falsity of sample claims to an enormous universe of unreviewed claims. Put another way, mathematical probabilities and a "trial by formula" cannot substitute for the individualized proof of falsity that the FCA requires when claims are alleged to be false by the government and relator based on the clinical decision-making of thousands of independent physicians regarding inpatient admissions and diagnoses for tens of thousands of different Medicare patients treated at 14 different Prime hospitals during a seven-year period.

IV. CONCLUSION

For the reasons set forth above, this Court should grant the Prime Defendants' motion to preclude the government's and relator's use of sampling and extrapolation to prove the falsity of claims under the FCA as a matter of law under the particular circumstances of this case.

DATED: September 1, 2016

NELSON HARDIMAN LLP

/S/ *M.S. Hardiman*

MARK S. HARDIMAN
Attorneys for Prime Defendants

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DECLARATION OF MARK S. HARDIMAN

I, Mark S. Hardiman, declare and state, as follows:

1. I am an attorney duly admitted to practice before this Court. I am an attorney at Nelson Hardiman, LLP, attorneys of record for Prime Defendants in this action. This declaration is made in support of Defendants' motion to exclude statistical sampling to prove falsity of claims under the FCA based on medically unnecessary admissions or clinically unsupported diagnoses. I have personal knowledge of the facts set forth in this declaration. If called as a witness, I could and would competently testify to such facts.

2. During its investigation, on June 12, 2012, the government served a subpoena on Prime requesting documents regarding Prime's Medicare coding practices, including with respect to 27 specific diagnoses relating to various CCs or MCCs. A true and correct copy of this subpoena is attached as Exhibit A. This subpoena also requested medical and billing records for 600 Medicare patients treated on an inpatient basis at the 14 Prime hospitals with dates of service between October 2007 and December 2011. Based on my review, the government's patient sample particularly focused on Medicare patients who were diagnosed with an MCC or CC of sepsis, acute respiratory failure, encephalopathy, malnutrition, acute renal failure, heart failure, acute pancreatitis and autonomic disorder.

3. On December 23, 2013, the government served a separate subpoena requesting medical records for an additional 131 Medicare patients treated on an inpatient basis at the 14 Prime hospitals who had lengths of stay of less than 3 days with dates of services between January 2006 and June 2013. A true and correct copy of this subpoena is attached as Exhibit B.

4. On July 8, 2016, I participated in a telephonic discussion with counsel for the government and relator during which their counsel informed me that the government and relator would oppose Prime Defendants' motion to exclude statistical sampling and extrapolation to prove the falsity of any Prime hospital

claims.

Executed under penalty of perjury on September 1, 2016 in Los Angeles, California.

/S/ *M.S. Hardiman*

MARK S. HARDIMAN

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1 **DECLARATION OF AKILA PASUPULATI**

2 I, Akila Pasupulati, declare and state, as follows:

3 1. I am a resident of California employed by Prime Healthcare
4 Management, Inc. as a Recovery Audit Contractor ("RAC") Healthcare Manager
5 in Ontario, California. This declaration is made in support of Defendants' motion
6 to exclude statistical sampling to prove falsity of claims under the FCA based on
7 medically unnecessary admissions or clinically unsupported diagnoses. I have
8 personal knowledge of the facts set forth in this declaration. If called as a witness,
9 I could and would competently testify to such facts.

10 2. I have a Bachelor of Medicine, Bachelor of Surgery (MBBS) from
11 Mamata Medical College (2007), and a Master's degree in Public Health (MPH)
12 from Western Kentucky University (2010). I am also enrolled in Bachelor in
13 Health Informatics program at Western Governors University with my degree
14 expected in December 2016. I also have the following certifications: Certified
15 Coding Specialist (American Health Information Management Association
16 (AHIMA) 2012), Certified Professional Coder (American Association of
17 Professional Coders (AAPC) 2015), Certified Professional Coding Instructor
18 (AAPC 2015), and Certified ICD-10-CM/PCS Trainer (AHIMA 2013).

19 3. I have been employed as RAC Healthcare Manager since May 2014.
20 As a RAC Healthcare Manager, my duties including supervising staff who compile
21 medical records and other data to support the administrative appeals by Prime
22 Healthcare hospitals of claims denied by Medicare RACs or the Medicare MACs,
23 and also track and ensure the timely submission of the documentation required for
24 each of the five levels of the Medicare administrative appeals process. Prior to this
25 position, between 2011 and May 2014, I was employed by Chino Valley Medical
26 Center as a Clinical Documentation Specialist ("CDS") and had the responsibility
27 of ensuring that the records contain accurate, complete, and timely data used by
28 Prime hospitals in coding and submitting claims to healthcare payors, including the

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Medicare program.

4. All Prime hospitals in California, other than Alvarado Hospital Medical Center, use the Meditech electronic health record (EHR) and billing computer system to create and maintain medical records and create, submit and maintain claims for health care services in the regular course of the hospital's business operations. This system is also used to track the status of Medicare administrative appeals by Prime hospitals of CMS claim denials. I am familiar with the Meditech system and how to search patient medical and claim records by specific data categories, including hospital, payor class, date of service, length of stay, and, in the case of Medicare claims, the MS-DRG and MCCs or CCs billed, and status of appeals of any denied claims.

5. Using the Meditech system, my staff and I have conducted various searches of the Medicare Part A claims submitted by Centinela Hospital Medical Center, Chino Valley Medical Center, Desert Valley Hospital, Encino Hospital Medical Center, Garden Grove Hospital Medical Center, Huntington Beach Hospital, La Palma Intercommunity Hospital, Montclair Hospital Medical Center, Paradise Valley Hospital, San Dimas Community Hospital, Shasta Regional Medical Center, Sherman Oaks Hospital, and West Anaheim Medical Center (the "Prime Hospitals") during the years 2006 through 2013. Due to its different computer system, Alvarado Hospital Medical Center was excluded from this analysis. While the final results of these data searches of not yet been finalized and various hospitals had missing or incomplete data for certain years, my preliminary review indicates that (a) between 2006 and 2013, these 13 Prime Healthcare hospitals treated approximately 228,000 Medicare patients on an inpatient basis, with their claims reflecting 219,605 diagnoses of sepsis (36,461), acute respiratory failure (26,727), encephalopathy (39,159), malnutrition (46,741), acute renal failure (42,105), heart failure (24,763), and autonomic disorder (3,649) listed as a primary or secondary diagnosis, including an MCC or CC, on the claim

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forms submitted to the Medicare Program; and (b) between 2006 and 2013, these 13 hospitals treated over 78,000 Medicare patients with lengths of stay of less than or equal to three days and over 35,000 Medicare patients with a lengths of stay of less than or equal to two days.

6. Between 2009 and present, our data review also revealed that CMS (through its MAC and RAC contractors) has audited 13,326 inpatient claims for the 14 Prime hospitals in California and approved the necessity of inpatient admissions for 7,197 claims, including 4,198 that were approved without appeal and 691 that were determined to have been underpayments. Prime Healthcare has also successfully reversed 2,168 of CMS's claim denials on the ground that the inpatient stay should have been billed as observation care through the Medicare administrative appeals process. This also includes 598 written decisions by Medicare Administrative Law Judges (ALJs) findings that physicians at Prime Healthcare hospitals admitted the patients for inpatient care because their medical conditions could not be appropriately treated at a lower level of care, including through observation care. Prime's success rate of appeal to date has been nearly 100% with 4,277 appeals (including 351 unfavorable ALJ decisions) pending at various stages. In addition, during the same time period, CMS contractors (MAC, RAC and QIO) have conducted 693 coding audits of inpatient claims, with 260 claims approved on audit or administrative appeal, and with Prime's appeals of approximately 357 claim denials currently pending at various levels.

7. I have also compared the emergency room admission rates of the 14 Prime hospitals compared to peer hospitals (acute care hospitals with comparable annual emergency room visits) as reflected in admission data maintained by the Office of Statewide Health Planning and Development (OSHPD). Based on my review, these 14 hospitals had an average emergency room admission rate of

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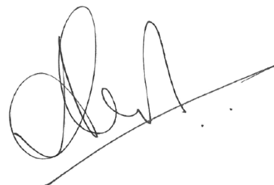
approximately 20% which falls within about the 75th percentile of peer hospitals in Southern California.

Executed under penalty of perjury on September 1, 2016 in Ontario, California.



AKILA PASUPULATI

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