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UNITED STATES DISTRICT COURT

NORTHEN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *ex rel.* RONDA OSINEK, Plaintiffs, v. KAISER PERMANENTE, et al., Defendants.	CASE NO. 3:13-cv-03891-EMC SECOND AMENDED COMPLAINT BY RELATORS MARCIA STEIN AND RODOLFO BONE FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL
UNITED STATES OF AMERICA, *ex rel.* NASER AREFI, AJITH KUMAR, and PRIME HEALTHCARE SERVICES, Plaintiffs, v. KAISER FOUNDATION HEALTH PLAN, INC., et al., Defendants.	CASE NO. 3:16-cv-01558-EMC SECOND AMENDED COMPLAINT BY RELATORS MARCIA STEIN AND RODOLFO BONE FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL

(Captions continued on next page)

UNITED STATES OF AMERICA, *ex rel.* MARCIA STEIN and RODOLFO BONE,

Plaintiffs,

vs.

KAISER FOUNDATION HEALTH PLAN, INC., a California corporation, KAISER FOUNDATION HOSPITALS, a California corporation, KAISER FOUNDATION HEALTH PLAN OF COLORADO, a Colorado corporation, KAISER FOUNDATION HEALTH PLAN OF GEORGIA, INC., a Georgia corporation, KAISER FOUNDATION HEALTH PLAN OF THE MID-ATLANTIC STATES, INC., a Maryland corporation, KAISER FOUNDATION HEALTH PLAN OF THE NORTHWEST, an Oregon corporation, KAISER FOUNDATION HEALTH PLAN OF WASHINGTON, a Washington corporation, THE PERMANENTE MEDICAL GROUP, INC., a California corporation, SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP, a business entity, form unknown, COLORADO PERMANENTE MEDICAL GROUP, a Colorado corporation, THE SOUTHEAST PERMANENTE MEDICAL GROUP, a Georgia corporation, HAWAII PERMANENTE MEDICAL GROUP, a Hawaii corporation, MID-ATLANTIC PERMANENTE MEDICAL GROUP, a Maryland corporation; NORTHWEST PERMANENTE, P.C., an Oregon corporation; GROUP HEALTH PERMANENTE, a Washington corporation, and KAISER PERMANENTE, a business entity, form unknown,

Defendants.

CASE NO. 3:16-CV-05337-EMC

SECOND AMENDED COMPLAINT BY RELATORS MARCIA STEIN AND RODOLFO BONE FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL

(Captions continued on next page)

UNITED STATES OF AMERICA and STATE OF CALIFORNIA, *ex rel.* GLORYANNE BRYANT and VICTORIA M. HERNANDEZ, Plaintiffs, v. KAISER PERMANENTE, INC., et al., Defendants.	CASE NO. 3:18-cv-01347-EMC SECOND AMENDED COMPLAINT BY RELATORS MARCIA STEIN AND RODOLFO BONE FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL
UNITED STATES OF AMERICA and STATE OF CALIFORNIA, *ex rel.* MICHAEL BICOCCA, Plaintiffs, v. PERMANENTE MEDICAL GROUP, INC., et al., Defendants.	CASE NO. 3:21-cv-03124-EMC SECOND AMENDED COMPLAINT BY RELATORS MARCIA STEIN AND RODOLFO BONE FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL
UNITED STATES OF AMERICA, *ex rel.* JAMES M. TAYLOR, Plaintiffs, v. KAISER PERMANENTE, INC., et al., Defendants.	CASE NO. 3:21-cv-03894-EMC SECOND AMENDED COMPLAINT BY RELATORS MARCIA STEIN AND RODOLFO BONE FOR VIOLATIONS OF THE FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL

COME NOW, Plaintiffs and Qui Tam Relators Marcia Stein and Rodolfo Bone, individually and on behalf of the United States of America, and allege as follows:

JURISDICTION AND VENUE

1. Plaintiffs and Qui Tam Relators Marcia Stein and Rodolfo Bone (Relators) file this action on behalf and in the name of the United States of America (Government) seeking damages and civil penalties against the defendants for violations of 31 U.S.C. § 3729(a).

2. This Court's jurisdiction over the claims for violations of 31 U.S.C. § 3729(a) is based upon 31 U.S.C. § 3732(a).

3. Venue is vested in this Court under 31 U.S.C. § 3732(a) because at least one of the defendants transacts business in the Central District of California and many acts constituting violations of 31 U.S.C. § 3729(a) occurred in the Central District of California. Venue is also vested in this Court under 28 U.S.C. § 1391(b) because at least one of the defendants transacts business in the Central District of California and many acts constituting violations of 31 U.S.C. § 3729(a) occurred in the Central District of California.

THE PARTIES

4. Relators are citizens of the United States and residents of the State of California. Relators bring this action of behalf of the Government under 31 U.S.C. § 3730(b).

5. At all times relevant, defendants Kaiser Foundation Health Plan, Inc. (KFHP) and Kaiser Foundation Hospitals (KFH) are and were corporations organized under the laws of California and transacted business in, among other places, the Central District of California.

6. At all times relevant, defendants Kaiser Foundation Health Plan of Colorado (KFHPCO), Kaiser Foundation Health Plan of Georgia, Inc. (KFHPGA), Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. (KFHPMAS), Kaiser Foundation Health Plan of the Northwest (KFHPNW), and Kaiser Foundation Health Plan of Washington (KFHPWA) are and were corporations organized under the laws of Colorado, Georgia, Maryland, Oregon and Washington, respectively.

7. KFHP, KFHPCO, KFHPGA, KFHPMAS, KFHPNW and KFHPWA are collectively referred to as "Kaiser Health Plans."

8. At all times relevant, defendant The Permanente Medical Group (TPMG) is and was a corporation organized under the laws of California.

9. At all times relevant, defendants Southern California Permanente Medical Group (SCPMG) and Kaiser Permanente (KP) are and were business organizations, forms unknown, and transacted business in, among other places, the Central District of California.

10. At all times relevant, defendant Colorado Permanente Medical Group (CPMG) is and was a Colorado corporation.

11. At all times relevant, defendant The Southeast Permanente Medical Group

(SEPMG) is and was a Georgia corporation.

12. At all times relevant, defendant Hawaii Permanente Medical Group (HPMG) is and was a Hawaii corporation.

13. At all times relevant, defendant Mid-Atlantic Permanente Medical Group (MAPMG) is and was a Maryland corporation.

14. At all times relevant, defendant Northwest Permanente, P.C. (NWP) is and was an Oregon corporation.

15. At all times relevant, defendant Group Health Permanente (GHP) is and was a Washington corporation.

16. Defendants TPMG, SCPMG, CPMG, SEPMG, HPMG, MAPMG, NWP, and GHP are collectively referred to as "Physician Medical Groups" or "PMGs."

17. Kaiser Permanente (KP) is a business entity, form unknown, that is, and at all times mentioned was, made up of three groups of interdependent entities, the Kaiser Health Plans, KFH and the PMGs, through an exclusive contractual relationship, that operates as one the nation's largest integrated health care delivery system focused on providing managed health care services to HMO beneficiaries and to seniors through the federal Medicare Advantage health care program. The Kaiser Health Plans provide, among other things, infrastructure and support in Information Technology (IT), Human Resources (HR), Compliance, Coding, Health Information Management (HIM), and Finance to KFH and its regional hospitals, medical centers and clinics, and to the PMGs and their regional medical groups and medical clinics. KFH provides hospital facilities and services to the Kaiser Health Plans' HMO and Medicare Advantage beneficiaries, and has various infrastructure functions and departments, including but not limited to HIM. The PMGs provide medical, diagnostic and physician services to the Kaiser Health Plans' HMO and Medicare Advantage beneficiaries.

18. In California, there are two regional medical groups: (a) defendant SCPMG, consisting of California physicians providing medical services to KP patients in the areas of Ventura County and all counties south thereof; and (b) defendant TPMG, consisting of

California physicians providing medical services to KP patients in all remaining counties north of Ventura County.

19. CPMG is a regional medical group consisting of physicians providing medical services in Colorado to KP patients.

20. SEPMG is a regional medical group consisting of physicians providing medical services in Georgia to KP patients.

21. HPMG is a regional medical group consisting of physicians providing medical services in Hawaii to KP patients.

22. MAPMG is a regional medical group consisting of physicians providing medical services in Maryland, Virginia and Washington, D.C. to KP patients.

23. NWP is a regional medical group consisting of physicians providing medical services is Oregon and Washington to KP patients.

24. GHP is a regional medical group consisting of physicians providing medical services in Washington to KP patients.

25. Relator Marcia Stein (Stein) is an AHIMA Registered Health Information Administrator (RHIA) and was employed by both the SCPMG and KFH. At SCPMG worked at Panorama City as the clinic records administrator and worked at KFH's Panorama City, California hospital as the Regional Director of KFH's Health Information Managers from about October 1987 until about May 2011. Health Information Managers are professionals with expertise in managing health information systems, and processing, analyzing and reporting information vital to the operations of hospitals, medical groups, medical clinics and health plans. Typically, Health Information Managers are also responsible for training physicians, health care professionals and coders on utilizing the available health information systems, electronic health records (EHR) and correct coding and documentation practices.

26. While employed at KFH Hospital-Panorama City, Stein reported to both the regional SCPMG and the KFH Hospital-Panorama City's managements. On behalf of SCPMG, Stein supervised a staff of over 100 full-time employees, including coders, billers, trainers, clinic staff and legal assistants (with regard to physician malpractice claims), and was

charged with implementing defendants' policies and procedures regarding medical record documentation and compliance, HIPAA security, and physician training and education. Stein attended monthly SCPMG Clinic Administrator and Regional Department meetings. Stein was also responsible for overseeing the Panorama City hospital's health information systems, coding, medical record documentation, HIPAA security, and related compliance issues, as well as being a contact person for various state and federal hospital data reporting questions or issues. Stein co-chaired the monthly regional HIM Director's meetings (for the Southern California Region), chairing the majority. Such meetings addressed coding and documentation problems with SCPMG senior leadership on behalf of other regional KFH HIM Directors.

27. Between 2010 and 2016, Rodolfo Bone (Bone) was a part employee of KFH at its South Bay hospital in Harbor City, California as a per diem coder. At the beginning of 2016 his position was moved to KFH's Southern California corporate offices in Pasadena, California where he continued as a per diem coder reporting to KFH's Regional Revenue Cycle. Beginning in 1996 and continuing until the present, Bone has been employed full time by Good Samaritan Hospital, located in Los Angles California, as a Coding Supervisor and Coding Auditor. Bone was born and raised in the Philippines where he graduated from medical school, and was and is licensed to practice medicine in the Philippines.

MEDICARE ADVANTAGE AND RISK ADJUSTMENT

28. At all times relevant, the United States (Government) funded the Medicare program, administered by the Centers for Medicare and Medicaid Services (CMS), which provides payment of healthcare services for, among others, Americans 65 years of age and older. Medicare provides an option, Medicare Advantage (MA), in which eligible Medicare beneficiaries can enroll with a health plan or managed care organization (collectively, "MAO") contracted with CMS for a capitated rate paid by CMS that generally provides at least those services provided to standard fee-for-service (FFS) Medicare beneficiaries. (*See,* 42 U.S.C. § 1395w-21(a).)

29. At all times relevant, each of the Kaiser Health Plans had a MA contract with CMS, the federal agency that administers the Medicare program, to provide MA benefits to

eligible enrollees. Eligible MA enrollees selected the Kaiser Health Plan in their locale and selected a primary care physician from a directory of PMG physicians near the enrollees' residence. The revenues from these MA contracts were a significant source of revenues for defendants. The revenues the PMGs received for the MA enrollees they serviced were also the primary source of funding for any physician bonuses that were paid.

30. At all times relevant, Section 1853(a)(3) of the Social Security Act [42 U.S.C. § 1395w-23(a)(3)] required the Government's Centers for Medicare and Medicaid Services (CMS) to risk adjust payments to Medicare Advantage organizations (MAOs), such as the Kaiser Health Plans. In general, the risk adjustment methodology relied on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification (ICD-9) Guidelines (ICD-9 Guidelines), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes (ICD-9 codes) collected from physicians and related information (collectively, "risk adjustment data") submitted by MAOs, such as the Kaiser Health Plans, to CMS were used to develop Hierarchical Condition Category (HCC)[1] risk scores that are used by CMS to risk adjust the capitated payment rates paid by the Government to that particular MAO. The HCC risk scores compensated a MAO with a population of patients with more severe illnesses than normal through higher capitation rates. Likewise, a MAO with a population of patients with less severe illnesses than normal would see a downward adjustment of its capitation rates because it was servicing a healthier than normal population of patients. By risk adjusting MAO payments, CMS attempts to make appropriate and accurate payments for enrollees with differences in expected healthcare costs. Risk adjustment data records the health status and demographic characteristics of an enrollee.

31. In order to obtain an HCC risk adjustment score for a MA enrollee for a given year, the enrollee must have an encounter with a medical provider or examiner that generates

[1]Not all diagnoses result in a HCC risk score. Only certain diagnosis codes or combinations thereof result in HCC risk scores. CMS reviews and publishes the list of relevant ICD-9 diagnosis codes and their related HCC coefficients annually. A HCC risk score will vary upon the diagnosis codes or combinations thereof according to a matrix determined by the Government.

a diagnosis code or codes, which were timely submitted to CMS. If a MA enrollee does not have a reported encounter with a medical provider or examiner that generates a diagnosis code or codes during the year, the following year, CMS will pay the MAO a capitated rate for that MA enrollee as though s/he was perfectly healthy, even though in prior years the MA enrollee had a number of diagnoses that resulted in significant HCC risk adjustment scores and correspondingly high capitation rates.

32. Risk adjustment data (RAD) submitted by or on behalf of a MAO to CMS must be supported by properly documented medical records from the encounter that led to the RAD. 42 C.F.R. §§ 422.310(c)(2) and (d), 422.504(l); Medicare Managed Care Manual, Ch. 7, § 40 [Medicare Advantage Organizations "must . . . [e]nsure the accuracy and integrity of risk adjustment data submitted to CMS. All diagnosis codes must be documented in the medical record and must be documented as a result fo a face-to-face visit. . . ."]; *see also,* 79 Fed.Reg. No. 100, 29844, 29923 (May 23, 2014) ["Further, CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation."] In order to be a properly documented medical record, the medical record entries must, among other things, (1) be the result of a MA enrollee's face-to-face encounter with a medical provider or examiner legally authorized to perform the service rendered under applicable Medicare laws, regulations and rules,[2] (2) that accurately and truthfully documents the findings necessary to support the medical diagnoses by the medical provider/examiner in accordance with applicable Medicare laws, regulations and rules,[3] and (3) signed by the

[2] *See,* Medicare Managed Care Manual, Ch. 7, § 40 ["All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. . . . "]; 42 U.S.C. § 1395x(r) , (aa)(5)(A), (aa)(6); 42 C.F.R. §§ 410.20(b), 410.74(a)(2), 410.75(b)-(c), made applicable to Medicare Advantage by 42 C.F.R. §§ 422.101(b)(2) and 422.310(d).

[3] 42 C.F.R. §§ 422.310(c)(2) and (d), 422.504(l)(2)-(3); CMS Pub.100-08, Medicare Program Integrity Manual, Ch. 3, §3.3.2.5; International Classification of Disease 9th Revision Guidelines (ICD-9), made applicable to Medicare Advantage by 42 C.F.R. §§ 422.101(b)(2) and 422.310(d), and Medicare Managed Care Manual, Ch. 7, § 40 ["The diagnosis must be coded according to International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting."]

medical provider/examiner as required by Medicare.[4] Further, the diagnoses must be coded in accordance with all applicable national guidelines, including but not limited to International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting, and the American Health Information Management Association (AHIMA) national guidelines for ethical coding.[5] AHIMA is a member of the ICD9CM and the ICD10CM Cooperating Parties, thus their practice briefs are considered "industry standards." Failure to meet any of these required elements results in the medical record not being properly documented and being unable to support RAD arising therefrom and invalidating the submission of such RAD (i.e., ICD-9 diagnosis codes).

33. MAOs do not typically submit claims for services rendered to CMS in the traditional FFS sense. The capitation payments are paid in advance, and by accepting the capitated payments, MAOs agree to be at risk for all of the health care costs for the MA enrollees assigned to it. Capitation payments are made prospectively with the data for the current calender year being used to risk adjust the capitation payments for that specific MA enrollee in the subsequent calender year. Instead of submitting traditional FFS claims, MAOs submit RAD which are used by CMS to calculate and risk adjust the capitation payments paid by CMS to the MAOs for each MA enrollee. Because the capitation payments are adjusted based upon the MAOs' submission of RAD, the submission of RAD is considered by the Government as the submission of claims for payment to CMS for purposes of enforcing civil and criminal penalties for making false claims under Social Security Act §§1128A [42 U.S.C. § 1320a–7a], 1128 B [42 U.S.C. § 1320a–7b] and the False Claims Act, 31 U.S.C. § 3729.

34. CMS has made it clear that MAOs, such as the Kaiser Health Plans, "must be

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[4]Medicare Program Integrity Manual, Ch. 3, §3.3.2.4, made applicable to Medicare Advantage by 42 C.F.R. §§ 422.101(b)(2) and 422.310(d).

[5]42 C.F.R. § 422.310(d)(1) ["MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. . . ."]; Medicare Managed Care Manual, Ch. 7, § 40 ["The diagnosis must be coded according to International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting."]; AHIMA 2009, Amendments, Corrections ans Deletions in the electronic Health Record: Toolkit, pp. 1-8, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_044678.hcsp?dDocName=bok1_044678; Medicare Program Integrity Manual, Ch. 3, §3.3.2.5(A)-(B).

continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS" and "are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments." Additionally, "we [CMS] have always expected that MA organizations or Part D sponsors implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment." (79 Fed.Reg. 29,884, 29,921, 29,923-29,924 (May 14, 2014).)

35. The MA program requires MAOs provide, at a minimum, all of the benefits available under original Medicare (Parts A and B). The MA program incorporates into it all of the coverage determinations, rules and regulations of Medicare Parts A and B unless such regulations are specifically altered or superceded by the Medicare Part C regulations that specifically govern the MA program.

36. As will be explained in detail below, at various times during and between 2010 and the present, the defendants submitted false and fraudulent claims to CMS in violation of 31 U.S.C. § 3729(a) by (a) making and submitting to CMS false, inaccurate and exaggerated diagnoses for sepsis that were not supported by properly documented medical records, (b) making and submitting to CMS false, inaccurate and exaggerated diagnoses for malnutrition that were not supported by properly documented medical records, (c) making and submitting to CMS false, inaccurate and exaggerated diagnoses for aortic atherosclerosis that were not supported by properly documented medical records, (d) making and submitting to CMS diagnoses resulting from improper and unethical leading physician queries, (e) performing medical record reviews designed to only identify and report to CMS previously unreported diagnosis codes that concealed and failed to withdraw from CMS previously reported diagnosis codes that were unsupported by the reviewed medical records, and (f) providing medically unnecessary and non-covered routine physical examinations in order to identify and submit invalid RAD for use in calculating Kaiser Health Plans' capitation payments to CMS.

37. Although the majority of Kaiser's Medicare patients are beneficiaries under the MA program, approximately 20% of Kaiser's Medicare patients are beneficiaries under

original fee-for-service (FFS) Medicare, i.e., Medicare Part A and/or Part B. Defendants' fraudulent misconduct alleged below concerning sepsis and malnutrition, (briefly mentioned in paragraph 36(a)-(b)) involved Kaiser's FFS Medicare patients and MA patients. Inpatient hospital facilities, such as KFH, bill CMS for FFS Medicare services by mapping ICD-9 and later ICD-10 diagnosis codes, into diagnostic related groups (DRGs), major complications and co-morbidities (MCCs) each of which is assigned a monetary value by CMS, depending in part, on the county where the hospital is located. In FFS Medicare hospital billing, DRGs are primary diagnoses and MCCs are secondary diagnoses. Some but not all MCCs cause an increase in the DRG's value.

SEPSIS

38. The current lay-person definition of sepsis and sepsis with acute organ failure (collectively, "Sepsis") is "Sepsis is a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs." (The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), *JAMA*, (February 23, 2016) Vol. 315, No. 8, 801, 807.) "Sepsis is not a specific illness but rather a syndrome encompassing a still-uncertain pathobiology. At present, it can be identified by a constellation of clinical signs and symptoms in a patient with suspected infection." (*Id.* at 803.) Sepsis is characterized by "signs of inflammation (vasodilator, leukocyte accumulation, increased micro vascular permeability) occurring in tissues that are remote from the infection. Systemic inflammatory response syndrome (SIRS) is an identical clinical syndrome that complicates a noninfectious insult (e.g., acute pancreatitis, pulmonary contusion). . . . This response can lead to multiple organ dysfunction syndrome (MODS), which is the cause of the high mortality associated with these syndromes." (Sepsis Definitions: Time for Change, *Lancet,* (March 2, 2013), Vol. 381, No. 9868, 774–775 (See, http://doi.org/10.1016/S0140-6736(12)61815-7).)

39. The term Sepsis is usually reserved for patients that need to be admitted to the hospitals intensive care unit (ICU). (See, Sepsis Definition: Time For Change, *Lancet* (March 2, 2013) Vol. 381, No. 9868, pp. 774–775.) Patients who develop Sepsis face a substantial likelihood of death as it is one of the main causes of death among hospital patients. Sepsis has

been estimated to be the cause or related to of as many as 1 out of every 2 to 3 in-patient hospital deaths. (Hospital Deaths in Patients With Sepsis From 2 Independent Cohorts, *JAMA,* (July 2, 2014) Vol. 312, No. 1, 90-92 at p. 90. (See, http://jama.jamanetwork.com/article.aspx?articleid=1873131).) During 2009, the national mean length of stay for patients who had Sepsis as their principal diagnosis was 8.8 days and 15.8 days for patients with Sepsis as a secondary diagnosis. (Agency for Healthcare Research and Quality (AHRQ), HealthCare Cost and Utilization Project (H-CUP), Statistical Brief #122, p. 4 (October 2011).)

40. During 1991, the American College of Chest Physicians (ACCP) and the Society of Critical Care Medicine (SCCM) convened a Sepsis "Consensus Conference" the purpose of which, "[I]s to propose a conceptual framework for future studies of the clinical phenomenon of organ system dysfunction in critical illness, and to lay the foundations for common terminology and criteria to describe the syndrome." (The ACCP/SCCM Consensus Conference Statement - 1991, *Chest*, (June 1992) Vol. 101, 1644, 1648.) In other words, to provide some broad definitions of Sepsis so that researches could conduct effective clinical trials. (*See,* 2001 International Sepsis Definitions Conference, *Intensive Care Med.,* (March 28, 2003) Vol. 29, 530, 531.) The 1991 Consensus Conference introduced into common parlance the term "systemic inflammatory response syndrome" (SIRS). The term provided a reference for the complex findings that result from a systemic activation of the innate immune response, regardless of cause. (*Id*.) "This systemic inflammatory response can be seen following a wide variety of insults and includes, but is not limited to, more than one of the following clinical manifestations:

– Body temperature higher than 38°C or lower than 36°C

– Heart rate higher than 90/min

– Hyperventilation evidenced by respiratory rate higher than 20/min or PaCO2lower than 32 mmHg

– White blood cell count higher than 12,000 cells/ µl or lower than 4,000/ µl

These physiologic changes should represent an acute alteration from baseline in the absence of other known causes for such abnormalities. . . ." (The ACCP/SCCM Consensus Conference

Statement - 1991, *Chest*, (June 1992) Vol. 101, 1644, 1645.) The SIRS concept has been globally adopted by clinical investigators resulting in approximately 800 research articles about SIRS and/or Sepsis between 1992 and 2002.

41. The 1991 Consensus Conference introduced the concept that Sepsis is the body's inflammatory response to infection. The conference concluded that patients with elevations in at least two of four variables that are indicators of inflamation (temperature, heart rate, respiratory rate, and white blood cell count) were suspect of having SIRS, and that patients with elevations in at least two of the four variables and an infection were potential indicators of sepsis. However, the Consensus Conference instructed physicians **not** to use the SIRS criteria plus infection as a diagnostic standard, "To help identify these manifestations as sepsis, it should be determined whether they are a part of the direct systemic response to the presence of an infectious process. Also, the physiologic changes measured should represent an acute alteration from baseline **in the absence of other known causes for such abnormalities**." (Emphasis added; The ACCP/SCCM Consensus Conference Statement - 1991, *Chest,* (June 1992) Vol.101, 1644, 1646.)

42. In 2001, the definitions of sepsis and SIRS were revisited at the International Sepsis Definitions Conference sponsored by the ACCP, SCCM, the European Society of Intensive Care Medicine (ESICM), the American Thoracic Society (ATS), and the Surgical Infection Society (SIS). The 2001 International Sepsis Definitions Conference ("2001 Conference") goals included identification of ways to improve the current sepsis definitions and to identify methodologies for increasing the accuracy, reliability, and/or clinical utility of the diagnosis of sepsis. (2001 International Sepsis Definitions Conference, *Intensive Care Med.,* (March 28, 2003) Vol. 29, 530, 531.) The 2001 Conference addressed at length the short-comings of the then current sepsis and SIRS definitions. The SIRS criteria had been found to have no practical use to a clinician for diagnosing Sepsis and concluded, among other things, "[T]he specific criteria proposed in the 1992 consensus definitions are widely considered to be too nonspecific to be of utility in diagnosing a cause of the syndrome or in

identifying a distinct pattern of host response."[6] (2001 International Sepsis Definitions Conference, *Intensive Care Med.*, (2003) Vol. 29, 530, 532.) The final Report from the 2001 Conference further concluded, "Unfortunately a clinically useful set of criteria for diagnosing sepsis and related conditions will necessarily be somewhat arbitrary. There is no 'gold standard' (such as the infarcted myocardium) against which the diagnostic criteria can be calibrated." (*Id.* at 532.)

43. Although the 2001 Conference did not result in a new definition of sepsis, it clarified that SIRS criteria were not intended to be used as a physician diagnostic tool but rather a starting point for researchers to identify clinical trials participants. (*Id.* at 532.) In response to the limitations noted of the SIRS definition, the 2001 Conference Report stated that clinical findings such as, "[H]emodynamic instability, arterial hypoxemia, oliguria, coagulopathy, and altered liver function tests among the list of criteria that can be used to establish the diagnosis of sepsis." (*Id.* at 533.) The Report included an expansive list of possible signs, symptoms and potentially sceptic values, grouped into five main categories, General Parameters, Inflammatory Parameters Hemodynamic Parameters, Organ Dysfunction Parameters, and Tissues Perfusion Parameters, to aid physicians in making and confirming Sepsis as opposed to less severe medical conditions.[7] (*Id.* at 533-34.)

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[6]The 2001 International Sepsis Definitions Conference cited the work of J.C. Marshall who concluded, "The four criteria that define SIRS are non-specific measures of physiologic severity, rather than distinctive manifestations of a disease process....However, the complexity of the biologic processes involved suggest that a clinical syndrome of systemic inflammation is of no more use to the clinician than a clinical syndrome of cancer." (SIRS and MODs: What is Their Relevance to the Science and Practice of Intensive Care, *Shock,* (December 2000) Vol. 12, No. 6, 586-9.

[7]The complete list of Sepsis diagnostic criteria was stated as Infection documented or suspected and some of the following:

> General parameters
> Fever (core temperature >38.3°C) Hypothermia (core temperature <36°C Heart rate >90 bpmor >2 SD above the normal value for age Tachypnea: >30 bpm Altered mental status Significant edema or positive fluid balance (>20 ml/kg over 24 h) Hyperglycemia (plasma glucose >110 mg/dl or 7.7 mM/l) in the absence of diabetes
>
> Inflammatory parameters
> Leukocytosis (white blood cell count >12,000/µl) Leukopenia (white blood cell count <4,000/µl) Normal white blood cell count with >10%

44. The Report emphasized that its expanded list of clinical findings were not specific to sepsis and therefore, like the SIRS criteria, the list could not be used as a diagnostic standard in all cases. The physician still had to determine if a medical condition other than sepsis was the cause of the patient's symptoms and/or elevated values before diagnosing sepsis or sepsis acute organ failure, when applicable, and separately determine if such organ failure was a result of Sepsis or some other cause. Other medical conditions besides Sepsis can also account for increases in the 2001 Conference criteria including, but not limited to, post operative surgery recovery, minor respiratory infections, minor urinary tract infections, trauma as well as certain medications. The Report stressed, "It is important that as a practitioner 'checks off the boxes' to establish the diagnosis of sepsis; only findings that cannot be easily explained by other causes should be included." *Id.* "Most clinicians do not refer to patients as septic when they develop an uncomplicated mild upper-respiratory viral infection with slight fever and tachycardia, (i.e., a faster than normal heart rate.)" (Sepsis Definitions: Time For Change, *Lancet*, March 2, 2013, Vol. 381, No. 9868, 774–775.)

45. Between 2001 and 2010 several organized approaches to identify and treat Sepsis were proposed. The two most prominent of these organized treatment approaches were Early Goal-Directed Therapy for the treatment of Sepsis and Sceptic Shock (EGDT) published in the New England Journal of Medicine (N Engl J Med (November 8, 2001) Vol. 345, 1368-

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> immature forms Plasma C reactive protein>2 SD above the normal value Plasma procalcitonin >2 SD above the normal value
>
> Hemodynamic parameters
> Arterial hypotensionb (systolic blood pressure <90 mmHg, mean arterial pressure <70, or a systolic blood pressure decrease >40 mmHg in adults or <2 SD below normal for age) Mixed venous oxygen saturation >70%b Cardiac index >3.5 l min−1 m−2c,d
>
> Organ dysfunction parameters
> Arterial hypoxemia (PaO2/FIO2 <300) Acute oliguria (urine output <0.5 ml kg−1 h−1 or 45 mM/l for at least 2 h) Creatinine increase ≥0.5 mg/dl Coagulation abnormalities (international normalized ratio >1.5 or activated partial thromboplastin time >60 s) Ileus (absent bowel sounds) Thrombocytopenia (platelet count <100,000/μl) Hyperbilirubinemia (plasma total bilirubin >4 mg/dl or 70 mmol/l)
>
> Tissue perfusion parameters
> Hyperlactatemia (>3 mmol/l) Decreased capillary refill or mottling

1377), and continuing since 2002, the Surviving Sepsis Campaign, a joint collaboration of the Society of Critical Care Medicine and the European Society of Intensive Care Medicine. The Surviving Sepsis Campaign (SSC) published and continuously updated Surviving Sepsis Bundles that outline the basic treatment protocols along with detailed treatment guidelines to provide institutions and physicians with a coordinated effort to measure and manage each of the five parameters for diagnosing Sepsis identified in the 2001 Conference (i.e., General Parameters, Inflammatory Parameters Hemodynamic Parameters, Organ Dysfunction Parameters, and Tissues Perfusion Parameters).

46. The SSC Surviving Sepsis Bundle states:

TO BE COMPLETED WITHIN 3 HOURS:

1) Measure lactate level
2) Obtain blood cultures prior to administration of antibiotics
3) Administer broad spectrum antibiotics
4) Administer 30 ml/kg crystalloid for hypotension or lactate 4mmol/L

"Time of presentation" is defined as the time of triage in the emergency department or, if presenting from another care venue, from the earliest chart annotation consistent with all elements of severe sepsis or septic shock ascertained through chart review.

TO BE COMPLETED WITHIN 6 HOURS:

5) Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥65 mm Hg
6) In the event of persistent hypotension after initial fluid administration (MAP < 65 mm Hg) or if initial lactate was ≥4 mmol/L, re-assess volume status and tissue perfusion and document findings according to Table 1.
7. Re-measure lactate if initial lactate elevated.

TABLE 1

DOCUMENT REASSESSMENT OF VOLUME STATUS AND TISSUE PERFUSION WITH:

EITHER:

• Repeat focused exam (after initial fluid resuscitation) including vital signs, cardiopulmonary, capillary refill, pulse, and skin findings.

OR TWO OF THE FOLLOWING:

• Measure CVP
• Measure ScvO2
• Bedside cardiovascular ultrasound

• Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge. (http://www.survivingsepsis.org/Bundles/Pages/default.aspx.)

47. The SSC guidelines and EGDT each contemplate that physicians timely diagnose Sepsis, take multiple blood samples prior to the administration of antibiotics for obtaining an accurate blood culture, monitor and managing the patients fluid retention, monitor arterial pressure via central venous catheter (i.e. an arterial catheter placed in the Vena Cava artery) administer IV fluids, measure and adjust lactate levels (a precursor to organ failure), and administer various medications including, but not limited to, antibiotics to fight the infection, and vasopressors and corticosteroids, as needed, to manage fluid retention and prevent organ failure.[8] (Early Goal-Directed Therapy for the treatment of Sepsis and Sceptic Shock, *N Engl J Med,* (November 8, 2001) Vol. 345, 1368-1377; http://www.survivingsepsis.org/Guidelines/Pages/default.aspx.) Typically, MA enrollees that have a central venous catheter inserted are admitted to or already in the ICU.

48. The SSC's detailed treatment guidelines, provided in conjunction with the Surviving Sepsis Bundles, include but are not limited to: Initial Resuscitation and Infection Issues; Hemodynamic Support and Adjunctive Therapy; Blood Product, Immunoglobulins and Selinum Administration; Mechanical Ventilation of Sepsis-Induced Acute Respiratory Distress Syndrome (ARDS); Sedation, Analgesia, and Neuromuscular Blockade; Glucose Control; Renal Replacement Therapy; Bicarbonate Therapy; Deep Vein Thrombosis Prophylaxis; Stress Ulcer Prophylaxis; and Nutrition to address various patient responses and provide treatment options. (Id.) Administering such complex Sepsis treatments routinely take place in the hospital's ICU. (*Id.*)

49. Based on the 2001 Conference's final report, during 2003 the ICD-9 Guidelines and the ICD-9 codes were modified to include the 2001 International Sepsis Definition Conference's expanded list of sepsis and sepsis with acute organ failure, resulting in a more expansive and detailed diagnostic and coding scheme for properly documenting and coding

[8]In 2015, based on the best available evidence, the Surviving Sepsis Bundle was updated making the use of a central venous catheter to monitor blood oxygen or pressure levels optional instead of required.

Sepsis. The ICD-9 Guidelines explain in detail the precise sequence of steps required to properly code the various stages of Sepsis, including but not limited to, sepsis, sepsis with organ dysfunction, sepsis with multiple organ dysfunction, sepsis caused by various types of infections, and septic shock. (*ICD-9-CM Official Guidelines for Coding and Reporting*, §I.C.1.b.1.-12.) Further, the ICD-9 Guidelines repeatedly stress that coders will likely have to query physicians when documenting Sepsis to trigger proper documentation that supports the Sepsis diagnosis due the complex nature of those diseases.[9] While the ICD-9 Guidelines explain the minium information required for coders to properly record a particular ICD-9 diagnosis code, it does not explain to the physician all of the steps and criteria for making a particular diagnosis. It is not uncommon for the medical standard of care to be more detailed and complex than the ICD-9 Guidelines.

50. On or about February 23, 2016, JAMA published the Report of The Third International Sepsis Definitions Conference. This Third Sepsis Definitions Conference (Sepsis-3) adopted a new definition of Sepsis that was consistent with the current state of the medical practice and research since the 2001 Conference. "The task force sought to differentiate sepsis from uncomplicated infection and to update definitions of sepsis and septic shock to be consistent with improved understanding of the pathobiology.... The sepsis illness concept is predicated on infection as its trigger, acknowledging the current challenges in the microbiological identification of infection. . . . The task force recognized that sepsis is a syndrome without, at present, a validated criterion standard diagnostic test." (The Third International Consensus Definitions for Sepsis and Septic Shock, *JAMA* (Feb. 2016) Vol. 315, No. 8, 801, 803.) The new sepsis definition from Sepsis-3 was stated as:

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[9]The ICD-9 Guidelines state, "Due to the complex nature of sepsis and severe sepsis, some cases may require querying the provider prior to assignment of the codes." §I.C.1.b.1.c. "If a patient has sepsis and an acute organ dysfunction, but the medical record documentation indicates that the acute organ dysfunction is related to a medical condition other than the sepsis, do not assign code 995.92, Severe sepsis. An acute organ dysfunction must be associated with the sepsis in order to assign the severe sepsis code. If the documentation is not clear as to whether an acute organ dysfunction is related to the sepsis or another medical condition, query the provider." §I.C.1.b.5. "Sepsis or severe sepsis may be present on admission but the diagnosis may not be confirmed until sometime after admission. If the documentation is not clear whether the sepsis or severe sepsis was present on admission, the provider should be queried." §I.C.1.b.2.c.

> In lay terms, sepsis is a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs.
>
> Patients with suspected infection who are likely to have a prolonged ICU stay or to die in the hospital can be promptly identified at the bedside with qSOFA, ie, alteration in mental status, systolic blood pressure 100 mm Hg, or respiratory rate 22/min.
>
> Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality.
>
> Patients with septic shock can be identified with a clinical construct of sepsis with persisting hypotension requiring vasopressors to maintain MAP 65 mm Hg and having a serum lactate level >2 mmol/L (18 mg/dL) despite adequate volume resuscitation. With these criteria, hospital mortality is in excess of 40%. Abbreviations: MAP, mean arterial pressure; qSOFA, quick SOFA; SOFA: Sequential [Sepsis-related] Organ Failure Assessment. (*Id*. at 805.)

The Sepsis-3 Report concludes that, "The current use of 2 or more SIRS criteria to identify sepsis was unanimously considered by the task force to be unhelpful. Changes in white blood cell count, temperature, and heart rate reflect inflammation, the host response to 'danger' in the form of infection or other insults. The SIRS criteria do not necessarily indicate a dysregulated, life-threatening response. SIRS criteria are present in many hospitalized patients, including those who never develop infection and never incur adverse outcomes." (*Id*.) This conclusion is very similar to the conclusions published from the 2001 Conference. (2001 International Sepsis Definition Conference, *Intensive Care Med.* (2003) Vol. 29, 530, 532-4.) A further change was to abandon the use of the term "severe sepsis," i.e., sepsis with organ dysfunction, because all sepsis cases are severe due to their potential to cause death. Lastly, the Sepsis-3 Report recognized that Septic Shock, i.e., sepsis involving multiple organ failure, has an even higher likelihood of patient death than sepsis. In an e-mail to its staff dated March 8, 1016, KFHP unequivocally rejected the modern Sepsis-3 definitions and diagnostic recommendations.

DEFENDANTS' FRAUDULENT MISCONDUCT

51. During or about 2009, KFH in conjunction with TPMG and SCPMG adopted and implemented early treatment protocols purportedly to identify and treat all patients suspected of having Sepsis. These Sepsis treatment protocols where subsequently adopted by all PMGs. The Sepsis treatment protocols KHF, TPMG and SCPMG implemented where intentionally

over-broad to ensure that all patients with Sepsis were timely diagnosed and treated. However, KFH's overly-broad Sepsis treatment protocols also resulted in over-diagnosing Sepsis in patients that had presented with uncomplicated mild upper-respiratory viral infection and/or urinary tract infections, with slight fever and tachycardia, (i.e., a faster than normal heart rate). Such patients where not suffering from Sepsis, Sepsis with organ dysfunction, nor severe Sepsis. SCPMG and KFH's Sepsis treatment protocols did not provide any process to correct any false-positive Sepsis diagnoses made by TPMG and/or SCPMG physicians. Efforts by coders employed by KFH, SCPMG or TPMG to correct such over-diagnosed and false Sepsis diagnoses were overruled and/or disallowed by TPMG and SCPMG physicians. None of the falsely diagnosed Sepsis patients where admitted to the hospital as inpatients nor the ICU. Instead, such falsely diagnosed Sepsis patients were held in the emergency room's observation beds for a period of up to 72 hours before being sent home. However, most were sent home within 48 hours or less.

52. During and between approximately 2010 to the present, SCPMG, TPMG, KFH and KFHP participated in a fraudulent scheme to up-code and falsely diagnose MA enrollees with sepsis and/or severe sepsis, i.e., sepsis with acute organ failure, (collectively referred to as "Sepsis") when Sepsis was not present. Such false Sepsis diagnoses were made in order to increase the risk adjustment scores for the MA enrollees so diagnosed and thereby increase CMS's capitation payments to KFHP, TPMG and SCPMG. This scheme was also promoted by KFH to falsely lower KFH's reported Sepsis mortality rates thereby improve KFH's reputation and prestige as a quality hospital provider. This fraudulent scheme concerned the identification and treatment of Sepsis for KFHP's MA enrollees that presented in the emergency room (ER) of KFH hospitals and was accomplished by (a) KFHP, PMG and SCPMG and KFH implementing unwritten policies that prohibited coders employed by , KFH, SCPMG and/or TPMG, (collectively referred to as "Kaiser's coders") from performing physician queries for Sepsis diagnoses as required by the ICD-9 Guidelines, (b) implementing unwritten policies requiring Kaiser's coders to code ICD-9 diagnosis codes for Sepsis based solely on the physician's instructions to code Sepsis instead of relying on the supporting clinical

findings documented in the medical record, (c) using an improper Sepsis diagnostic standard that overstated the frequency of Sepsis diagnoses, (d), aggressively diagnosing Sepsis as part of a strategy to lower the reported Sepsis mortality rate at KFH hospitals throughout California, and (e) KFHP, TPMG and SCPMG, as an express condition of receiving capitation payments from CMS, routinely and annually falsely certifying that such ICD-9 diagnosis codes for Sepsis were accurate, complete and truthful to their best knowledge, information and belief, required by CMS as a condition of receiving payment, when KFHP, TPMG and SCPMG knew or should have known that such certifications were false.

53. During or about 2008 and 2009, TPMG and SCPMG adopted unwritten policies instructing Kaiser's coders to code Sepsis based upon a physician's instruction to code Sepsis and prohibiting Kaiser's coders from performing coding queries regarding Sepsis diagnoses. Kaiser's coders are required to perform coding queries by the ICD-9 Guidelines and AHIMA's Ethical Coding Guidelines when such queries are needed to trigger clinical documentation required to properly support or to properly rule out a Sepsis diagnosis.

54. In 2009, several KFHP HIM directors from Southern California KFH hospitals including the HIM Director for KFH Hospital-Woodland Hills, Vivian Wachs, Registered Health Information Technician (RHIT), informed Stein, co-chair of the Southern California Region monthly HIM meetings, and all of the HIM Directors in attendance, that their local SCPMG physician leadership was insisting that Sepsis be coded at the physician's discretion and without supporting clinical findings properly documented in the medical record as required by the ICD-9 Guidelines and by CMS. (42 C.F.R. §422.310(b)-(d); CMS Publication 100-16, Medicare Managed Care Manual, Ch. 7 §40 et seq.) In response, Stein requested and was granted permission by Dr. Kirk Tamaddon, SCPMG's Chief Regional Physician Liaison, who chaired the SCPMG regional meetings, to make a presentation on Sepsis coding guidelines and Sepsis medical record documentation requirements at the October 2009, SCPMG physician leadership meeting.[10] In addition to Dr. Tamaddon, the meeting was attended by at several

[10]Physician Liaisons are responsible for implementing monitoring and communicating to physicians and staff the PMG's regional directives regarding coding and documentation.

SCPMG Regional Medical Directors, and several Regional Operational Directors, approximately 15 SCPMG Physician Liaisons and/or physician representatives and 20 SCPMG Data Quality Managers and Encounter Coding Specialists.

55. Stein's presentation explained, among other things, that all of the symptoms and clinical findings that supported a diagnosis of Sepsis and all clinical findings and test results that support a diagnoses of organ dysfunction caused by Sepsis had to be documented in the medical records. Additionally, because of the complexity of the diagnoses, it was likely that Kaiser's coder needed to clarify the clinical findings and symptoms by making queries to physicians intended to trigger clarifying responses of the medical record's supporting documentation. Shortly after Stein finished her presentation, Dr. Albert Dreskin, SCPMG's Woodland Hill's Physician Liaison, informed the attendees to disregard the presentation Stein had just given, falsely asserting that SCPMG physicians had no requirement to provide additional clinical documentation for a Sepsis diagnoses because Sepsis was a clinical decision therefore all that was required was for the physician to write Sepsis. Dr. Dreskin concluded his remarks by reminding the attendees that diagnosing Sepsis was worth a lot of money to the defendants because it increased the MA enrollees' risk adjustment scores. In fact, the submission of the ICD-9 diagnosis code for sepsis resulted in a HCC risk score of.754 which increased the capitation payments for each such diagnosed MA enrollee by approximately $8,500 for the next year.

56. Following the October 2009 SCPMG physician leadership meeting and continuing through to the present, SCPMG physician and coding leadership routinely insisted that Sepsis be coded whenever the physician wrote the word Sepsis in the medical record and prohibited Kaiser's coders from making coding queries to clarify the supporting medical record documentation. Such coding instructions and query restrictions violate ICD-9 Guidelines and AHIMA ethical coding guidelines. The blatantly improper coding practice was unique to the defendants' coding and documentation of Sepsis. Kaiser's coders did not have such coding instructions or query restrictions with regards to any other diagnoses. Stein witnessed these improper Sepsis coding policies at KFH Hospital-Panorama City and was informed by other

HIMs that such polices were adopted by the defendants throughout KP's Southern California region.

57. Throughout the term of his employment at KFH Hospital-South Bay, Bone had been instructed that he was **not** to query physicians regarding Sepsis diagnoses and was required to code Sepsis as instructed by the physician regardless of the medical record documentation. Bone had learned from other coders that such Sepsis coding instructions and query restrictions had been adopted by the defendants throughout KP's Southern California region. Stein and Bone are informed and believe, and upon such information and belief alleges, that the SCPMG's policy to prohibit physician queries of Sepsis diagnoses and to require Kaiser's coders to code Sepsis based on the physician's instructions (as opposed to the supporting clinical findings documented in the medical record) originated with TPMG and then was implemented by SCPMG during or about 2009.

58. As part of KP's national agenda to lower its reported Sepsis mortality rates at KFH hospitals, during or about 2009, KFHP and TPMG implemented Sepsis identification and treatment protocols that were then implemented by SCPMG on or about 2011 and eventually by all PMGs. These Sepsis treatment protocols were purportedly based upon the EGDT treatment protocols. These Sepsis diagnostic criteria improperly used the Sepsis definition promulgated at the 1991 Consensus Conference, i.e., Sepsis is SIRS plus infection, as a diagnostic standard, even though by 2009 it was well established the SIRS criteria could not be properly used as a diagnostic standard. Specifically, defendants' Sepsis diagnostic standard required an elevated value in two or more SIRS criteria plus an infection to diagnose Sepsis.

59. As discussed above in paragraph 40, the 1991 Sepsis definition was adopted to assist researchers identify subjects to participate in clinical trials and promote Sepsis research. By 2001 it was well established that Sepsis could not be diagnosed just be using the SIRS criteria plus infection (i.e., whenever two or more SIRS criteria were elevated and the patient had an infection) because such criteria applies to many patients who are suffering less severe conditions than Sepsis. Instead, the SIRS criteria potentially diagnosed Sepsis only when no other possible explanation or medical condition that accounted for the elevated levels. (The

ACCP/SCCM Consensus Conference Statement - 1991, *Chest,* June 1992, Vol.101, 1644, 1646.) The 2001 Conference published an expanded list of criteria to diagnose Sepsis but concluded that these criteria, like the SIRS criteria, were not specific to Sepsis so such criteria could not be adopted as a diagnostic "gold standard" that could be used conclusively in every instance. The physician still had to make a judgment call to determine if the symptoms were the result of the patient having a life threatening inflammatory response to infection that potentially threatened to shut down organs resulting in death, i.e., Sepsis, or had some less severe medical condition that explained the abnormal criteria values.

60. Defendants, in adopting a diagnostic standard based on two elevated SIRS criteria, ignored the then current standard of medical care by not including the well accepted expanded criteria from the 2001 Conference to diagnose Sepsis and to diagnose Sepsis with acute organ failure. (2001 International Sepsis Definitions Conference, *Intensive Care Med.* (2003) Vol. 29, 530, 532.) Defendants' Sepsis diagnostic standard also disregards the 2001 Conference's conclusions which unequivocally stated that the SIRS criteria were overly broad, too sensitive and nonspecific for sepsis making them unsuitable for use as a diagnostic standard. A conclusion that also was well accepted by the then concurrent and future medical literature.

61. Despite these flaws, Defendants nonetheless adopted the SIRS criteria as a diagnostic standard for KP's national Sepsis program knowing that using the SIRS diagnostic standard results in false and inaccurate Sepsis diagnoses. KP's physician training materials regarding diagnosing Sepsis failed to instruct KP's physicians **not** to diagnose Sepsis if the elevated SIRS criteria were due to a condition other than Sepsis, failed to instruct physicians to perform timely blood draws, i.e., prior to the administration of antibiotics, so accurate blood cultures are obtained (required to identify blood-born pathogens) and fails to discuss or incorporate any of the additional Sepsis diagnostic criteria from the 2001 International Sepsis Definitions Conference that physicians are suppose to use in making a Sepsis diagnosis.

62. SCPMG's, TPMG's and KP's adoption of improper Sepsis specific coding policies, (i.e., policies that required Kaiser's coders to code Sepsis based on the physician's

instruction and also prohibited Kaiser's coders from making coding queries regarding Sepsis diagnoses), ensured that the Kaiser Health Plans submitted false and inaccurate Sepsis diagnoses to CMS as valid RAD. Such improper coding policies were and are unique to Sepsis for SCPMG, TPMG and KFH and violated the ICD-9 Guidelines and AHIMA ethical coding Guidelines. For all other syndromes, diseases, illnesses or injuries, Kaiser's coders were able to perform coding queries without restrictions. Sepsis was the only diagnoses that Kaiser's coders were not allowed to use coding queries to clarify the supporting documentation in the medical record.

63. During and between 2010 and 2014, while working at KFH Hospital-South Bay, Bone coded approximately three to four Sepsis diagnoses a week for MA enrollees that were not admitted to the ICU or the hospital but were discharged home after being put in an emergency room observation bed for between 3 to 48 hours. Frequently, such MA enrollees were not treated aggressively for Sepsis per KP's Sepsis treatment protocols, including but not limited to, failing to insert a central venous catheter and failing to perform blood draws prior to the administration of antibiotics to obtain blood cultures. During this time period, Bone also routinely coded Sepsis diagnoses for MA enrollees who were not admitted to the ICU but were admitted to the hospital for a brief stay of up to three days. Such MA enrollees typically were not treated aggressively for Sepsis per KP's Sepsis treatment protocols, including but not limited to, failing to insert a central venous catheter and failing to perform blood draws prior to the administration of antibiotics to obtain blood cultures. Bone observed, that the medical records of MA enrollees diagnosed with Sepsis, but not admitted to the hospital and MA enrollees admitted to the hospital for a brief stay but were not treated for Sepsis aggressively, did not have sufficient clinical findings documented in their medical records that supported the Sepsis diagnoses.

64. The fact that MA enrollees that were diagnosed with Sepsis in the ER but discharged without being admitted to the ICU or the hospital is a strong indication that such MA enrollees did not have Sepsis, and that such Sepsis diagnosis and coding were false. It is not credible that an MA enrollee is diagnosed with sepsis and/or sepsis with acute organ failure

does not require an admission to the ICU for treatment let alone is discharged without ever being admitted to the hospital. Rather, such MA enrollees did not have Sepsis and the ER observations confirmed this fact allowing the physician to confidently send the MA enrollee home without admission to the hospital or ICU.

65. As a result of KP's emphasis on diagnosing Sepsis and adopting an improper and overly broad Sepsis diagnostic standard, the number of Sepsis diagnoses by PMG and SCPMG physicians, between 2009 and 2013, increased dramatically at all California KFH hospitals; as much as, between 200% to 300% at some facilities. This increase in the number of Sepsis diagnoses had the effect of dramatically lowering KFH California Hospital's reported Sepsis mortality rates. The reported Sepsis mortality rates were a ratio comparing the number of Sepsis cases diagnosed at KFH Hospitals to the number of patients that expired as a result of having Sepsis. As such, the reported Sepsis mortality ratio was easy to manipulate by increasing the number of Sepsis diagnoses with false Sepsis diagnoses. By 2013, KP claimed that its reported Sepsis mortality rate had dropped to approximately 9% and its average length of stay for such cases had dropped to 3.5 days. . (An Innovative Approach to Sepsis Prevention Saves Lives, (Dec 6, 2013) https://businesshealth.kaiserpermanente. org/insights /sepsis-prevention.) KP's reported Sepsis mortality rate and average length of stay during 2010 through 2013 are unrealistic numbers and an indication that the Kaiser Health Plans submitted false Sepsis diagnoses. As discussed below in greater detail, at least one KP physician complained, challenging the validity of KP's reported sepsis mortality rates. A recent landmark study comparing the difference in effectiveness between EGDT treatment protocols and traditional treatment methods, when properly implemented using hospital systems with best practices, achieved sepsis mortality rates of 19%-20%. (A Randomized Trial of Protocol-Based Care for Early Septic Shock, The ProCESS Investigators, *N Engl J Med* (July 24, 2014); Vol. 370, 1683, 1690.) For 2010, the national mean length of stay for MA enrollees with Sepsis as a primary diagnosis was 9 days and 15 days for those with Sepsis as a secondary diagnosis. (AHRQ, H-CUP Statistical Brief #122, p.4 (October 2011).)

66. In November 2010, KP's management identified KFH Hospital-Panorama City

as being an outlier for its reported Sepsis mortality rates of 25% despite noting, that all by all other quality measures, the facility was one of KFH's very best hospitals. The e-mail instructed executives responsible for KFH Hospital Panorama City to solve this problem by identifying more cases of Sepsis. Dr. Chiara Conrado, KFH-Panorama City Hospital's Pulmonary and Intensive Care Specialist, responded complaining that the sepsis mortality rates from other KFH facilities was not believable, that the data used was not verified for accuracy, that Kaiser's coders and physicians incorrectly diagnose and code sepsis and that the KP's reported Sepsis mortality rates for 2010 were lower than what other significant studies achieved and therefore KP's data was not credible.

67. Dr. Conrado received no response to her complaints. At all times relevant defendants were required to maintain an effective compliance program designed to identify and ameliorate Medicare fraud waste and abuse (FWA). (42 C.F.R. §422.503(b)(4)(vi); Medicare Managed Care Manual, Ch.21 §§30-50 et seq.) Pursuant to statutory and CMS requirements, defendants' compliance officer was required to initiate a timely investigation into Dr. Conrado's accusations regarding the potential Medicare FWA issues raised by Dr. Conrado's complaints but failed to do so. (42 C.F.R.§422.503(b)(4)(vi); CMS Publication 100-16, Medicare Managed Care Manual, Ch. 21 §Ch.21 §50.7.1.)[11] [12]

68. KP's use of an overly broad and improper Sepsis diagnostic standard imposes on KFHP, TMPG, SCPMG and KFH, a duty to exercise reasonable diligence to identify, and redact false and incorrect Sepsis diagnoses from the RAD submitted to CMS. This duty is an integral part of the Medicare Advantage's regulatory framework intended to help MAOs, such

[11] 42 C.F.R. §422.504(b)(4)(vi) states in part: [Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse.]

[12] Medicare Managed Care Manual, Ch.21 §50.7.1 – Conducting a Timely and Reasonable Inquiry of Detected Offenses, states in part, "Sponsors must conduct a timely and well-documented reasonable inquiry into any compliance incident or issue involving potential Medicare program noncompliance or potential FWA. . . . It may be discovered through a hotline, a website, an enrollee complaint. . . . Regardless of how the noncompliance or FWA is identified, sponsors must initiate a reasonable inquiry as quickly as possible, but not later than 2 weeks after the date the potential noncompliance or potential FWA incident was identified."

as KFHP, avoid the submission of false and fraudulent claims to CMS and avoid the receipt and retention of improper overpayments from CMS. (42 C.F.R. §§ 422.326(c), 422.503(b)(4)(iv), 422.504(l)(2); CMS Publication 100-16, Medicare Managed Care Manual, Ch.7 §40 et seq. and Ch.21 §§30-50 et seq.; 79 Fed.Reg. 29844, 29923-24 (March 23, 2014).)

69. KFHP failed to use reasonable diligence in its selection of its Sepsis diagnostic standard and also by failing to identify and redact false and unsupported Sepsis diagnoses from the RAD submitted to CMS. As an express condition of receiving its monthly capitation payments on behalf of MA enrollees, KFHP certified based on its best knowledge, information and belief that the RAD it submitted to CMS was accurate, truthful and complete. (42 C.F.R. §422.504(l)(2).) Because KFHP did not attempt to identify and redact the potentially false and fraudulent Sepsis diagnoses obtained from its contracted medical groups, KFHP's statutorily required certifications were false. KFHP's best knowledge, information and belief were that many of the Sepsis diagnoses were inaccurate, untruthful and incomplete, and were not supported by the clinical documentation in the medical record as required by CMS. (CMS Publication 100-16, Medicare Managed Care Manual, Ch.7 §40 et seq.) Furthermore, without a process to identify known potentially inaccurate Sepsis diagnoses, KFHP had no legitimate basis for making such a certification. (See, 79 Fed.Reg. 29844, 29923-24 (March 23, 2014).)

70. During and between approximately 2008 until the present, KFH hospital facilities, including all those in California, utilized the above described, false sepsis diagnoses and documentation practices to up-coded its FFS Medicare hospital claims that KHF submitted to CMS on behalf of FFS Medicare patients. The false and fraudulent sepsis ICD-9 and later ICD-10 diagnosis codes where mapped to the KFH's hospital's master claim bill, CMS form UB-04 as DRG 871 or 872 and submitted to CMS, resulting in a false and fraudulent claims in violation of the FCA. Each such false sepsis claim resulted in KFH receiving approximately $7000 to $12,000 of additional revenue from CMS.

71. Stein is informed and believes and upon such information and belief alleges, that between 2010 until her departure in 2011, the Kaiser Health Plans, KFH and PMGs adopted and implemented the Sepsis diagnosis, coding and treatment policies described above and in

paragraphs 53 through 58 as national policies and procedures.

72. Bone is informed and believes, and upon such information and belief alleges, that throughout the term of his employment (2010 until the present) the Kaiser Health Plans, KFH and PMGs adopted and implemented the unwritten Sepsis diagnosis, coding and treatment policies described above and in paragraphs 53 through 58 as national policies and procedures.

MALNUTRITION

73. During and between approximately 2006 until on or about December 11, 2013, SCPMG, TPMG, KFH and KFHP participated in a fraudulent scheme to up-code and falsely diagnose malnutrition and severe malnutrition of their MA enrollees in order to increase the risk adjustment scores for the MA enrollees so diagnosed. This fraudulent scheme was conducted at all KFH Hospitals throughout California and involved the diagnoses and coding of malnutrition and severe malnutrition based upon assessments performed by dieticians employed by KFH. The KFH dietician used a rubber stamp on the MA enrollee's medical record indicating that in his/her opinion the MA enrollee suffered from malnutrition or severe malnutrition. SCPMG and TPMG physicians then countersigned the stamp in the MA enrollees' medical record. Based solely on the presence of the physician's countersignature of the dietician's rubber stamp, KFH coders recorded the ICD-9 diagnosis codes for malnutrition or severe malnutrition as indicated by the rubber stamp. KFHP submitted to CMS these malnutrition and severe malnutrition ICD-9 diagnosis codes as RAD for use in calculating that MA enrollees' risk adjustment scores, which increased CMS's capitated payments to defendants.

74. Valid RAD must be the result of a face-to-face encounter with a physician or other qualified clinician that has been identified by CMS as an acceptable source of RAD. (CMS Publication 100-16, Medicare Managed Care Manual, Ch. 7 §40 et seq., §120.1.1, Table 19; 42 C.F.R. 422.310(b)-(d).) In order for RAD to be valid for submission to CMS, each ICD-9 diagnosis code submitted must have the appropriate clinical findings documented in the MA enrollee's medical record. (CMS Publication 100-16, Medicare Managed Care Manual, Ch. 7 §40 et seq.; 42 C.F.R. § 422.310(b)-(d).) KFH Hospitals' use of the dietician's stamp for

diagnosing and documenting malnutrition fails on both accounts, there is no face-to-face-encounter with a qualified physician where the physician makes a diagnoses of malnutrition, nor does the dietician's rubber stamp substitute for physician documenting in the medical record a diagnosis of malnutrition or the clinical indicators and clinical findings reviewed and observed necessary to support the malnutrition or severe malnutrition diagnosis.

75. The Medicare Managed Care Manual, Ch. 7, §120.1.1, Table 19, lists physician speciality types and other clinicians that are acceptable sources of RAD. Dieticians are not included in this list. KP's dieticians cannot make medical diagnosis on behalf of MA enrollees. The physicians' countersignatures of the dietician's stamp does not constitute a valid physician diagnosis or medical record documentation of such.

76. Kaiser's coders did not record the ICD-9 diagnosis code for malnutrition or severe malnutrition when the physician's countersignature was missing from the stamp. In those instances, the medical record was routed back to the physician for his/her countersignature. Physician's counter-signatures that were initially missing from the dieticians's stamp were routinely "rubber stamped" without question and countersigned but no entry showing that the physician made a diagnosis of malnutrition was made in the medical record itself.

77. The ICD-9 code book contains the following malnutrition diagnosis codes: 260 Kwashiorkor; 261 Nutritional marasmus; 262 Other severe, protein-calorie malnutrition; 263.0 Malnutrition of moderate degree; 263.1 Malnutrition of mild degree; 263.2 Arrested development following protein-calorie malnutrition; 263.8 Other protein-calorie malnutrition; and 263.9 Unspecified protein-calorie malnutrition. Each of these distinct ICD-9 diagnosis codes for malnutrition require specific and appropriate supporting clinical findings in order to be properly documented and submitted as a valid diagnoses and valid RAD.

78. Clinical findings, such as the number of folds in the patients' skin, the size of their triceps, their body mass index, weight changes over time, dietary intake, wasting of muscle and debility, albumin and pre-albumin blood test, digestive difficulties or digestive diseases, absorption problems, eating disorders and feeding method (i.e. oral or tubal feeding)

are examples of clinical findings that treating physicians were required to record in the MA enrollees' medical record as the result of a face-to-face encounter as part of documenting a diagnosis of malnutrition or severe malnutrition. Without appropriate clinical findings, Kaiser's coders were unable to determine which malnutrition ICD-9 diagnosis code to record.

79. During on or about December 13, 2013, KFH disseminated instructions prohibiting the continued practice of allowing physicians to countersign a dieticians stamp as a method of diagnosing and documenting malnutrition. The instruction states, among other things, "It is not appropriate to have physicians counter-sign the dieticians stamp as a means of establishing the diagnosis by the physician." (Citing, CMS 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Resource Guide.) KHF and KFHP's new policy required the treating physician to document the appropriate clinical findings in the MA enrollees' medical records to support malnutrition diagnoses.

80. 42 C.F.R. § 422.326, the Medicare Advantage Overpayment Report and Return regulation, requires KFHP to notify CMS within 60 days from the time it knew or should have known that it received an overpayment and make arrangements with CMS for the return of such overpayments. KFHP violated 42 C.F.R. § 422.326 by failing and refusing to exercise reasonable diligence with respect to the identification and return of overpayments resulting from the improper diagnosing, documenting and coding of malnutrition and severe malnutrition of its MA enrollees as described above. Failing to notify CMS of the receipt of an overpayment within 60 days is an obligation under the False Claims Act and subjects KFHP to FCA liability under 31 U.S.C. §3729(a). KFHP's and/or the other defendants' policy change regarding the diagnoses, documentation and coding of malnutrition is evidence that KFHP was aware that it submitted invalid malnutrition RAD to CMS that resulted in the receipt and retention of overpayments during prior periods.

81. During and between 2006 and at December 11, 2013, KFHP, SCPMG, TPMG and KFH knowingly submitted or caused to be submitted false and fraudulent malnutrition diagnoses to CMS as valid RAD for use in calculating KFHP's capitation payments. Such submissions of false malnutrition diagnoses resulted in false and fraudulent claims in violation

of the FCA. The impact of KFHP's false malnutrition diagnoses and upcoding is profound. In Los Angeles County, each fraudulent diagnosis of malnutrition increased the subsequent CMS's capitation payments for that MA enrollee by approximately $9,000 per year. During the time frame referenced above, KFHP submitted to CMS tens of thousands of such fraudulent malnutrition diagnoses on behalf of KFHP's MA enrollees.

82. During and between 2006 until approximately December 11, 2013, KFH hospital facilities, including all those in California, allowed physicians to improperly countersign dieticians stamps as a means of diagnosing and documenting malnutrition for Medicare FFS patients. The false and fraudulent malnutrition ICD-9 diagnosis codes where mapped to the KFH's hospital's master claim bill, CMS form UB-04 as MCCs (i.e., secondary diagnoses, increasing the DRG's value) and submitted to CMS, resulting in false claims in violation of the FCA. KFH received between $1,000 to $5,000 of additional revenue per patient discharge from CMS as a result of the false malnutrition claims. KFHP nor KFH made no effort to notify CMS of overpayments that resulted from the submission of such false and fraudulent Medicare FFS malnutrition claims, although per 42 C.F.R. §401.305, KFHP was obligated to report and timely return such overpayments.

83. Stein and Bone are informed and believe, and upon such information and belief allege, that the above-described improper diagnosis, coding and documentation practices for malnutrition described above in paragraphs 73 through 82 are, and since 2006 were, national polices and performed in the same improper manner nationwide by Kaiser Health Plans, KFH and the PMGs.

AORTIC ATHEROSCLEROSIS

84. Aortic atherosclerosis is a chronic condition that results in the build up of arterial plaque or fatty deposits in the patient's aorta. Treatment typically involves a medication regimen of statin family drugs (also used to lower cholesterol) and life style changes, such as diet and exercise. Severe cases can cause fatal episodes of coronary artery disease, while less severe conditions can be tolerated by some patients as long as the disease does not rapidly progress. Aortic atherosclerosis can be detected and diagnosed from a typical chest x-ray.

85. During and between 2007 until on or about April 4, 2016, KFH and the Kaiser Health Plans instructed their coders to code the ICD-9 and later ICD-10 diagnosis code associated with aortic atherosclerosis (AA) any time there was an X-Ray report indicating that AA was present and also anytime that a physician noted the presence of AA or listed AA in the patient's medical record. This instruction applied to MA patients admitted to Kaiser inpatient facilities in, among other states, California. Pursuant to these instructions, KFH coders coded KFH's MA patients with an AA diagnosis based simply upon an X-ray or the physician's notation of AA in the medical record, without the medical record reflecting that the patient was treated for his/her AA condition. These instructions directly contradict CMS's instructions set forth in the 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations, RESOURCE GUIDE, (the "CMS 2008 Resource Guide") available at, https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSC%20Archive2008%20Resource%20Guidea.pdf/$FILE/2008%20Resource%20Guidea.pdf. The CMS 2008 Resource Guide clearly prohibits coding risk adjustment data from X-rays stating in part, "MA organizations **must not submit documentation from laboratory and diagnostic radiology services as a standalone medical record for data validation.** This type of medical documentation is insufficient for coding purposes." (Emphasis added.) CMS 2008 Resource Guide at p. 16.

86. Kaiser's coding and documentation of AA was not in compliance with the ICD-9 and later ICD-10 Coding and Documentation Guidelines, which requires the patient to have received treatment for a chronic condition, such as AA, in order to validly code the ICD-9 or ICD-10 diagnosis code for such chronic condition, and prohibits coding based upon an abnormal test result, such as from an x-ray. The bare notation of AA in the medical record or noting the presence of AA without documentation of the medical services provided to treat the AA condition is insufficient documentation to support the submission of an AA diagnosis code to CMS, as RAD for use in calculating KFHP's capitation payments. As a result of the foregoing, KFHP submitted RAD that included the improperly diagnosed and documented AA for use in calculating KFHP's capitation payments. The submission of such RAD to CMS

resulted false and fraudulent claims in violation of the FCA. AA has a HCC risk score of approximately .300 resulting in increased prospective capitation payments of approximately $2000-$3000 for each enrollee for which KFHP submitted improperly diagnosed or documented AA RAD.

87. On or about April 4, 2016, KFH issued the following instructions regarding the coding of AA:

> After having gone through a clinical review at the time of updating the list of examples of systemic conditions, AA was determined not to meet the definition of a systemic condition and does not appear on the final list of examples of systemic conditions. The clinician must do more than just list this condition. There must be documentation to show how it impacted the current encounter. It will be up to the region to decide if they want to query the provider about this condition when it is only listed. Without a query and additional documentation from the provider to show it impacted the encounter it cannot be coded.

88. After April 4, 2016 instruction regarding coding and documentation of AA was disseminated, the ICD-10 diagnosis code for AA were recorded by Kaiser coders when medical record documented treatment for AA, as opposed to the condition simply being identified. This change is consistent with the ICD-10 Coding and Documentation Guidelines, Section III(B) and Section IV(I) Chronic Diseases, which states:

> Section III(B) Abnormal Findings - "Abnormal findings and other diagnostic results are not coded and reported unless the provider indicates their clinical significance."
>
> Section IV(I) Chronic Diseases - "Chronic diseases treated on an ongoing basis may be coded and reported as many times as the patient receives treatment and care for the condition(s)"

89. Prior to the April 4, 2016 instruction, KFH and the Kaiser Health Plans regularly monitored the coding of AA for their hospital patients to ensure that every time AA was noted in the medical record, AA was coded by Kaiser's coders, but did not ensure that such AA coded diagnoses met the requirements for coding AA under the ICD-9 and later the ICD-10 Coding and Documentation Guidelines. On at least two occasions during the course of Bone's employment, KFH's internal auditors notified him that he failed to properly code AA diagnoses where the only documentation in the medical record was that AA had been observed as a result

of a chest x-ray, but no treatment for AA had been documented. Bone was required to fix the problem by coding the ICD-9 diagnosis code for AA for such encounters.

90. All RAD to be submitted to CMS for use in calculating the Kaiser Health Plans' capitation payments must be the result of face-to-face physician encounters that are supported by properly documented medical records. All medical record documentation must be performed in accordance with ICD-9 and later ICD-10 Coding and Documentation Guidelines. (Medicare Managed Care Manual, Ch. 7 §40, et seq.) As a result of the foregoing, all of the ICD-9 and/or ICD-10 diagnosis codes for AA, that where inaccurately coded, including but not limited to, because there was no medical documentation of the patient receiving contemporaneous treatment for AA, are invalid to submit to CMS as RAD for use in calculating Kaiser's capitation payments and result in the submission of false claims.

91. Kaiser made no attempt to determine the amount of the overpayments it received from CMS resulting from the submission of falsely diagnosed and improperly documented AA diagnoses and failed to notify CMS of the receipt of overpayments nor attempt to refund the same as required by 42 C.F.R §422.326. .

REFRESH FRAUDS

92. As will be explained in greater detail below, between 2010 and the present, KFHP, KFH, TPMG and SCPMG and the remaining PMGs submitted or caused to be submitted false and fraudulent RAD resulting from KFHP's practice of "refreshing" missing HCC diagnosis codes. These frauds were accomplished by (a) routinely and intentionally making improper late medical record entries, (b) amending the medical record without valid face-to-face encounters, (c) failing to include the supporting clinical documentation in the amended medical record required to support the new HCC diagnosis codes, (d) performing improper written leading physician queries, (e) improperly making diagnoses from problem lists, (f) concealing the frauds by illegally destroying the written queries, and (g) deceiving MA enrollees to obtain medically unnecessary and non-covered medical services.

93. At all times relevant, CMS allowed MAOs an additional period of time (Data Lag Period) after the end of the payment year to submit additional valid RAD and withdraw

previously submitted invalid RAD arising from services rendered during that payment year. The end of the Data Lag Period was the final RAD cutoff date after which CMS no longer accepted any new or withdrawn RAD for that payment year, and CMS used the RAD for that payment year to risk adjust the MAO's capitation payments for the next payment year. When the HCC risk adjustment model was relatively new, the Data Lag Period was two years after the end of the payment year. Over time, CMS shortened the Data Lag Period to 13 months after the end of the payment year.

94. After the end of the payment year, but before the end of the Data Lag Period, MAOs such as KFHP can retrospectively review the medical records of its MA enrollees to ensure that the RAD submitted to CMS was properly supported by medical records and withdraw unsupported diagnosis codes. MAOs can also submit to CMS previously unreported HCC diagnosis codes if the medical record supports such additional diagnoses, or in certain cases, make an amendment to the medical record based on the last face-to-face encounter the physician had during the payment year if the physician has a recollection of the face-to-face encounter and there is sufficient clinical findings in the existing medical record to make such a diagnoses.

95. Beginning in 2006 and continuing to the present, TPMG and SCPMG and the other PMGs implemented separate programs designed to identify "missing" HCC diagnosis codes and have the physicians "refresh" the missing HCC diagnoses. TPMG and SCPMG considered HCC diagnoses to be missing when the HCC diagnoses had been submitted to CMS as RAD arising from services rendered during the last closed payment year, but had not been submitted in the subsequent payment year, subject to a pending Data Lag Period (e.g., if 2010 was the last closed payment year, 2011 is the subsequent payment year with a Lag Data Period pending between January 1, 2012 through January 31, 2013). TPMG and SCPMG separately monitored the success of their respective programs to increase the number of HCC related diagnoses that were submitted to CMS and then shared information regarding best practices. TPMG achieved its upcoding objectives by using complex computer technology such as convergent medical terminology (CMT) and data mining algorithms to build upcoding into

the coding process then carefully tracked the ongoing implementation of its data mining results to ensure its HCC coding objectives were achieved. SCPMG developed a simpler approach that did not use CMT or complex data mining algorithms. Instead, SCPMG upcoding relied primarily on using improper leading written and verbal coding queries to instruct physicians to add high value HCC related diagnoses to their patients medical records. This allowed SCPMG coders to instruct SCPMG physicians to add via addendums, missing HCC related ICD-9 and ICD-10 diagnosis codes to their patients medical records. The use of such leading coding queries is a very efficient and effective way to increase the patient's HCC score and related capitation payments; however, it is also deemed an illegal practice that results in fraudulent and improper medical record documentation.

96. During on or about 2009, plaintiff and Relator Marcia Stein attended a conference sponsored by SCPMG at its Regional Office in Pasadena California. In attendance were representatives from TPMG and all other PMGs both in person and via teleconferencing. The purpose of the meeting was to share best practice information with the PMGS for capturing missing HCC related diagnoses. SCPMG's use of leading written and verbal leading coding queries had clearly achieved the best results of all the PMGs regarding the quantity of additional HCC related diagnoses captured and submitted to CMS. Many out of state PMGs expressed an interest in having SCPMG help them implement similar programs for their PMG. Based upon this meeting, Stein is informed and believes and thereupon alleges that a majority of the PMGs adopted SCPMG's tactics of utilizing improper written and verbal leading queries to fraudulently document missing HCC related ICD-9 and ICD-10 diagnosis codes for submission to CMS as RAD. SCPMG's increase in HCC diagnosis codes submitted to CMS as RAD from improper leading queries dramatically increased their patients' RAD and resulted in several hundred million dollars of increased revenue for KP. This number increased as more PMGs incorporated SCPMG's improper leading query practice into their process for capturing missing HCCs.

97. The refresh process started with KFHP's contracted medical groups compiling a "hit-list" of high value HCC risk adjustment scores and their related ICD-9 diagnosis codes

("HCC diagnoses") from which to work from. The hit-list included, but was not limited to, all of the complications related to diabetes, and the different manifestations and complications of coronary disease, chronic kidney disease, old myocardial infarction, and cancer. Each year, TPMG, SCPMG and other PMGs performed a computer searches to data-mine the RAD submissions from the last closed payment year to identify the MA enrollees with a history of hit-list HCC diagnoses, and used those results to identify missing HCC related diagnoses. SCPMG's coders then sent written leading queries to the MA enrollees' attending physicians with a list of the missing HCC diagnoses. The leading physician queries instructed the SCPMG physicians to "refresh" (i.e., add) the missing HCC diagnosis to a particular MA enrollee's medical record. SCPMG's coders would follow up with verbal queries during one-on-one meetings with SCPMG physicians to ensure that the hit-list HCC diagnoses were added by a signed addendum. Most SCPMG physicians readily complied with SCPMG coders' requests to add the hit-list HCC diagnoses identified in the leading queries.

98. All RAD that MAOs, such as the Kaiser Health Plans, submit to CMS must be the result of a face-to-face physician encounter and must be supported by a medical record documented in accordance with ICD-9 Guidelines. (Medicare Managed Care Manual, Ch. 7 §40 et seq.; 42 C.F.R. §422.310(d).) An addendum is new documentation used to add information to an original entry. Addenda should be timely and bear the current date and reason for the additional information to an original entry. (AHIMA (2015) Amendments, Corrections and Deletions in the Electronic Health Record Tool Kit, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_044678.hcsp?dDocName=bok1_044678.)

99. CMS's rule governing late medical entries states, "All services provided to beneficiaries **are expected to be documented in the medical record at the time they are rendered**. Occasionally, certain entries related to services provided are not properly documented. In this event, the documentation will need to be amended, corrected, or entered after rendering the service." (Emphasis added.) (Medicare Program Integrity Manual, Ch. 3, §3.3.2.5(A) and made applicable to Medicare Advantage by 42 C.F.R. §§ 422.101(b),

422.310(d).) Similarly, AHIMA Guidelines state, "When documenting an omission, validate the source of additional information as much as possible. Late entries should be documented as soon as possible. While there is no time limit for writing a late entry, the more time that passes, the less reliable the entry becomes."[13] (AHIMA (2015) Maintaining a Legally Sound Health Record: Paper and Electronic, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028509.hcsp?dDocName=bok1_028509.)

100. The "refreshed" HCC diagnoses were invalid as RAD for submission to CMS by the Kaiser Health Plans because they violated the requirements described in the preceding two paragraphs. First, the refreshed HCC diagnoses were not the result of a face-to-face encounter. In order to document an omission via a late entry amendment, the physician must have a specific recollection of the subject face-to-face encounter with the MA enrollee. As the encounters being "refreshed" were between 6 to 12 months before the hit-list addenda were added to the medical records, the physicians did not have specific detailed recollections of the encounter required to add clinical findings in support of hit-list HCC diagnoses being added.

101. Second, the addenda themselves were not supported by required clinical documentation in the medical record in accordance with ICD-9 Guidelines. This is apparent on the face of the addenda which consist of just the addition of the hit-list HCC diagnoses, signed and dated by the physician. Physicians who executed the addenda did not review the medical record entries (i.e., the portion being amended) to confirm that the medical record contained the necessary clinical findings to support the new HCC diagnoses, nor did they include language in the addenda that identified the reasons for the late entry nor any required clinical findings to support adding the new HCC diagnoses as required by the ICD-9 and AHIMA coding and documentation guidelines. The mere conclusion of the new HCC diagnoses, without the supporting clinical findings necessary to support the conclusion, is not an acceptable method of medical record documentation. Additionally, such incomplete documentation does not indicate that it is "related to a service that was provided" during the

[13]For reference, 42 C.F.R. § 482.24(c)(4)(viii) requires hospitals to complete the medical record entries of the final diagnoses within 30 days of discharge.

prior encounter as required by CMS's rule for late entries. (Medicare Program Integrity Manual, Ch. 3, §3.3.2.5(A).) Therefore, such improperly "refreshed" HCC diagnoses codes should not have been submitted to CMS as RAD.

102. Typically, the hundreds of employee physicians, including but not limited to Drs. Steven Steinberg, Margabanhu Ramanathan, Edward Brosnan, David Wong, Sivakumar, and Young Cho, who worked for KFHP's contracted medical groups, responded to the leading queries by signing any "refresh" addenda that their employers requested via the leading physician queries and problem lists.

103. The addenda refreshing HCC diagnoses were also invalid because they (a) failed to provide an explanation regarding why the late entry needed to be made as required by the AHIMA standards for making addenda, (b) failed to identify the services rendered during the subject encounter that the refreshed HCC diagnoses are related to as required by CMS's rules for late entries, and (c) failed to identify the clinical findings required to support the new HCC diagnosis codes as required by the ICD-9 Guidelines.

104. "To support why a query was initiated, all queries must include the clinical indicator(s) that show why a more complete or accurate diagnosis or procedure is requested."[14] (AHIMA Practice Brief, Guidelines for Achieving a Compliant Query Practice (9-13-2015) at p.2; http://ahima.org/library.) The Kaiser's coders' queries used for refreshing missing HCC diagnoses did not contain any clinical indicators or explanations in support of why they was initiated. Kaiser's coders only reviewed the problem list of missing HCC diagnoses and the prior year's medical record visit to confirm that the HCC diagnoses identified by the computer data mining was present. The medical record visit to be refreshed was not reviewed by the Kaiser's coders and thus they had no basis to make the queries.

105. Defendants' refreshing of HCC diagnoses relied on using invalid, leading physician queries that instructed physicians which HCC diagnoses to add to the medical records. "A leading query is one that is not supported by the clinical elements in the health

[14]AHIMA is a member of the ICD9CM and the ICD10CM Cooperating Parties, thus their practice briefs are considered "industry standards" for coding and query policy and procedure.

record and/or directs a provider to a specific diagnosis or procedure." (AHIMA Practice Brief, Guidelines for Achieving a Compliant Query Practice (9-13-2015) at p. 2; http://ahima.org/library.) AHIMA sets the national standards regarding coding and documentation, and as such its policies are incorporated into the medical record documentation requirements by CMS. (42 C.F.R. § 422.310(d).) The AHIMA guidelines do not allow leading queries because they result in inaccurate and/or false medical record documentation. After the leading queries were used by TPMG and SCPMG physicians, the queries were illegally destroyed.

106. At all times mentioned, CMS required the Defendants to maintain the medical record on some type of retrievable format for at least ten years. No part of the medical record is supposed to be destroyed. CMS and AHIMA requirements make it clear that if the physician query results in adding new diagnoses, then the query becomes part of the medical record and must be maintained for use in auditing the validity of the diagnoses contained therein. (Medicare Quarterly Compliance Newsletter, Vol 2, Issue 3 at p. 13 (April 2012); https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/medqtrlycomp_newsletter_icn907927.pdf.) Further, AHIMA Guidelines strongly recommend that the queries to physicians be preserved as part of the medical record and if a different policy is adopted, then the query must be maintained as business record. (AHIMA Practice Brief, Guidelines for Achieving a Compliant Query Practice (9-13-2015) at p. 4; http://ahima.org/library.)

107. At all times mentioned, KFH's medical record retention policy included Kaiser's coders' queries as part of the medical record. At al times mentioned, the Kaiser Health Plans allowed their contracted medical groups, including TPMG and SCPMG, to adopt different and conflicting medical record retention policies that improperly failed to preserve Kaiser's coders' queries as part of the medical record or as a business record. Instead, Kaiser's coders' queries were destroyed immediately after the queries had been reviewed by the physicians. The Kaiser Health Plans always had the ability to require their exclusively contracted medical groups, including TPMG and SCPMG, to adopt unified policies for medical record retention, query

practices, late entries into the medical records and medical record documentation. CMS's regulations mandates that the Kaiser Health Plans' contracts contain such rights and provisions. (42 C.F.R. § 422.504(i)(3)(iii).)

108. Realtors are informed and believe, and based upon such information and belief allege, that the Kaiser Health Plans knowingly allowed its exclusively contracted medical groups, including TPMG and SCPMG, to adopt conflicting policies for using leading queries, preserving queries as part of the medical record, making late entries and amendments to the medical record, and medical record documentation expressly for the purpose of committing the Medicare frauds described in this complaint.

109. During or about 2006, several HIM managers, such as Sarah Lynch, the HIM Director KFH-Hospital, Orange County, and Jennifer Squires, Encounter Coding Manager, vigorously protested the required use of leading queries and their immediate destruction after the physicians had "refreshed" the medical record. Ms. Lynch was informed by her supervisor, that SCPMG and Kaiser requested that Ms. Lynch be terminated for complaining about the use and destruction of leading queries and was informed by her supervisor that in order to avoid termination Ms. Lynch had to refrain from further complaints regarding these issues. Ms. Lynch's complaints regarding leading queries and destruction of medical records should have triggered a compliance investigation by the Kaiser Health Plans to identify the Medicare FWA caused by the leading Kaiser coders' queries complained of and issued appropriate corrective action plans. (42 C.F.R. § 422.503(b)(4)(vi); Medicare Managed Care Manual, Ch. 21 §30-50, et seq.)

110. In a number of instances, the MA enrollees had not been seen by their PCP during the open payment year and/or had not been seen during the current year. These MA enrollees' medical records could not be refreshed with a late entry addenda because there was no face-to-face encounter, and therefore no medical record entry during the relevant time period to amend. TPMG and SCPMG contacted these MA enrollees and falsely informed them that they needed to schedule a follow-up visit with their primary care physician (PCP). In addition, there were MA enrollees who had been seen during the open payment year, but for whom no HCC

diagnoses were identified during those encounters. These MA enrollees were also scheduled for a follow up visit for the sole purpose of identifying HCC diagnoses to submit to CMS.

111. The RAD obtained from the physician followup encounters to refresh the MA enrollees' hit-list HCC diagnoses were invalid because the RAD was obtained from medically unnecessary and uncovered services. Among the services that are specifically excluded from original Medicare are routine physicals and medically unnecessary services. (42 C.F.R. § 411.15(a)(1),(k), and made applicable to Medicare Advantage by 42 C.F.R. § 422.101(b)(1)-(2).) The improper followup visits that the Kaiser Health Plans and their contracted medical groups, including TPMG and SCPMG performed, were in fact routine physicals or otherwise medically unnecessary services because the MA enrollees were deceived into having the exam, the MA enrollees had no medical complaint that required followup, and the true secret purpose of the visit was specifically to "refresh" certain hit-list HCC diagnoses that the Kaiser Health Plans had identified. The Kaiser Health Plans cannot submit to CMS improperly obtained, non-covered and excluded services as valid RAD. (42 C.F.R. § 422.310(c).)

112. Although the Kaiser Health Plans cover routine physicals as a supplemental benefit, such coverage is limited to exams that are, "[M]edically appropriate preventative care in accordance with generally accepted professional standards of practice." The Kaiser Health Plans' Evidence of Coverage (2011) at p. 51, available at: https://www.sjretirement.com/Uploads/PF/2011%20Kaiser %20Hawaii %20KPSA% 20EOC.pdf.) As will be explained in greater detail below, because the purpose of the visit was to deceitfully obtain hit-list HCC diagnoses, the refresh followup visits do no meet The Kaiser Health Plans' coverage criteria under its supplemental benefits. Further, the services the MA enrollees received during such physician encounters to "refresh" their prior HCC diagnoses were not documented as a covered routine physical by the Kaiser Health Plans, TPMG, SCPMG and the other PMGs, but were falsely documented as some other type of consultative visit. Because the MA enrollees' physician visits to refresh old HCC diagnoses were medically unnecessary, the services were not covered under the Kaiser Health Plans' MA plans, and the Kaiser Health Plans could not legally submit RAD to CMS arising from such services.

113. On or about, 2006 Stein was present at a meeting with SCPMG regional physician leadership from the Panorama City Medical Clinic, including but not limited to Drs. Zollner, Hoffman, Steinberg, and Candac Lumeg. Present by telephone were the SCPMG physician leaders, from the Santa Clarita Medical Clinic. The purpose of the meeting was to discuss the data-mining results provided by SCPMG's Pasadena headquarters that identified MA enrollees who needed a current physician encounter in order for their HCC diagnoses to be refreshed. A telephone call script had been provided by defendants that was used to schedule the appointments with the MA enrollees and was read out loud for the meeting participants. The call script informed the MA enrollees that they needed to come in for a follow up visit for the HCC condition that had been identified by defendants. This statement was false. The SCPMG physician leaders candidly admitted that the follow-up exams were medically unnecessary and being used as pretext; the true purpose of the visits was for the PCPs to refresh the hit-list HCC diagnoses.

114. During this meeting it was decided that Mary Stefanec, RN, Department Administrator for Internal Medicine, would be responsible for supervising staff to contact the identified enrollees assigned to physicians located at the SCPMG medical clinics in Panorama City and convince such MA enrolles to come in for the purported follow-up visits. Similar meetings were schedule throughout California.

115. None of the MA enrollees were informed the that the true purpose of the visit was for the Kaiser Health Plans' contracted medical groups to "refresh" prior HCC diagnoses so that the Kaiser Health Plans would receive a higher capitation payment from CMS. Instead, the MA enrollees were deceived into scheduling medically unnecessary routine physicals by being falsely informed that their medical condition required a follow-up visit. These untrue MA enrollee solicitations violated CMS's regulations that prohibit making untrue or misleading statements to enrollees. (42 C.F.R. § 422.752(a)(5)(ii).)

116. Beginning in 2006 and continuously thereafter, Kaiser Health Plans, KFH and the PMGs annually scheduled tens of thousands of MA enrollee visits for the purpose of "refreshing" prior hit-list HCC diagnoses by falsely claiming such visits were medically

necessary follow-up visits. The true purpose of the MA enrollees' medical appointments was for the Kaiser Health Plans' contracted medical groups to collect HCC diagnoses for submission to CMS by the Kaiser Health Plans. The untruthful statements to the MA enrollees constituted a false statement material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

FIRST CLAIM FOR RELIEF

(Violation of 31 U.S.C. §3729(a) against all Defendants: False Sepsis Claims)

117. Relators reallege and incorporate by reference paragraphs 1 through 72 of this complaint as though fully set forth at length.

118. At all times mentioned during the six years prior to the filing of this action and continuing, the Kaiser Health Plans periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*) to CMS to obtain overpayments from CMS. Likewise, at all times mentioned during the six years prior to the filing of this action, KFH and the PMGs periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*)(3) to assist the Kaiser Health Plans obtain overpayments from CMS.

119. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(A) and (B) by (a) knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval by CMS, and (b) knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims to CMS to get such false and fraudulent claims paid or approved by CMS.

120. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(C) by conspiring to violate 31 U.S.C. § 3729(a)(1)(A) and/or (B).

121. Defendants the Kaiser Health Plans knew or should have known that they had improperly received and retained excessive payments for Medicare FFS patients for whom the Kaiser Health Plans submitted to CMS Sepsis diagnoses that were routinely falsely and

fraudulently diagnosed, coded and lacked adequate supporting medical record documentation, in violation of 42 C.F.R. § 401.305. Such falsely diagnosed Sepsis patients were not admitted to the hospital nor the ICU, but held in an emergency room observation bed for up to 72 hours and then sent home.

122. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R. § 401.305.

123. At all times mentioned, the Kaiser Health Plans acted with reckless disregard and deliberate ignorance in failing to identify and notify CMS of such overpayments in violation of 42 C.F.R. § 401.305.

124. Defendants the Kaiser Health Plans knew or should have known that they had improperly received and retained excessive capitation payments for MA enrollees for whom the Kaiser Health Plans submitted to CMS Sepsis diagnoses that were routinely falsely and fraudulently diagnosed, coded and lacked adequate supporting medical record documentation, in violation of 42 C.F.R. § 422.326.

125. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

126. At all times mentioned, the Kaiser Health Plans acted with reckless disregard and deliberate ignorance in failing to identify and notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

127. The Kaiser Health Plans are, and at all times mentioned were, required to "be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS" and further expected to "implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment." (79 Fed.Reg. 29884, 29921, 29923-24 (May 14, 2014).) Because the Kaiser Health Plans adopted overly broad Sepsis diagnostic standards, they had an obligation to establish a process to identify and redact or withdraw

incorrect Sepsis diagnosis codes from the RAD they submitted to CMS. The Kaiser Health Plans did not adopt any such process to identify and redact or withdraw incorrect Sepsis ICD-9 diagnosis codes from the RAD they submitted to CMS and failed to do so. As a result of the Kaiser Health Plans' failure and refusal to reasonably attempt to meet this obligation, it had no legitimate basis for certifying that the Sepsis ICD-9 diagnosis codes it submitted to CMS were accurate, complete and truthful RAD.

128. Defendants were obligated to conduct a Medicare FWA investigation in response to Dr. Conrado's repeated complaints that sepsis was being inaccurately diagnosed and coded. The Kaiser Health Plans and their first tier contracted entities failed and refused to conduct such a compliance investigation, rendering the Kaiser Health Plans' compliance program, as it pertains to the submission of false Sepsis diagnosis codes, ineffective. Because the Kaiser Health Plans had an ineffective compliance program, they had no legitimate basis on which to certify the accuracy, completeness and truthfulness of the Sepsis ICD-9 diagnosis codes they submitted as RAD to CMS between 2010 to the present. (42 C.F.R. §§ 422.503(b)(4)(vi), 422.504(i)(3)(iii)&(l); Medicare Managed Care Manual, Ch. 21 §50.7.1; 79 Fed.Reg. 29884, 29923-24 (May 14, 2014).)

129. At all times mentioned during the six years prior to the filing of this action, Relators are informed and believe, and upon such information and belief allege, that as a result of the false claims, concealments and use of false records and statements, CMS paid more than it would have paid had defendants properly and truthfully diagnosed, coded, documented, reported and revealed and withdrawn the false diagnosis codes for Sepsis that it submitted to CMS, and that those diagnosis codes that were unsupported by their required documentation in the respective medical records. Relators are informed and believe, and upon such information and belief allege, that CMS overpaid defendant Kaiser Health Plans at least $500 million more than CMS would have as a result of the defendants' submission of false and fraudulent claims, concealments and use of false records and statements to get such false claims approved and paid by CMS.

130. At all times mentioned during the six years prior to the filing of this action, the

Kaiser Health Plans routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(G) by knowingly concealing or knowingly and improperly avoiding or decreasing their obligation to pay or transmit to the Government the overpayments made by CMS as a result of the submission of false and unsupported Sepsis diagnoses to CMS.

131. At all times mentioned during the six years prior to the filing of this action, the defendants routinely violated 31 U.S.C. § 3729(a)(1)(G) by repeatedly and annually falsely certifying that the ICD-9 diagnosis codes for Sepsis submitted to CMS as RAD were accurate, complete and truthful based upon the defendants' best knowledge, information and belief, and/or knowingly concealing or knowingly and improperly avoiding or decreasing defendants' obligation to pay or transmit CMS's overpayments to the Government.

132. As a result of defendants' conduct, defendants are liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent claims alleged above.

133. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants are liable to the Government for civil penalties for each such false and fraudulent claim for payment.

134. Relators are also entitled to recover their attorney's fees, costs and expenses from defendants pursuant to 31 U.S.C. § 3730(d).

SECOND CLAIM FOR RELIEF

(For violations of 31 U.S.C. § 3729(a) against all Defendants: False Malnutrition Claims)

135. Relators reallege and incorporate by reference paragraphs 1 through 37 and paragraphs 73 through 83 of this complaint as though fully set forth at length.

136. At all times mentioned during the six years prior to the filing of this action, the Kaiser Health Plans periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*) to CMS to obtain overpayments from CMS. Likewise, at all times mentioned during the six years prior to the filing of this action, KFH and the PMGs periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*)(3) to assist the Kaiser Health

Plans obtain overpayments from CMS.

137. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(A) and (B) by (a) knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval by CMS, and (b) knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims to CMS to get such false and fraudulent claims paid or approved by CMS.

138. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(C) by conspiring to violate 31 U.S.C. § 3729(a)(1)(A) and/or (B).

139. At all times mentioned during the six years prior to the filing of this action, defendant Kaiser Health Plans and defendant KFH knew or should have known that they had improperly received and retained excessive FFS Medicare payments for Medicare beneficiaries for whom the Kaiser Health Plans and K Foundation Hospitals submitted to CMS malnutrition diagnoses that were routinely and repeatedly falsely and fraudulently diagnosed and coded, and were lacking adequate supporting medical record documentation in violation of 42 C.F.R. § 401.305.

140. At all times mentioned, the Kaiser Health Plans and Kaiser Foundation Hospitals failed to exercise reasonable diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R. § 401.305.

141. At all times mentioned, the Kaiser Health Plans and the Kaiser Foundation Hospitals acted with reckless disregard and deliberate ignorance in failing to identify and notify CMS of such overpayments in violation of 42 C.F.R. § 401.305.

142. At all times mentioned during the six years prior to the filing of this action, defendant Kaiser Health Plans knew or should have known that they had improperly received and retained excessive capitation payments for MA enrollees for whom the Kaiser Health Plans submitted to CMS malnutrition diagnoses that were routinely and repeatedly falsely and fraudulently diagnosed and coded, and were lacking adequate supporting medical record

documentation in violation of 42 C.F.R. § 422.326.

143. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

144. At all times mentioned, the Kaiser Health Plans acted with reckless disregard and deliberate ignorance in failing to identify and notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

145. The Kaiser Health Plans are, and at all times mentioned were, required to "be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS" and further expected to "implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment." (79 Fed.Reg. 29884, 29921, 29923-24 (May 14, 2014).) KFHP had an obligation to establish a process to identify and redact or withdraw incorrect or unsupported malnutrition diagnosis codes from the RAD it submitted to CMS. KFHP did not adopt any such process to identify and redact or withdraw incorrect or unsupported malnutrition ICD-9 diagnosis codes from the RAD it submitted to CMS and failed to do so. As a result of KFHP's failure and refusal to reasonably attempt to meet this obligation, it had no legitimate basis for certifying that the malnutrition ICD-9 diagnosis codes it submitted to CMS were accurate, complete and truthful RAD.

146. At all times mentioned during the six years prior to the filing of this action, Relators are informed and believe, and upon such information and belief allege, that as a result of the false claims, concealments and use of false records and statements, CMS paid more than it would have paid had defendants properly and truthfully diagnosed, coded, documented, reported and revealed and withdrawn the false diagnosis codes for malnutrition that it submitted to CMS, and that those diagnosis codes that were unsupported by their required documentation in the respective medical records. Relators are informed and believe, and upon such information and belief allege, that CMS overpaid defendant KFHP at least $500 million more than CMS would have as a result of the defendants' submission of false and fraudulent claims,

concealments and use of false records and statements to get such false claims approved and paid by CMS.

147. At all times mentioned during the six years prior to the filing of this action, the defendants routinely violated 31 U.S.C. § 3729(a)(1)(G) by repeatedly and annually falsely certifying that the ICD-9 diagnosis codes for malnutrition submitted to CMS as RAD were accurate, complete and truthful based upon the defendants' best knowledge, information and belief, and/or knowingly concealing or knowingly and improperly avoiding or decreasing defendants' obligation to pay or transmit CMS's overpayments to the Government.

148. As a result of defendants' conduct, defendants are liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent claims alleged above.

149. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants are liable to the Government for civil penalties for each such false and fraudulent claim for payment.

150. Relators are also entitled to recover their attorney's fees, costs and expenses from defendants pursuant to 31 U.S.C. § 3730(d).

THIRD CLAIM FOR RELIEF

(For violations of 31 U.S.C. § 3729(a) against all Defendants: False Aortic Atherosclerosis Claims)

151. Relators reallege and incorporate by reference paragraphs 1 through 37 and paragraphs 84 through 91 of this complaint as though fully set forth at length.

152. At all times mentioned during the six years prior to the filing of this action, the Kaiser Health Plans periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*) to CMS to obtain overpayments from CMS. Likewise, at all times mentioned during the six years prior to the filing of this action, KFH and the PMGs periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*)(3) to assist the Kaiser Health Plans obtain overpayments from CMS.

153. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(A)&(B) by (a) knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval by CMS, and (b) knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims to CMS to get such false and fraudulent claims paid or approved by CMS.

154. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(C) by (a) conspiring violate 31 U.S.C. § 3729(a)(1)(A) and/or (B). At all times mentioned during the six years prior to the filing of this action, defendant Kaiser Health Plans knew or should have known that they had improperly received and retained excessive capitation payments for MA enrollees for whom the Kaiser Health Plans submitted to CMS aortic atherosclerosis diagnoses that were routinely and repeatedly falsely and fraudulently diagnosed and coded, and were lacking adequate supporting medical record documentation in violation of 42 C.F.R. § 422.326.

155. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

156. At all times mentioned, the Kaiser Health Plans acted with reckless disregard and deliberate ignorance in failing to identify and notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

157. The Kaiser Health Plans are, and at all times mentioned were, required to "be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS" and further expected to "implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment." (79 Fed.Reg. 29884, 29921, 29923-24 (May 14, 2014).) KFHP had an obligation to establish a process to identify and redact or withdraw incorrect or unsupported malnutrition diagnosis codes from the RAD it submitted to CMS. KFHP did not adopt any such process to identify and redact or withdraw incorrect or

unsupported aortic atherosclerosis ICD-9 diagnosis codes from the RAD it submitted to CMS and failed to do so. As a result of KFHP's failure and refusal to reasonably attempt to meet this obligation, it had no legitimate basis for certifying that the aortic atherosclerosis ICD-9 diagnosis codes it submitted to CMS were accurate, complete and truthful RAD.

158. At all times mentioned during the six years prior to the filing of this action, Relators are informed and believe, and upon such information and belief allege, that as a result of the false claims, concealments and use of false records and statements, CMS paid more than it would have paid had defendants properly and truthfully diagnosed, coded, documented, reported and revealed and withdrawn the false diagnosis codes for aortic atherosclerosis that it submitted to CMS, and that those diagnosis codes that were unsupported by their required documentation in the respective medical records. Relators are informed and believe, and upon such information and belief allege, that CMS overpaid defendant KFHP at least $500 million more than CMS would have as a result of the defendants' submission of false and fraudulent claims, concealments and use of false records and statements to get such false claims approved and paid by CMS.

159. At all times mentioned during the six years prior to the filing of this action, the defendants routinely violated 31 U.S.C. § 3729(a)(1)(G) by repeatedly and annually falsely certifying that the ICD-9 diagnosis codes for aortic atherosclerosis submitted to CMS as RAD were accurate, complete and truthful based upon the defendants' best knowledge, information and belief, and/or knowingly concealing or knowingly and improperly avoiding or decreasing defendants' obligation to pay or transmit CMS's overpayments to the Government.

160. As a result of defendants' conduct, defendants are liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent claims alleged above.

161. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants are liable to the Government for civil penalties for each such false and fraudulent claim for payment.

162. Relators are also entitled to recover their attorney's fees, costs and expenses from

defendants pursuant to 31 U.S.C. § 3730(d).

FOURTH CLAIM FOR RELIEF

(For violations of 31 U.S.C. § 3729(a) against all Defendants: False Refresh Claims)

163. Relators reallege and incorporate by reference paragraphs 1 through 37 and paragraphs 92 through 116 of this complaint as though fully set forth at length.

164. At all times mentioned during the six years prior to the filing of this action, the Kaiser Health Plans periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*) to CMS to obtain overpayments from CMS. Likewise, at all times mentioned during the six years prior to the filing of this action, KFH and the PMGs periodically, and at least annually, submitted knowingly false and fraudulent certifications required under 42 C.F.R. § 422.504(*l*)(3) to assist the Kaiser Health Plans obtain overpayments from CMS.

165. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(A) and (B) by (a) knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval by CMS, and (b) knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims to CMS to get such false and fraudulent claims paid or approved by CMS.

166. At all times mentioned during the six years prior to the filing of this action, defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(C) by conspiring to violate 31 U.S.C. § 3729(a)(1)(A) and/or (B).

167. At all times mentioned, defendant the Kaiser Health Plans knew or should have known that they had improperly received and retained excessive capitation payments for MA enrollees for whom the Kaiser Health Plans submitted to CMS HCC diagnoses that were routinely and repeatedly falsely and fraudulently "refreshed", diagnosed and coded, and were lacking adequate supporting medical record documentation in violation of 42 C.F.R. § 422.326.

168. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R.

§ 422.326.

169. At all times mentioned, the Kaiser Health Plans acted with reckless disregard and deliberate ignorance in failing to identify and notify CMS of such overpayments in violation of 42 C.F.R. § 422.326.

170. The Kaiser Health Plans are, and at all times mentioned during the six years prior to the filing of this action were, required to "be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS" and further expected to "implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment." (79 Fed.Reg. 29884, 29921, 29923-24 (May 14, 2014).) The Kaiser Health Plans had an obligation to establish a process to identify and redact or withdraw incorrect or unsupported "refreshed" HCC diagnosis codes from the RAD it submitted to CMS. The Kaiser Health Plans did not adopt any such process to identify and redact or withdraw incorrect or unsupported "refreshed" ICD-9 diagnosis codes from the RAD they submitted to CMS and failed to do so. As a result of the Kaiser Health Plans' failure and refusal to reasonably attempt to meet this obligation, they had no legitimate basis for certifying that the "refreshed" ICD-9 diagnosis codes they purportedly added to their MA enrollees' medical records and submitted to CMS were accurate, complete and truthful RAD.

171. At all times mentioned during the six years prior to the filing of this action, Relators are informed and believe, and upon such information and belief allege, that as a result of the false claims, concealments and use of false records and statements, CMS paid more than it would have paid had defendants properly and truthfully diagnosed, coded, documented, reported and revealed and withdrawn the false diagnosis codes for improperly and invalid "refreshed" ICD-9 diagnosis codes that it submitted to CMS, and that those diagnosis codes that were unsupported by their required documentation in the respective medical records. Relators are informed and believe, and upon such information and belief allege, that CMS overpaid the Kaiser Health Plans at least $500 million more than CMS would have as a result of the defendants' submission of false and fraudulent claims, concealments and use of false

records and statements to get such false claims approved and paid by CMS.

172. At all times mentioned during the six years prior to the filing of this action and continuing, the defendants routinely violated 31 U.S.C. § 3729(a)(1)(G) by repeatedly and annually falsely certifying that the "refreshed" ICD-9 diagnosis codes submitted to CMS as RAD were accurate, complete and truthful based upon the defendants' best knowledge, information and belief, and/or knowingly concealing or knowingly and improperly avoiding or decreasing defendants' obligation to pay or transmit CMS's overpayments to the Government.

173. As a result of defendants' conduct, defendants are liable to the Government for three times the amount of damages sustained by the Government as a result of the false and fraudulent claims alleged above.

174. As a result of defendants' conduct, 31 U.S.C. § 3729(a) provides that defendants are liable to the Government for civil penalties for each such false and fraudulent claim for payment.

175. Relators are also entitled to recover their attorney's fees, costs and expenses from defendants pursuant to 31 U.S.C. § 3730(d).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Qui Tam Relators pray for relief as follows:

FOR THE FIRST CLAIM FOR RELIEF

1. Treble the Government's damages according to proof;

2. Civil penalties according to proof;

3. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR THE SECOND CLAIM FOR RELIEF

4. Treble the Government's damages according to proof;

5. Civil penalties according to proof;

6. A relator's award of up to 30% of the amounts recovered by or on behalf of the

Government;

FOR THE THIRD CLAIM FOR RELIEF

7. Treble the Government's damages according to proof;

8. Civil penalties according to proof;

9. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR THE FOURTH CLAIM FOR RELIEF

10. Treble the Government's damages according to proof;

11. Civil penalties according to proof;

12. A relator's award of up to 30% of the amounts recovered by or on behalf of the Government;

FOR ALL CLAIMS FOR RELIEF

13. Attorney's fees, expenses, and costs; and

14. Such other and further relief as the Court deems just and proper.

THE ZINBERG LAW FIRM
A Professional Corporation

HANAGAMI LAW
A Professional Corporation

Dated: Nov 12, 2021

By: _____
William K. Hanagami
Attorneys for Plaintiffs and Qui Tam Relators,
Marcia Stein and Rodolfo Bone

REQUEST FOR JURY TRIAL

Plaintiffs and Qui Tam Relators hereby request a trial by jury.

THE ZINBERG LAW FIRM
A Professional Corporation

HANAGAMI LAW
A Professional Corporation

Dated: Nov 12, 2021

By: _____
William K. Hanagami
Attorneys for Plaintiffs and Qui Tam Relators,
Marcia Stein and Rodolfo Bone