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OAKLAND

9 Attorneys for Plaintiffs and Qui Tam Relators,
10 Marcia Stein and Rodolfo Bone

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA
13 OAKLAND COURTHOUSE

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

16 Plaintiffs,

17 vs.

18 KAISER FOUNDATION HEALTH PLAN,
19 INC., a California corporation, KAISER
20 FOUNDATION HOSPITALS, a California
21 corporation, KAISER FOUNDATION
22 HEALTH PLAN OF COLORADO, a
23 Colorado corporation, KAISER
24 FOUNDATION HEALTH PLAN OF
25 GEORGIA, INC., a Georgia corporation,
26 KAISER FOUNDATION HEALTH PLAN
27 OF THE MID-ATLANTIC STATES, INC., a
28 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

CASE NO. 16-CV-05337-DMR

FIRST AMENDED COMPLAINT
FOR VIOLATIONS OF THE
FALSE CLAIMS ACT, AND
REQUEST FOR JURY TRIAL

[UNDER SEAL PER 31 U.S.C. §
3730(b)(2)]

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.

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 in Oregon and Washington to KP patients.

24. GHP is a regional medical group consisting of physicians providing medical

1 services in Washington to KP patients.

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

12 26. While employed at KFH Hospital-Panorama City, Stein reported to both the
13 regional SCPMG and the KFH Hospital-Panorama City's managements. On behalf of
14 SCPMG, Stein supervised a staff of over 100 full-time employees, including coders, billers,
15 trainers, clinic staff and legal assistants (with regard to physician malpractice claims), and was
16 charged with implementing defendants' policies and procedures regarding medical record
17 documentation and compliance, HIPAA security, and physician training and education. Stein
18 attended monthly SCPMG Clinic Administrator and Regional Department meetings. Stein was
19 also responsible for overseeing the Panorama City hospital's health information systems,
20 coding, medical record documentation, HIPAA security, and related compliance issues, as well
21 as being a contact person for various state and federal hospital data reporting questions or
22 issues. Stein co-chaired the monthly regional HIM Director's meetings (for the Southern
23 California Region), chairing the majority. Such meetings addressed coding and documentation
24 problems with SCPMG senior leadership on behalf of other regional KFH HIM Directors.

25 27. Between 2010 and 2016, Rodolfo Bone (Bone) was a part employee of KFH
26 at its South Bay hospital in Harbor City, California as a per diem coder. At the beginning of
27 2016 his position was moved to KFH's Southern California corporate offices in Pasadena,
28 California where he continued as a per diem coder reporting to KFH's Regional Revenue

1 Cycle. Beginning in 1996 and continuing until the present, Bone has been employed full time
2 by Good Samaritan Hospital, located in Los Angeles California, as a Coding Supervisor and
3 Coding Auditor. Bone was born and raised in the Philippines where he graduated from
4 medical school, and was and is licensed to practice medicine in the Philippines.

5 MEDICARE ADVANTAGE AND RISK ADJUSTMENT

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

14 29. At all times relevant, each of the Kaiser Health Plans had a MA contract with
15 CMS, the federal agency that administers the Medicare program, to provide MA benefits to
16 eligible enrollees. Eligible MA enrollees selected the Kaiser Health Plan in their locale and
17 selected a primary care physician from a directory of PMG physicians near the enrollees’
18 residence. The revenues from these MA contracts were a significant source of revenues for
19 defendants. The revenues the PMGs received for the MA enrollees they serviced were also
20 the primary source of funding for any physician bonuses that were paid.

21 30. At all times relevant, Section 1853(a)(3) of the Social Security Act [42 U.S.C.
22 § 1395w-23(a)(3)] required the Government’s Centers for Medicare and Medicaid Services
23 (CMS) to risk adjust payments to Medicare Advantage organizations (MAOs), such as the
24 Kaiser Health Plans. In general, the risk adjustment methodology relied on enrollee diagnoses,
25 as specified by the International Classification of Disease, Ninth Revision Clinical
26 Modification (ICD-9) Guidelines (ICD-9 Guidelines), to prospectively adjust capitation
27 payments for a given enrollee based on the health status of the enrollee. Diagnosis codes
28 (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 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

¹Not 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.

1 diagnoses that MA organizations submit for payment be supported by medical record
 2 documentation.”] In order to be a properly documented medical record, the medical record
 3 entries must, among other things, (1) be the result of a MA enrollee’s face-to-face encounter
 4 with a medical provider or examiner legally authorized to perform the service rendered under
 5 applicable Medicare laws, regulations and rules,² (2) that accurately and truthfully documents
 6 the findings necessary to support the medical diagnoses by the medical provider/examiner in
 7 accordance with applicable Medicare laws, regulations and rules,³ and (3) signed by the
 8 medical provider/examiner as required by Medicare.⁴ Further, the diagnoses must be coded
 9 in accordance with all applicable national guidelines, including but not limited to International
 10 Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting,
 11 and the American Health Information Management Association (AHIMA) national guidelines
 12 for ethical coding.⁵ AHIMA is a member of the ICD9CM and the ICD10CM Cooperating
 13 Parties, thus their practice briefs are considered “industry standards.” Failure to meet any of
 14 these required elements results in the medical record not being properly documented and being
 15 unable to support RAD arising therefrom and invalidating the submission of such RAD (i.e.,
 16 ICD-9 diagnosis codes).

17
 18 ²See, Medicare Managed Care Manual, Ch. 7, § 40 [“All diagnosis codes submitted must be
 19 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).

20 ³42 C.F.R. §§ 422.310(c)(2) and (d), 422.504(l)(2)-(3); CMS Pub.100-08, Medicare Program
 21 Integrity Manual, Ch. 3, §3.3.2.5; International Classification of Disease 9th Revision Guidelines
 22 (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
 23 International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and
 Reporting.”]

24 ⁴Medicare 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).

25 ⁵42 C.F.R. § 422.310(d)(1) [“MA organizations must submit data that conform to CMS’
 26 requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant
 27 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 and Deletions in the electronic
 28 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).

1 33. MAOs do not typically submit claims for services rendered to CMS in the
2 traditional FFS sense. The capitation payments are paid in advance, and by accepting the
3 capitated payments, MAOs agree to be at risk for all of the health care costs for the MA
4 enrollees assigned to it. Capitation payments are made prospectively with the data for the
5 current calendar year being used to risk adjust the capitation payments for that specific MA
6 enrollee in the subsequent calendar year. Instead of submitting traditional FFS claims, MAOs
7 submit RAD which are used by CMS to calculate and risk adjust the capitation payments paid
8 by CMS to the MAOs for each MA enrollee. Because the capitation payments are adjusted
9 based upon the MAOs' submission of RAD, the submission of RAD is considered by the
10 Government as the submission of claims for payment to CMS for purposes of enforcing civil
11 and criminal penalties for making false claims under Social Security Act §§1128A [42 U.S.C.
12 § 1320a-7a], 1128 B [42 U.S.C. § 1320a-7b] and the False Claims Act, 31 U.S.C. § 3729.

13 34. CMS has made it clear that MAOs, such as the Kaiser Health Plans, "must be
14 continuously diligent regarding the accuracy and completeness of payment-related data they
15 submit to CMS" and "are expected to have effective and appropriate payment evaluation
16 procedures and effective compliance programs as a way to avoid receiving or retaining
17 overpayments." Additionally, "we [CMS] have always expected that MA organizations or Part
18 D sponsors implement, during the routine course of business, appropriate payment evaluation
19 procedures in order to meet the requirement of certifying the data they submit to CMS for
20 purposes of payment." (79 Fed.Reg. 29,884, 29,921, 29,923-29,924 (May 14, 2014).)

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

26 36. As will be explained in detail below, at various times during and between 2010
27 and the present, the defendants submitted false and fraudulent claims to CMS in violation of
28 31 U.S.C. § 3729(a) by (a) making and submitting to CMS false, inaccurate and exaggerated

1 diagnoses for sepsis that were not supported by properly documented medical records, (b)
 2 making and submitting to CMS false, inaccurate and exaggerated diagnoses for malnutrition
 3 that were not supported by properly documented medical records, (c) making and submitting
 4 to CMS false, inaccurate and exaggerated diagnoses for aortic atherosclerosis that were not
 5 supported by properly documented medical records, (d) making and submitting to CMS
 6 diagnoses resulting from improper and unethical leading physician queries, (e) performing
 7 medical record reviews designed to only identify and report to CMS previously unreported
 8 diagnosis codes that concealed and failed to withdraw from CMS previously reported
 9 diagnosis codes that were unsupported by the reviewed medical records, and (f) providing
 10 medically unnecessary and non-covered routine physical examinations in order to identify and
 11 submit invalid RAD for use in calculating Kaiser Health Plans' capitation payments to CMS.

12 37. Although the majority of Kaiser's Medicare patients are beneficiaries under the
 13 MA program, approximately 20% of Kaiser's Medicare patients are beneficiaries under
 14 original fee-for-service (FFS) Medicare, i.e., Medicare Part A and/or Part B. Defendants'
 15 fraudulent misconduct alleged below concerning sepsis and malnutrition (briefly mentioned
 16 in paragraph 36(a)-(b)) involved Kaiser's FFS Medicare patients and MA patients. Inpatient
 17 hospital facilities, such as KFH, billed CMS for FFS Medicare services by mapping ICD-9 and
 18 later ICD-10 diagnosis codes into diagnostic related groups (DRGs), major complications and
 19 co-morbidities (MCCs), each of which is assigned a monetary value by CMS depending, in
 20 part, on the county where the hospital is located. In FFS Medicare hospital billing, DRGs are
 21 primary diagnoses and MCCs are secondary diagnoses. Some but not all MCCs cause an
 22 increase in the DRG's value.

23 SEPSIS

24 38. The current lay-person definition of sepsis and sepsis with acute organ failure
 25 (collectively, "Sepsis") is "Sepsis is a life-threatening condition that arises when the body's
 26 response to an infection injures its own tissues and organs." (The Third International
 27 Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), *JAMA*, (February 23, 2016)
 28 Vol. 315, No. 8, 801, 807.) "Sepsis is not a specific illness but rather a syndrome

1 encompassing a still-uncertain pathobiology. At present, it can be identified by a constellation
 2 of clinical signs and symptoms in a patient with suspected infection.” (*Id.* at 803.) Sepsis is
 3 characterized by “signs of inflammation (vasodilator, leukocyte accumulation, increased micro
 4 vascular permeability) occurring in tissues that are remote from the infection. Systemic
 5 inflammatory response syndrome (SIRS) is an identical clinical syndrome that complicates a
 6 noninfectious insult (e.g., acute pancreatitis, pulmonary contusion). . . . This response can lead
 7 to multiple organ dysfunction syndrome (MODS), which is the cause of the high mortality
 8 associated with these syndromes.” (Sepsis Definitions: Time for Change, *Lancet*, (March 2,
 9 2013), Vol. 381, No. 9868, 774–775 (See, [http://doi.org/10.1016/S0140-6736\(12\)61815-7](http://doi.org/10.1016/S0140-6736(12)61815-7)).)

10 39. The term Sepsis is usually reserved for patients that need to be admitted to the
 11 hospitals intensive care unit (ICU). (See, Sepsis Definition: Time For Change, *Lancet* (March
 12 2, 2013) Vol. 381, No. 9868, pp. 774–775.) Patients who develop Sepsis face a substantial
 13 likelihood of death as it is one of the main causes of death among hospital patients. Sepsis has
 14 been estimated to be the cause or related to of as many as 1 out of every 2 to 3 in-patient
 15 hospital deaths. (Hospital Deaths in Patients With Sepsis From 2 Independent Cohorts, *JAMA*,
 16 (July 2, 2014) Vol. 312, No. 1, 90-92 at p. 90. (See, [http://jama.jamanetwork.com/article](http://jama.jamanetwork.com/article.aspx?articleid=1873131)
 17 [.aspx?articleid=1873131](http://jama.jamanetwork.com/article.aspx?articleid=1873131)).) During 2009, the national mean length of stay for patients who
 18 had Sepsis as their principal diagnosis was 8.8 days and 15.8 days for patients with Sepsis as
 19 a secondary diagnosis. (Agency for Healthcare Research and Quality (AHRQ), HealthCare
 20 Cost and Utilization Project (H-CUP), Statistical Brief #122, p. 4 (October 2011).)

21 40. During 1991, the American College of Chest Physicians (ACCP) and the Society
 22 of Critical Care Medicine (SCCM) convened a Sepsis “Consensus Conference” the purpose
 23 of which, “[I]s to propose a conceptual framework for future studies of the clinical
 24 phenomenon of organ system dysfunction in critical illness, and to lay the foundations for
 25 common terminology and criteria to describe the syndrome.” (The ACCP/SCCM Consensus
 26 Conference Statement - 1991, *Chest*, (June 1992) Vol. 101, 1644, 1648.) In other words, to
 27 provide some broad definitions of Sepsis so that researches could conduct effective clinical
 28 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 PaCO₂ lower than 32 mmHg
- White blood cell count higher than 12,000 cells/ μ l or lower than 4,000/ μ l

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 inflammation (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

⁶The 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.

1 establish the diagnosis of sepsis.” (*Id.* at 533.) The Report included an expansive list of
 2 possible signs, symptoms and potentially septic values, grouped into five main categories,
 3 General Parameters, Inflammatory Parameters Hemodynamic Parameters, Organ Dysfunction
 4 Parameters, and Tissues Perfusion Parameters, to aid physicians in making and confirming
 5 Sepsis as opposed to less severe medical conditions.⁷ (*Id.* at 533-34.)

6 44. The Report emphasized that its expanded list of clinical findings were not
 7 specific to sepsis and therefore, like the SIRS criteria, the list could not be used as a diagnostic
 8 standard in all cases. The physician still had to determine if a medical condition other than
 9 sepsis was the cause of the patient’s symptoms and/or elevated values before diagnosing sepsis
 10 or sepsis acute organ failure, when applicable, and separately determine if such organ failure
 11 was a result of Sepsis or some other cause. Other medical conditions besides Sepsis can also

12
 13 ⁷The complete list of Sepsis diagnostic criteria was stated as Infection documented or
 14 suspected and some of the following:

15 General parameters

16 Fever (core temperature $>38.3^{\circ}\text{C}$) Hypothermia (core temperature
 17 $<36^{\circ}\text{C}$ Heart rate >90 bpm or >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

18 Inflammatory parameters

19 Leukocytosis (white blood cell count $>12,000/\mu\text{l}$) Leukopenia (white
 20 blood cell count $<4,000/\mu\text{l}$) Normal white blood cell count with $>10\%$
 immature forms Plasma C reactive protein >2 SD above the normal
 value Plasma procalcitonin >2 SD above the normal value

21 Hemodynamic parameters

22 Arterial hypotension (systolic blood pressure <90 mmHg, mean
 23 arterial pressure <70 , or a systolic blood pressure decrease >40 mmHg
 in adults or <2 SD below normal for age) Mixed venous oxygen
 saturation $>70\%$ Cardiac index >3.5 l min 1 m^2 ,d

24 Organ dysfunction parameters

25 Arterial hypoxemia ($\text{PaO}_2/\text{FIO}_2 <300$) Acute oliguria (urine output
 26 <0.5 ml kg 1 h or 45 mM/l for at least 2 h) Creatinine increase
 27 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 $<100,000/\mu\text{l}$)
 Hyperbilirubinemia (plasma total bilirubin >4 mg/dl or 70 mmol/l)

28 Tissue perfusion parameters

Hyperlactatemia (>3 mmol/l) Decreased capillary refill or mottling

1 account for increases in the 2001 Conference criteria including, but not limited to, post
 2 operative surgery recovery, minor respiratory infections, minor urinary tract infections, trauma
 3 as well as certain medications. The Report stressed, “It is important that as a practitioner
 4 ‘checks off the boxes’ to establish the diagnosis of sepsis; only findings that cannot be easily
 5 explained by other causes should be included.” *Id.* “Most clinicians do not refer to patients
 6 as septic when they develop an uncomplicated mild upper-respiratory viral infection with
 7 slight fever and tachycardia, (i.e., a faster than normal heart rate.)” (Sepsis Definitions: Time
 8 For Change, *Lancet*, March 2, 2013, Vol. 381, No. 9868, 774–775.)

9 45. Between 2001 and 2010 several organized approaches to identify and treat
 10 Sepsis were proposed. The two most prominent of these organized treatment approaches were
 11 Early Goal-Directed Therapy for the treatment of Sepsis and Sceptic Shock (EGDT) published
 12 in the New England Journal of Medicine (N Engl J Med (November 8, 2001) Vol. 345, 1368-
 13 1377), and continuing since 2002, the Surviving Sepsis Campaign, a joint collaboration of the
 14 Society of Critical Care Medicine and the European Society of Intensive Care Medicine. The
 15 Surviving Sepsis Campaign (SSC) published and continuously updated Surviving Sepsis
 16 Bundles that outline the basic treatment protocols along with detailed treatment guidelines to
 17 provide institutions and physicians with a coordinated effort to measure and manage each of
 18 the five parameters for diagnosing Sepsis identified in the 2001 Conference (i.e., General
 19 Parameters, Inflammatory Parameters Hemodynamic Parameters, Organ Dysfunction
 20 Parameters, and Tissues Perfusion Parameters). During or about 2013, the SSC’s Surviving
 21 Sepsis Bundles and guidelines were adopted by CMS and Center For Disease Control (CDC).

22 46. The SSC Surviving Sepsis Bundle states:

23 TO BE COMPLETED WITHIN 3 HOURS:

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

27 “Time of presentation” is defined as the time of triage in the emergency department or,
 28 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.

1 TO BE COMPLETED WITHIN 6 HOURS:

2 5) Apply vasopressors (for hypotension that does not respond to initial fluid
3 resuscitation) to maintain a mean arterial pressure (MAP) 65 mm Hg

4 6) In the event of persistent hypotension after initial fluid administration (MAP < 65
5 mm Hg) or if initial lactate was 4 mmol/L, re-assess volume status and tissue
6 perfusion and document findings according to Table 1.

7 7. Re-measure lactate if initial lactate elevated.

8 TABLE 1

9 DOCUMENT REASSESSMENT OF VOLUME STATUS AND TISSUE
10 PERFUSION WITH:

11 EITHER:

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

14 OR TWO OF THE FOLLOWING:

- 15 • Measure CVP
16 • Measure ScvO2
17 • Bedside cardiovascular ultrasound
18 • Dynamic assessment of fluid responsiveness with passive leg raise or fluid challenge.
19 (<http://www.survivingsepsis.org/Bundles/Pages/default.aspx>.)

20 47. The SSC guidelines and EGDT each contemplate that physicians timely
21 diagnose Sepsis, take multiple blood samples prior to the administration of antibiotics for
22 obtaining an accurate blood culture, monitor and managing the patients fluid retention, monitor
23 arterial pressure via central venous catheter (i.e. an arterial catheter placed in the Vena Cava
24 artery) administer IV fluids, measure and adjust lactate levels (a precursor to organ failure),
25 and administer various medications including, but not limited to, antibiotics to fight the
26 infection, and vasopressors and corticosteroids, as needed, to manage fluid retention and
27 prevent organ failure.⁸ (Early Goal-Directed Therapy for the treatment of Sepsis and Sceptic
28 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.

⁸In 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.

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 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

⁹The 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.

1 particular diagnosis. It is not uncommon for the medical standard of care to be more detailed
2 and complex than the ICD-9 Guidelines.

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

14 In lay terms, sepsis is a life-threatening condition that arises when the body’s response
15 to an infection injures its own tissues and organs.

16 Patients with suspected infection who are likely to have a prolonged ICU stay or to die
17 in the hospital can be promptly identified at the bedside with qSOFA, ie, alteration in
18 mental status, systolic blood pressure 100 mm Hg, or respiratory rate 22/min.

19 Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic
20 abnormalities are profound enough to substantially increase mortality.

21 Patients with septic shock can be identified with a clinical construct of sepsis with
22 persisting hypotension requiring vasopressors to maintain MAP 65 mm Hg and having
23 a serum lactate level >2 mmol/L (18 mg/dL) despite adequate volume resuscitation.
24 With these criteria, hospital mortality is in excess of 40%. Abbreviations: MAP, mean
25 arterial pressure; qSOFA, quick SOFA; SOFA: Sequential [Sepsis-related] Organ
26 Failure Assessment. (*Id.* at 805.)

27 The Sepsis-3 Report concludes that, “The current use of 2 or more SIRS criteria to
28 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

1 conclusion is very similar to the conclusions published from the 2001 Conference. (2001
 2 International Sepsis Definition Conference, *Intensive Care Med.* (2003) Vol. 29, 530, 532-4.)
 3 A further change was to abandon the use of the term “severe sepsis,” i.e., sepsis with organ
 4 dysfunction, because all sepsis cases are severe due to their potential to cause death. Lastly, the
 5 Sepsis-3 Report recognized that Septic Shock, i.e., sepsis involving multiple organ failure, has
 6 an even higher likelihood of patient death than sepsis. In an e-mail to its staff dated March 8,
 7 1016, KFHP unequivocally rejected the modern Sepsis-3 definitions and diagnostic
 8 recommendations.

9 DEFENDANTS’ FRAUDULENT MISCONDUCT

10 51. During and between approximately 2010 to the present, SCPMG, TPMG, KFHP
 11 and KFHP participated in a fraudulent scheme to up-code and falsely diagnose MA enrollees
 12 with sepsis and/or severe sepsis, i.e., sepsis with acute organ failure, (collectively referred to
 13 as “Sepsis”) when Sepsis was not present. Such false Sepsis diagnoses were made in order to
 14 increase the risk adjustment scores for the MA enrollees so diagnosed and thereby increase
 15 CMS’s capitation payments to KFHP. This scheme was also promoted by KFHP to falsely
 16 lower KFHP’s reported Sepsis mortality rates thereby improve KFHP’s reputation and prestige
 17 as a quality hospital provider. This fraudulent scheme concerned the identification and
 18 treatment of Sepsis for KFHP’s MA enrollees that presented in the emergency room (ER) of
 19 KFHP hospitals and was accomplished by (a) KFHP, PMG and SCPMG and KFHP implementing
 20 unwritten policies that prohibited coders employed by KFHP, KFHP, SCPMG and TPMG,
 21 (individually and collectively referred to as “Kaiser’s coders”) from performing physician
 22 queries for Sepsis diagnoses as required by the ICD-9 Guidelines, (b) implementing unwritten
 23 policies requiring Kaiser’s coders to code ICD-9 diagnosis codes for Sepsis based solely on the
 24 physician’s instructions to code Sepsis instead of relying on the supporting clinical findings
 25 documented in the medical record, (c) using an improper Sepsis diagnostic standard that
 26 overstated the frequency of Sepsis diagnoses, (d), aggressively diagnosing Sepsis as part of a
 27 strategy to lower the reported Sepsis mortality rate at KFHP hospitals throughout California, and
 28 (e) KFHP, TPMG and SCPMG, as an express condition of receiving capitation payments from

1 CMS, routinely and annually falsely certifying that such ICD-9 diagnosis codes for Sepsis were
2 accurate, complete and truthful to their best knowledge, information and belief, required by
3 CMS as a condition of receiving payment, when KFHP, TPMG and SCPMG knew or should
4 have known that such certifications were false.

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

11 53. In 2009, several KFHP HIM directors from Southern California KFH hospitals
12 including the HIM Director for KFH Hospital-Woodland Hills, Vivian Wachs, Registered
13 Health Information Technician (RHIT), informed Stein, co-chair of the Southern California
14 Region monthly HIM meetings, and all of the HIM Directors in attendance, that their local
15 SCPMG physician leadership was insisting that Sepsis be coded at the physician's discretion
16 and without supporting clinical findings properly documented in the medical record as required
17 by the ICD-9 Guidelines and by CMS. (42 C.F.R. §422.310(b)-(d); CMS Publication 100-16,
18 Medicare Managed Care Manual, Ch. 7 §40 et seq.) In response, Stein requested and was
19 granted permission by Dr. Kirk Tamaddon, SCPMG's Chief Regional Physician Liaison, who
20 chaired the SCPMG regional meetings, to make a presentation on Sepsis coding guidelines and
21 Sepsis medical record documentation requirements at the October 2009, SCPMG physician
22 leadership meeting.¹⁰ In addition to Dr. Tamaddon, the meeting was attended by at several
23 SCPMG Regional Medical Directors, and several Regional Operational Directors,
24 approximately 15 SCPMG Physician Liaisons and/or physician representatives and 20 SCPMG
25 Data Quality Managers and Encounter Coding Specialists.

26 54. Stein's presentation explained, among other things, that all of the symptoms and
27

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

1 clinical findings that supported a diagnosis of Sepsis and all clinical findings and test results
2 that support a diagnoses of organ dysfunction caused by Sepsis had to be documented in the
3 medical records. Additionally, because of the complexity of the diagnoses, it was likely that
4 Kaiser's coder needed to clarify the clinical findings and symptoms by making queries to
5 physicians intended to trigger clarifying responses of the medical record's supporting
6 documentation. Shortly after Stein finished her presentation, Dr. Albert Dreskin, SCPMG's
7 Woodland Hill's Physician Liaison, informed the attendees to disregard the presentation Stein
8 had just given, falsely asserting that SCPMG physicians had no requirement to provide
9 additional clinical documentation for a Sepsis diagnoses because Sepsis was a clinical decision
10 therefore all that was required was for the physician to write Sepsis. Dr. Dreskin concluded his
11 remarks by reminding the attendees that diagnosing Sepsis was worth a lot of money to the
12 defendants because it increased the MA enrollees' risk adjustment scores. In fact, the
13 submission of the ICD-9 diagnosis code for sepsis resulted in a HCC risk score of .754 which
14 increased the capitation payments for each such diagnosed MA enrollee by approximately
15 \$8,500 for the next year.

16 55. Following the October 2009 SCPMG physician leadership meeting and
17 continuing through to the present, SCPMG physician and coding leadership routinely insisted
18 that Sepsis be coded whenever the physician wrote the word Sepsis in the medical record and
19 prohibited Kaiser's coders from making coding queries to clarify the supporting medical record
20 documentation. Such coding instructions and query restrictions violate ICD-9 Guidelines and
21 AHIMA ethical coding guidelines. The blatantly improper coding practice was unique to the
22 defendants' coding and documentation of Sepsis. Kaiser's coders did not have such coding
23 instructions or query restrictions with regards to any other diagnoses. Stein witnessed these
24 improper Sepsis coding policies at KFH Hospital-Panorama City and was informed by other
25 HIMs that such policies were adopted by the defendants throughout KP's Southern California
26 region.

27 56. Throughout the term of his employment at KFH Hospital-South Bay, Bone had
28 been instructed that he was **not** to query physicians regarding Sepsis diagnoses and was

1 required to code Sepsis as instructed by the physician regardless of the medical record
2 documentation. Bone had learned from other coders that such Sepsis coding instructions and
3 query restrictions had been adopted by the defendants throughout KP's Southern California
4 region. Stein and Bone are informed and believe, and upon such information and belief
5 alleges, that the SCPMG's policy to prohibit physician queries of Sepsis diagnoses and to
6 require Kaiser's coders to code Sepsis based on the physician's instructions (as opposed to the
7 supporting clinical findings documented in the medical record) originated with TPMG and then
8 was implemented by SCPMG during or about 2009.

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

18 58. As discussed above in paragraph 40, the 1991 Sepsis definition was adopted to
19 assist researchers identify subjects to participate in clinical trials and promote Sepsis research.
20 By 2001 it was well established that Sepsis could not be diagnosed just by using the SIRS
21 criteria plus infection (i.e., whenever two or more SIRS criteria were elevated and the patient
22 had an infection) because such criteria applies to many patients who are suffering less severe
23 conditions than Sepsis. Instead, the SIRS criteria potentially diagnosed Sepsis only when no
24 other possible explanation or medical condition that accounted for the elevated levels. (The
25 ACCP/SCCM Consensus Conference Statement - 1991, *Chest*, June 1992, Vol.101, 1644,
26 1646.) The 2001 Conference published an expanded list of criteria to diagnose Sepsis but
27 concluded that these criteria, like the SIRS criteria, were not specific to Sepsis so such criteria
28 could not be adopted as a diagnostic "gold standard" that could be used conclusively in every

1 instance. The physician still had to make a judgment call to determine if the symptoms were
2 the result of the patient having a life threatening inflammatory response to infection that
3 potentially threatened to shut down organs resulting in death, i.e., Sepsis, or had some less
4 severe medical condition that explained the abnormal criteria values.

5 59. Defendants, in adopting a diagnostic standard based on two elevated SIRS
6 criteria, ignored the then current standard of medical care by not including the well accepted
7 expanded criteria from the 2001 Conference to diagnose Sepsis and to diagnose Sepsis with
8 acute organ failure. (2001 International Sepsis Definitions Conference, *Intensive Care Med.*
9 (2003) Vol. 29, 530, 532.) By 2009, such the 2001 Conference Sepsis diagnostic criteria had
10 become, the very well accepted, Surviving Sepsis Bundles and related guidelines endorsed by
11 CMS, the CDC and internationally. Defendants' Sepsis diagnostic standard also disregards the
12 2001 Conference's conclusions which unequivocally stated that the SIRS criteria were overly
13 broad, too sensitive and nonspecific for sepsis making them unsuitable for use as a diagnostic
14 standard. A conclusion that also was well accepted by the then concurrent and future medical
15 literature.

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

25 61. KP's adoption of improper Sepsis specific coding policies, (i.e., policies that
26 required Kaiser's coders to code Sepsis based on the physician's instruction and also prohibited
27 Kaiser's coders from making coding queries regarding Sepsis diagnoses), ensured that the
28 Kaiser Health Plans submitted false and inaccurate Sepsis diagnoses to CMS as valid RAD.

1 Such improper coding policies were and are unique to Sepsis and violate the ICD-9 Guidelines
2 and AHIMA ethical coding Guidelines. For all other syndromes, diseases, illnesses or injuries,
3 Kaiser's coders were able to perform coding queries without restrictions. Sepsis is the only
4 diagnoses that Kaiser's coders were not allowed to use coding queries to clarify the supporting
5 documentation in the medical record.

6 62. During and between 2010 and 2014, while working at KFH Hospital-South Bay,
7 Bone coded approximately three to four Sepsis diagnoses a week for MA enrollees that were
8 not admitted to the ICU or the hospital but were discharged home after being put in an
9 observation bed for between 3 to 48 hours. Such MA enrollees were not treated aggressively
10 for Sepsis per KP's Sepsis treatment protocols, including but not limited to, failing to insert a
11 central venous catheter not was not inserted and blood draws were not taken prior to the
12 administration of antibiotics to obtain blood cultures. During this time period, Bone also
13 routinely coded Sepsis diagnoses for MA enrollees who were not admitted to the ICU but were
14 admitted to the hospital for a brief stay of up to three days. Such MA enrollees typically were
15 not treated aggressively for Sepsis per KP's Sepsis treatment protocols, including but not
16 limited to, failing to insert a central venous catheter and failing to perform blood draws prior
17 to the administration of antibiotics to obtain blood cultures. Bone observed, that the medical
18 records of MA enrollees diagnosed with Sepsis, but not admitted to the hospital and MA
19 enrollees admitted to the hospital for a brief stay but were not treated for Sepsis aggressively,
20 did not have sufficient clinical findings documented in their medical records that supported the
21 Sepsis diagnoses.

22 63. The fact that MA enrollees that were diagnosed with Sepsis in the ER but
23 discharged without being admitted to the ICU or the hospital is a strong indication that such
24 MA enrollees did not have Sepsis, and that such Sepsis diagnosis and coding were false. It is
25 not credible that an MA enrollee is diagnosed with sepsis and/or sepsis with acute organ failure
26 does not require an admission to the ICU for treatment let alone is discharged without ever
27 being admitted to the hospital. Rather, such MA enrollees did not have Sepsis and the ER
28 observations confirmed this fact allowing the physician to confidently send the MA enrollee

1 home without admission to the hospital or ICU. The above reasoning also applies to the Kaiser
2 Health Plans' MA enrollees that were not admitted to hospital ICU but instead just admitted
3 to hospital for a brief stay, of one to three days, that did not receive aggressive treatment for
4 Sepsis according to KP's treatment protocols prior to being discharged home.

5 64. As a result of KP's emphasis on diagnosing Sepsis and adopting an improper and
6 overly broad Sepsis diagnostic standard, the number of Sepsis diagnoses by PMG and SCPMG
7 physicians, between 2009 and 2013, increased dramatically at all California KFH hospitals; as
8 much as, between 200% to 300% at some facilities. This increase in the number of Sepsis
9 diagnoses had the effect of dramatically lowering KFH California Hospital's reported Sepsis
10 mortality rates. The reported Sepsis mortality rates were a ratio comparing the number of
11 Sepsis cases diagnosed at KFH Hospitals to the number of patients that expired as a result of
12 having Sepsis. As such, the reported Sepsis mortality ratio was easy to manipulate by
13 increasing the number of Sepsis diagnoses with false Sepsis diagnoses. By 2013, KP claimed
14 that its reported Sepsis mortality rate had dropped to approximately 9% and its average length
15 of stay for such cases had dropped to 3.5 days. . (An Innovative Approach to Sepsis
16 Prevention Saves Lives, (Dec 6, 2013) [https://businesshealth.kaiserpermanente.org/insights](https://businesshealth.kaiserpermanente.org/insights/sepsis-prevention)
17 /sepsis-prevention.) KP's reported Sepsis mortality rate and average length of stay during
18 2010 through 2013 are unrealistic numbers and an indication that the Kaiser Health Plans
19 submitted false Sepsis diagnoses. As discussed below in greater detail, at least one KP
20 physician complained, challenging the validity of KP's reported sepsis mortality rates. A recent
21 landmark study comparing the difference in effectiveness between EGDT treatment protocols
22 and traditional treatment methods, when properly implemented using hospital systems with
23 best practices, achieved sepsis mortality rates of 19%-20%. (A Randomized Trial of
24 Protocol-Based Care for Early Septic Shock, The ProCESS Investigators, *N Engl J Med* (July
25 24, 2014); Vol. 370, 1683, 1690.) For 2010, the national mean length of stay for MA enrollees
26 with Sepsis as a primary diagnosis was 9 days and 15 days for those with Sepsis as a secondary
27 diagnosis. (AHRQ, H-CUP Statistical Brief #122, p.4 (October 2011).)

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

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

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

18 67. KP's use of an overly broad and improper Sepsis diagnostic standard imposes on
 19 KFHP, TMPG, SCPMG and KFH, a duty to exercise reasonable diligence to identify, and
 20 redact false and incorrect Sepsis diagnoses from the RAD submitted to CMS. This duty is an
 21 integral part of the Medicare Advantage's regulatory framework intended to help MAOs, such
 22

23 ¹¹ 42 C.F.R. §422.504(b)(4)(vi) states in part: [Adopt and implement an effective compliance
 24 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.]

25 ¹² Medicare Managed Care Manual, Ch.21 §50.7.1 – Conducting a Timely and Reasonable
 26 Inquiry of Detected Offenses, states in part, "Sponsors must conduct a timely and well-documented
 27 reasonable inquiry into any compliance incident or issue involving potential Medicare program
 28 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."

1 as KFHP, avoid the submission of false and fraudulent claims to CMS and avoid the receipt and
2 retention of improper overpayments from CMS. (42 C.F.R. §§ 422.326(c), 422.503(b)(4)(iv),
3 422.504(l)(2); CMS Publication 100-16, Medicare Managed Care Manual, Ch.7 §40 et seq. and
4 Ch.21 §§30-50 et seq.; 79 Fed.Reg. 29844, 29923-24 (March 23, 2014).)

5 68. KFHP failed to use reasonable diligence in its selection of its Sepsis diagnostic
6 standard and also by failing to identify and redact false and unsupported Sepsis diagnoses from
7 the RAD submitted to CMS. As an express condition of receiving its monthly capitation
8 payments on behalf of MA enrollees, KFHP certified based on its best knowledge, information
9 and belief that the RAD it submitted to CMS was accurate, truthful and complete. (42 C.F.R.
10 §422.504(l)(2).) Because KFHP did not attempt to identify and redact the potentially false and
11 fraudulent Sepsis diagnoses obtained from its contracted medical groups, KFHP's statutorily
12 required certifications were false. KFHP's best knowledge, information and belief were that
13 many of the Sepsis diagnoses were inaccurate, untruthful and incomplete, and were not
14 supported by the clinical documentation in the medical record as required by CMS. (CMS
15 Publication 100-16, Medicare Managed Care Manual, Ch.7 §40 et seq.) Furthermore, without
16 a process to identify known potentially inaccurate Sepsis diagnoses, KFHP had no legitimate
17 basis for making such a certification. (See, 79 Fed.Reg. 29844, 29923-24 (March 23, 2014).)

18 69. During and between approximately 2008 until the present, KFH hospital
19 facilities, including all those in California, utilized the above-described false sepsis diagnoses
20 and documentation practices to up-code their FFS Medicare hospital claims that KFH submitted
21 to CMS on behalf of its FFS Medicare patients. The false and fraudulent sepsis ICD-9 and later
22 ICD-10 diagnosis codes were mapped to the KFH hospital's master claim bill, CMS form UB-
23 04 as DRG 871 or 872 and submitted to CMS, resulting in false and fraudulent claims in
24 violation of the FCA. Each such false sepsis claim resulted in KFH receiving approximately
25 \$7,000 to \$12,000 of additional revenue from CMS.

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

1 paragraphs 53 through 56 as national policies and procedures.

2 71. Bone is informed and believes, and upon such information and belief alleges, that
3 throughout the term of his employment (2010 until the present) the Kaiser Health Plans, KFH
4 and PMGs adopted and implemented the unwritten Sepsis diagnosis, coding and treatment
5 policies described above and in paragraphs 53 through 56 as national policies and procedures.

6 MALNUTRITION

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

22 73. Valid RAD must be the result of a face-to-face encounter with a physician or
23 other qualified clinician that has been identified by CMS as an acceptable source of RAD.
24 (CMS Publication 100-16, Medicare Managed Care Manual, Ch. 7 §40 et seq., §120.1.1, Table
25 19; 42 C.F.R. 422.310(b)-(d).) In order for RAD to be valid for submission to CMS, each ICD-
26 9 diagnosis code submitted must have the appropriate clinical findings documented in the MA
27 enrollee's medical record. (CMS Publication 100-16, Medicare Managed Care Manual, Ch. 7
28 §40 et seq.; 42 C.F.R. § 422.310(b)-(d).) KFH Hospitals' use of the dietician's stamp for

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

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

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

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

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

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

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

13 79. 42 C.F.R. § 422.326, the Medicare Advantage Overpayment Report and Return
14 regulation, requires KFHP to notify CMS within 60 days from the time it knew or should have
15 known that it received an overpayment and make arrangements with CMS for the return of such
16 overpayments. KFHP violated 42 C.F.R. § 422.326 by failing and refusing to exercise
17 reasonable diligence with respect to the identification and return of overpayments resulting
18 from the improper diagnosing, documenting and coding of malnutrition and severe malnutrition
19 of its MA enrollees as described above. Failing to notify CMS of the receipt of an overpayment
20 within 60 days is an obligation under the False Claims Act and subjects KFHP to FCA liability
21 under 31 U.S.C. § 3729(a). KFHP's and/or the other defendants' policy change regarding the
22 diagnoses, documentation and coding of malnutrition is evidence that KFHP was aware that
23 it submitted invalid malnutrition RAD to CMS that resulted in the receipt and retention of
24 overpayments during prior periods.

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

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

6 81. During and between 2006 until approximately December 11, 2013, KFHP hospital
7 facilities, including all those in California, allowed physicians to improperly countersign
8 dieticians' stamps as a means of diagnosing and documenting malnutrition for Medicare FFS
9 patients. The false and fraudulent malnutrition ICD-9 diagnosis codes were mapped to the
10 KFHP hospital's master claim bill, CMS form UB-04, as MCCs (i.e., secondary diagnoses
11 increasing the DRG's value) and submitted to CMS resulting in false claims in violation of the
12 FCA. KFHP received between \$1,000 to \$5,000 of additional revenue per patient discharge
13 from CMS as a result of the false malnutrition claims. KFHP and KFHP made no effort to notify
14 CMS of the overpayments that resulted from the submission of such false and fraudulent
15 Medicare FFS malnutrition claims, although per 42 C.F.R. §401.305, KFHP was obligated to
16 report and timely return such overpayments to CMS.

17 82. Stein and Bone are informed and believe, and upon such information and belief
18 allege, that the above-described improper diagnosis, coding and documentation practices for
19 malnutrition described above in paragraphs 72 through 81 are, and since 2006 were, national
20 policies and procedures, and performed in the same improper manner nationwide by Kaiser
21 Health Plans, KFHP and the PMGs.

22 AORTIC ATHEROSCLEROSIS

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

84. 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 the physician noted the presence of AA or listed AA in the patient's medical record. This instruction applied MA patients admitted to Kaiser inpatient facilities in, among other states, California. Pursuant to these instructions, Kaiser's coders coded KFH's MA patients with an AA diagnosis based simply upon 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.

85. 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.

86. 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

1 about this condition when it is only listed. Without a query and
2 additional documentation from the provider to show it impacted
the encounter it cannot be coded.

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

8 Section III(B) Abnormal Findings - "Abnormal findings and other
9 diagnostic results are not coded and reported unless the provider
indicates their clinical significance."

10 Section IV(I) Chronic Diseases - "Chronic diseases treated on an
11 ongoing basis may be coded and reported as many times as the
patient receives treatment and care for the condition(s)"

12 88. Prior to the April 4, 2016 instruction, KFH and the Kaiser Health Plans regularly
13 monitored the coding of AA for their hospital patients to ensure that every time AA was noted
14 in the medical record, AA was coded by Kaiser's coders, but did not ensure that such AA coded
15 diagnoses met the requirements for coding AA under the ICD-9 and later the ICD-10 Coding
16 and Documentation Guidelines. On at least two occasions during the course of Bone's
17 employment, KFH's internal auditors notified him that he failed to properly code AA diagnoses
18 where the only documentation in the medical record was that AA had been observed as a result
19 of a chest x-ray, but no treatment for AA had been documented. Bone was required to fix the
20 problem by coding the ICD-9 diagnosis code for AA for such encounters.

21 89. All RAD to be submitted to CMS for use in calculating the Kaiser Health Plans'
22 capitation payments must be the result of face-to-face physician encounters that are supported
23 by properly documented medical records. All medical record documentation must be
24 performed in accordance with ICD-9 and later ICD-10 Coding and Documentation Guidelines.
25 (Medicare Managed Care Manual, Ch. 7 §40, et seq.) As a result of the foregoing, all of the
26 ICD-9 and/or ICD-10 AA diagnosis codes that were inaccurately coded because, among other
27 reasons, the patient's medical record does not reflect the patient receiving contemporaneous
28 treatment for AA, are invalid for submission to CMS as RAD for use in calculating the Kaiser

1 Health Plans' capitation payments and resulted in the submission of false claims.

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

6 REFRESH FRAUDS

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

17 92. At all times relevant, CMS allowed MAOs an additional period of time (Data
18 Lag Period) after the end of the payment year to submit additional valid RAD and withdraw
19 previously submitted invalid RAD arising from services rendered during that payment year.
20 The end of the Data Lag Period was the final RAD cutoff date after which CMS no longer
21 accepted any new or withdrawn RAD for that payment year, and CMS used the RAD for that
22 payment year to risk adjust the MAO's capitation payments for the next payment year. When
23 the HCC risk adjustment model was relatively new, the Data Lag Period was two years after
24 the end of the payment year. Over time, CMS shortened the Data Lag Period to 13 months after
25 the end of the payment year.

26 93. After the end of the payment year, but before the end of the Data Lag Period,
27 MAOs such as KFHP can retrospectively review the medical records of its MA enrollees to
28 ensure that the RAD submitted to CMS was properly supported by medical records and

1 withdraw unsupported diagnosis codes. MAOs can also submit to CMS previously unreported
2 HCC diagnosis codes if the medical record supports such additional diagnoses, or in certain
3 cases, make an amendment to the medical record based on the last face-to-face encounter the
4 physician had during the payment year if the physician has a recollection of the face-to-face
5 encounter and there is sufficient clinical findings in the existing medical record to make such
6 a diagnoses.

7 94. Beginning in 2006 and continuing to the present, KFHP, KFH, TPMG, SCPMG
8 and the other PMGs implemented an improper program designed to identify “missing” HCC
9 diagnosis codes and have the physicians “refresh” the missing HCC diagnoses. KFHP
10 considered HCC diagnoses to be missing when the HCC diagnoses had been submitted to CMS
11 as RAD arising from services rendered during the last closed payment year, but had not been
12 submitted in the subsequent payment year subject to a pending Data Lag Period (e.g., if 2010
13 was the last closed payment year, 2011 is the subsequent payment year with a Lag Data Period
14 pending between January 1, 2012 through January 31, 2013). KFHP, KFH, TPMG and
15 SCPMG, with the assistance of KFH staff, engaged in several different tactics to have the
16 physicians “refresh” the missing HCC diagnoses. The progress and success of the refresh
17 program was internally well documented, and tracked the MA enrollees’ medical records, the
18 HCC diagnoses to be “refreshed,” the physicians who “refreshed” the HCC diagnoses, the
19 HCC diagnosis codes submitted to CMS as RAD as a result of the refresh process, and the
20 increased risk adjustment scores resulting from the refresh process. KFHP’s refresh process
21 resulted in increased risk adjustment scores of 5 to 6 points per MA enrollee program wide,
22 resulting in about \$400 million to \$500 million in additional annual capitation revenue per year.

23 95. The refresh process started with KFHP’s contracted medical groups compiling
24 a “hit-list” of high value HCC risk adjustment scores and their related ICD-9 diagnosis codes
25 (“HCC diagnoses”) from which to work from. The hit-list included, but was not limited to, all
26 of the complications related to diabetes, and the different manifestations and complications of
27 coronary disease, chronic kidney disease, old myocardial infarction, and cancer. Each year,
28 KFHP performed a computer search to data-mine the RAD submissions from the last closed

1 payment year to identify the MA enrollees with a history of hit-list HCC diagnoses, and used
 2 those results to determine which MA enrollees' medical records did not have such hit-list HCC
 3 diagnoses submitted in the subsequent payment year subject to a pending Data Lag Period.
 4 After Kaiser's coders reviewed the last closed payment year's medical records confirm the
 5 existence of the past hit-list HCC diagnoses, Kaiser's coders then sent written leading queries
 6 to the MA enrollees' attending physicians with a list of the missing HCC diagnoses. The
 7 leading physician queries instructed the physicians to "refresh" (i.e., add) the missing HCC
 8 diagnosis to a particular MA enrollee's medical record. Kaiser's coders then met with the
 9 physicians to ensure that the hit-list HCC diagnoses were refreshed. Most of TPMG and
 10 SCPMG physicians readily complied with Kaiser's coders' requests and added the hit-list HCC
 11 diagnoses identified in the Kaiser's coders' leading queries.

12 96. All RAD that MAOs, such as the Kaiser Health Plans, submit to CMS must be
 13 the result of a face-to-face physician encounter and must be supported by a medical record
 14 documented in accordance with ICD-9 Guidelines. (Medicare Managed Care Manual, Ch. 7
 15 §40 et seq.; 42 C.F.R. §422.310(d).) An addendum is new documentation used to add
 16 information to an original entry. Addenda should be timely and bear the current date and
 17 reason for the additional information to an original entry. (AHIMA (2015) Amendments,
 18 Corrections and Deletions in the Electronic Health Record Tool Kit,
 19 http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_044678.hcsp?dDocName=bok1_044678.)

21 97. CMS's rule governing late medical entries states, "All services provided to
 22 beneficiaries **are expected to be documented in the medical record at the time they are**
 23 **rendered**. Occasionally, certain entries related to services provided are not properly
 24 documented. In this event, the documentation will need to be amended, corrected, or entered
 25 after rendering the service." (Emphasis added.) (Medicare Program Integrity Manual, Ch. 3,
 26 §3.3.2.5(A) and made applicable to Medicare Advantage by 42 C.F.R. §§ 422.101(b),
 27 422.310(d).) Similarly, AHIMA Guidelines state, "When documenting an omission, validate
 28 the source of additional information as much as possible. Late entries should be documented

1 as soon as possible. While there is no time limit for writing a late entry, the more time that
 2 passes, the less reliable the entry becomes.”¹³ (AHIMA (2015) Maintaining a Legally Sound
 3 Health Record: Paper and Electronic, [http://library.ahima.org/xpedio/groups/public/documents/](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028509.hcsp?dDocName=bok1_028509)
 4 [ahima/bok1_028509.hcsp?dDocName=bok1_028509.](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_028509.hcsp?dDocName=bok1_028509))

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

13 99. Second, the addenda themselves were not supported by required clinical
 14 documentation in the medical record in accordance with ICD-9 Guidelines. This is apparent
 15 on the face of the addenda which consist of just the addition of the hit-list HCC diagnoses,
 16 signed and dated by the physician. Physicians who executed the addenda did not review the
 17 medical record entries (i.e., the portion being amended) to confirm that the medical record
 18 contained the necessary clinical findings to support the new HCC diagnoses, nor did they
 19 include language in the addenda that identified the reasons for the late entry nor any required
 20 clinical findings to support adding the new HCC diagnoses as required by the ICD-9 and
 21 AHIMA coding and documentation guidelines. The mere conclusion of the new HCC
 22 diagnoses, without the supporting clinical findings necessary to support the conclusion, is not
 23 an acceptable method of medical record documentation. Additionally, such incomplete
 24 documentation does not indicate that it is “related to a service that was provided” during the
 25 prior encounter as required by CMS’s rule for late entries. (Medicare Program Integrity
 26 Manual, Ch. 3, §3.3.2.5(A).) Therefore, such improperly “refreshed” HCC diagnoses codes
 27

28 ¹³For 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.

1 should not have been submitted to CMS as RAD.

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

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

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

22 103. Defendants' refreshing of HCC diagnoses relied on using invalid, leading
23 physician queries that instructed physicians which HCC diagnoses to add to the medical
24 records. "A leading query is one that is not supported by the clinical elements in the health
25 record and/or directs a provider to a specific diagnosis or procedure." (AHIMA Practice Brief,
26 Guidelines for Achieving a Compliant Query Practice (9-13-2015) at p. 2;

27
28 ¹⁴AHIMA 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.

1 <http://ahima.org/library>.) AHIMA sets the national standards regarding coding and
2 documentation, and as such its policies are incorporated into the medical record documentation
3 requirements by CMS. (42 C.F.R. § 422.310(d).) The AHIMA guidelines do not allow leading
4 queries because they result in inaccurate and/or false medical record documentation. After the
5 leading queries were used by TPMG and SCPMG physicians, the queries were illegally
6 destroyed.

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

19 105. At all times mentioned, KFHH's medical record retention policy included Kaiser's
20 coders' queries as part of the medical record. At all times mentioned, the Kaiser Health Plans
21 allowed their contracted medical groups, including TPMG and SCPMG, to adopt different and
22 conflicting medical record retention policies that improperly failed to preserve Kaiser's coders'
23 queries as part of the medical record or as a business record. Instead, Kaiser's coders' queries
24 were destroyed immediately after the queries had been reviewed by the physicians. The Kaiser
25 Health Plans always had the ability to require their exclusively contracted medical groups,
26 including TPMG and SCPMG, to adopt unified policies for medical record retention, query
27 practices, late entries into the medical records and medical record documentation. CMS's
28 regulations mandates that the Kaiser Health Plans' contracts contain such rights and provisions.

1 (42 C.F.R. § 422.504(i)(3)(iii).)

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

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

20 108. In a number of instances, the MA enrollees had not been seen by their PCP during
21 the open payment year and/or had not been seen during the current year. These MA enrollees’
22 medical records could not be refreshed with a late entry addenda because there was no face-to-
23 face encounter, and therefore no medical record entry during the relevant time period to amend.
24 TPMG and SCPMG contacted these MA enrollees and falsely informed them that they needed
25 to schedule a follow-up visit with their primary care physician (PCP). In addition, there were
26 MA enrollees who had been seen during the open payment year, but for whom no HCC
27 diagnoses were identified during those encounters. These MA enrollees were also scheduled
28 for a follow up visit for the sole purpose of identifying HCC diagnoses to submit to CMS.

109. 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).)

110. 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 not 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.

111. 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.

1 Zollner, Hoffman, Steinberg, and Candac Lumeg. Present by telephone were the SCPMG
2 physician leaders, from the Santa Clarita Medical Clinic. The purpose of the meeting was to
3 discuss the data-mining results provided by SCPMG's Pasadena headquarters that identified
4 MA enrollees who needed a current physician encounter in order for their HCC diagnoses to
5 be refreshed. A telephone call script had been provided by defendants that was used to
6 schedule the appointments with the MA enrollees and was read out loud for the meeting
7 participants. The call script informed the MA enrollees that they needed to come in for a
8 follow up visit for the HCC condition that had been identified by defendants. This statement
9 was false. The SCPMG physician leaders candidly admitted that the follow-up exams were
10 medically unnecessary and being used as pretext; the true purpose of the visits was for the
11 PCPs to refresh the hit-list HCC diagnoses.

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

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

24 114. Beginning in 2006 and continuously thereafter, Kaiser Health Plans, KFH and
25 the PMGs annually scheduled tens of thousands of MA enrollee visits for the purpose of
26 "refreshing" prior hit-list HCC diagnoses by falsely claiming such visits were medically
27 necessary follow-up visits. The true purpose of the MA enrollees' medical appointments was
28 for the Kaiser Health Plans' contracted medical groups to collect HCC diagnoses for

1 submission to CMS by the Kaiser Health Plans. The untruthful statements to the MA enrollees
2 constituted a false statement material to a false or fraudulent claim in violation of 31 U.S.C. §
3 3729(a)(1)(B).

4 FIRST CLAIM FOR RELIEF

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

6 115. Relator realleges and incorporates by reference paragraphs 1 through 71 of this
7 complaint as though fully set forth at length.

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

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

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

24 119. The Kaiser Health Plans knew or should have known that they had improperly
25 received and retained excessive payments for Medicare FFS patients for whom the Kaiser
26 Health Plans routinely submitted to CMS Sepsis diagnoses that were falsely and fraudulently
27 diagnosed and coded, and were lacking adequate supporting medical record documentation in
28 violation of 42 C.F.R. § 401.305.

1 120. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable
2 diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R.
3 § 401.305.

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

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

12 123. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable
13 diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R.
14 § 422.326.

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

18 125. The Kaiser Health Plans are, and at all times mentioned were, required to “be
19 continuously diligent regarding the accuracy and completeness of payment-related data they
20 submit to CMS” and further expected to “implement, during the routine course of business,
21 appropriate payment evaluation procedures in order to meet the requirement of certifying the
22 data they submit to CMS for purposes of payment.” (79 Fed.Reg. 29884, 29921, 29923-24
23 (May 14, 2014).) Because the Kaiser Health Plans adopted overly broad Sepsis diagnostic
24 standards, they had an obligation to establish a process to identify and redact or withdraw
25 incorrect Sepsis diagnosis codes from the RAD they submitted to CMS. The Kaiser Health
26 Plans did not adopt any such process to identify and redact or withdraw incorrect Sepsis ICD-9
27 diagnosis codes from the RAD they submitted to CMS and failed to do so. As a result of the
28 Kaiser Health Plans’ failure and refusal to reasonably attempt to meet this obligation, it had no

1 legitimate basis for certifying that the Sepsis ICD-9 diagnosis codes it submitted to CMS were
2 accurate, complete and truthful RAD.

3 126. Defendants were obligated to conduct a Medicare FWA investigation in response
4 to Dr. Conrado's repeated complaints that sepsis was being inaccurately diagnosed and coded.
5 The Kaiser Health Plans and their first tier contracted entities failed and refused to conduct
6 such a compliance investigation, rendering the Kaiser Health Plans' compliance program, as
7 it pertains to the submission of false Sepsis diagnosis codes, ineffective. Because the Kaiser
8 Health Plans had an ineffective compliance program, they had no legitimate basis on which to
9 certify the accuracy, completeness and truthfulness of the Sepsis ICD-9 diagnosis codes they
10 submitted as RAD to CMS between 2010 to the present. (42 C.F.R. §§ 422.503(b)(4)(vi),
11 422.504(i)(3)(iii)&(l); Medicare Managed Care Manual, Ch. 21 §50.7.1; 79 Fed.Reg. 29884,
12 29923-24 (May 14, 2014).)

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

24 128. At all times mentioned during the six years prior to the filing of this action, the
25 Kaiser Health Plans routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(G) by knowingly
26 concealing or knowingly and improperly avoiding or decreasing their obligation to pay or
27 transmit to the Government the overpayments made by CMS as a result of the submission of
28 false and unsupported Sepsis diagnoses to CMS.

129. 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.

130. 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.

131. 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.

132. 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)

133. Relator realleges and incorporates by reference paragraphs 1 through 37 and paragraphs 72 through 82 of this complaint as though fully set forth at length.

134. 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.

135. 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

1 CMS, and (b) knowingly making, using, or causing to be made or used, false records or
2 statements material to false or fraudulent claims to CMS to get such false and fraudulent claims
3 paid or approved by CMS.

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

7 137. At all times mentioned during the six years prior to the filing of this action, the
8 Kaiser Health Plans and KFH knew or should have known that they had improperly received
9 and retained excessive FFS Medicare payments from CMS for services rendered to FFS
10 Medicare beneficiaries based on malnutrition diagnoses that were falsely and fraudulently
11 diagnosed and coded, and were lacking adequate supporting medical record documentation in
12 violation of 42 C.F.R. § 401.305.

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

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

19 140. At all times mentioned during the six years prior to the filing of this action,
20 defendant Kaiser Health Plans knew or should have known that they had improperly received
21 and retained excessive capitation payments for MA enrollees for whom the Kaiser Health Plans
22 submitted to CMS malnutrition diagnoses that were routinely and repeatedly falsely and
23 fraudulently diagnosed and coded, and were lacking adequate supporting medical record
24 documentation in violation of 42 C.F.R. § 422.326.

25 141. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable
26 diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R.
27 § 422.326.

28 142. At all times mentioned, the Kaiser Health Plans acted with reckless disregard and

1 deliberate ignorance in failing to identify and notify CMS of such overpayments in violation
2 of 42 C.F.R. § 422.326.

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

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

26 145. At all times mentioned during the six years prior to the filing of this action, the
27 defendants routinely violated 31 U.S.C. § 3729(a)(1)(G) by repeatedly and annually falsely
28 certifying that the ICD-9 diagnosis codes for malnutrition submitted to CMS as RAD were

1 accurate, complete and truthful based upon the defendants' best knowledge, information and
 2 belief, and/or knowingly concealing or knowingly and improperly avoiding or decreasing
 3 defendants' obligation to pay or transmit CMS's overpayments to the Government.

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

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

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

12 THIRD CLAIM FOR RELIEF

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

15 149. Relator realleges and incorporates by reference paragraphs 1 through 37 and
 16 paragraphs 83 through 91 of this complaint as though fully set forth at length.

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

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

1 paid or approved by CMS.

2 152. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable
3 diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R.
4 § 422.326.

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

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

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

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

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

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

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

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

17 FOURTH CLAIM FOR RELIEF

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

19 160. Relator realleges and incorporates by reference paragraphs 1 through 37 and
20 paragraphs 90 through 113 of this complaint as though fully set forth at length.

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

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

1 defendants routinely and repeatedly violated 31 U.S.C. § 3729(a)(1)(A)&(B) by (a) knowingly
2 presenting or causing to be presented, false or fraudulent claims for payment or approval by
3 CMS, and (b) knowingly making, using, or causing to be made or used, false records or
4 statements material to false or fraudulent claims to CMS to get such false and fraudulent claims
5 paid or approved by CMS.

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

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

14 165. At all times mentioned, the Kaiser Health Plans failed to exercise reasonable
15 diligence to identify and promptly notify CMS of such overpayments in violation of 42 C.F.R.
16 § 422.326.

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

20 167. The Kaiser Health Plans are, and at all times mentioned during the six years prior
21 to the filing of this action were, required to “be continuously diligent regarding the accuracy
22 and completeness of payment-related data they submit to CMS” and further expected to
23 “implement, during the routine course of business, appropriate payment evaluation procedures
24 in order to meet the requirement of certifying the data they submit to CMS for purposes of
25 payment.” (79 Fed.Reg. 29884, 29921, 29923-24 (May 14, 2014).) The Kaiser Health Plans
26 had an obligation to establish a process to identify and redact or withdraw incorrect or
27 unsupported “refreshed” HCC diagnosis codes from the RAD it submitted to CMS. The Kaiser
28 Health Plans did not adopt any such process to identify and redact or withdraw incorrect or

1 unsupported “refreshed” ICD-9 diagnosis codes from the RAD they submitted to CMS and
2 failed to do so. As a result of the Kaiser Health Plans’ failure and refusal to reasonably attempt
3 to meet this obligation, they had no legitimate basis for certifying that the “refreshed” ICD-9
4 diagnosis codes they purportedly added to their MA enrollees’ medical records and submitted
5 to CMS were accurate, complete and truthful RAD.

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

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

23 170. As a result of defendants’ conduct, defendants are liable to the Government for
24 three times the amount of damages sustained by the Government as a result of the false and
25 fraudulent claims alleged above.

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

172. 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;

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FOR ALL CLAIMS FOR RELIEF

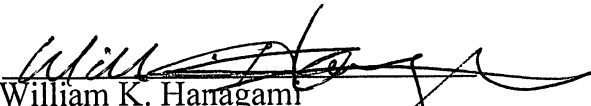
13. Attorney's fees, expenses, and costs; and

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

THE ZINBERG LAW FIRM
A Professional Corporation

THE HANAGAMI LAW FIRM
A Professional Corporation

Dated: November 3, 2016

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

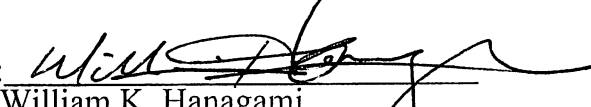
REQUEST FOR JURY TRIAL

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

THE ZINBERG LAW FIRM
A Professional Corporation

THE HANAGAMI LAW FIRM
A Professional Corporation

Dated: November 3, 2016

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

PROOF OF SERVICE

STATE OF CALIFORNIA
COUNTY OF LOS ANGELES }

I, the undersigned, certify and declare that I am over the age of 18 years, employed in the County of Los Angeles, State of California, and not a party to the above-entitled cause.

On November 3, 2016, I served a true copy of:

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT, AND REQUEST FOR JURY TRIAL

by depositing it in the United States Mail at Woodland Hills, California in a sealed envelope with the postage thereon fully prepaid addressed to the following:

Arthur S. Di Dio
U.S. DEPARTMENT OF JUSTICE
Ben Franklin Station
P.O. Box 261
Washington, DC 20044

Attorneys for United States of America

Erica Blachman Hitchings
OFFICE OF
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450 Golden Gate Avenue, 11th Floor
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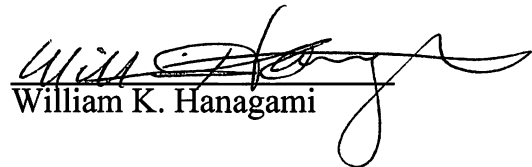
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Executed on November 3, 2016 at Woodland Hills, California.

I hereby certify that I am a member of the Bar of the United States District Court, Northern District of California.

I hereby certify under the penalty of perjury that the foregoing is true and correct.


William K. Hanagami