UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No.: 18-20394 **COMPLAINT FOR VIOLATION OF THE FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*]** GIV-SCOLA **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** TORRES **JURY TRIAL DEMANDED**

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Jeffrey W. Dickstein (FL Bar No. 434892)
PHILLIPS & COHEN LLP
Southeast Financial Center
200 S. Biscayne Blvd., Suite 2790
Miami, Florida 33131
Tel: (305) 372-5200
jdickstein@phillipsandcohen.com

Colette G. Matzzie
Luke J. Diamond
PHILLIPS & COHEN LLP
2000 Massachusetts Ave., NW
Washington, DC 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Edward H. Arens
PHILLIPS & COHEN LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Fax: (415) 836-9001

Attorneys for [UNDER SEAL]

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

UNITED STATES OF AMERICA *ex rel.* DEREK LEWIS and JOEY NEIMAN,

Plaintiffs,

v.

COMMUNITY HEALTH SYSTEMS, INC.; CHSPSC, LLC; ALLIANCE HEALTH PARTNERS, LLC D/B/A MERIT HEALTH BATESVILLE; AMORY HMA LLC D/B/A MERIT HEALTH GILMORE MEMORIAL; ANNA HOSPITAL CORPORATION D/B/A UNION COUNTY HOSPITAL; ARMC LP D/B/A ABILENE REGIONAL MEDICAL CENTER; AUGUSTA HOSPITAL LLC D/B/A TRINITY HOSPITAL OF AUGUSTA; BANNER HEALTH D/B/A BANNER PAYSON MEDICAL CENTER; BARTOW HMA LLC D/B/A BARTOW REGIONAL MEDICAL CENTER; BERWICK HOSPITAL COMPANY LLC D/B/A BERWICK HOSPITAL CENTER; BIG BEND HOSPITAL CORPORATION D/B/A BIG BEND REGIONAL MEDICAL CENTER; BIG SPRING HOSPITAL CORPORATION D/B/A SCENIC MOUNTAIN MEDICAL CENTER; BILOXI HMA LLC D/B/A MERIT HEALTH BILOXI; BLACKWELL HMA LLC D/B/A ALLIANCEHEALTH BLACKWELL; BLUE RIDGE GEORGIA HOSPITAL COMPANY LLC D/B/A FANNIN REGIONAL HOSPITAL; BLUEFIELD HOSPITAL COMPANY LLC D/B/A BLUEFIELD REGIONAL MEDICAL CENTER; BRANDON HMA LLC D/B/A MERIT HEALTH RANKIN; BROWNWOOD HOSPITAL LP D/B/A BROWNWOOD REGIONAL MEDICAL CENTER; BULLHEAD CITY HOSPITAL

Case No. 18-20394 CIV-SCOLA

COMPLAINT FOR VIOLATION OF THE FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*]

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

CORPORATION D/B/A WESTERN ARIZONA REGIONAL MEDICAL CENTER; CARLISLE HMA, LLC D/B/A CARLISLE REGIONAL MEDICAL CENTER; CARLSBAD MEDICAL CENTER LLC D/B/A CARLSBAD MEDICAL CENTER; CEDAR PARK HEALTH SYSTEM LP D/B/A CEDAR PARK REGIONAL MEDICAL CENTER; CENTRE HOSPITAL CORPORATION D/B/A CHEROKEE MEDICAL CENTER; CHESTER HMA LLC D/B/A CHESTER REGIONAL MEDICAL CENTER; CHESTERFIELD MARLBORO LP D/B/A CHESTERFIELD GENERAL HOSPITAL; CITRUS HMA INC D/B/A SEVEN RIVERS REGIONAL MEDICAL CENTER; CLARKSDALE HMA LLC D/B/A MERIT HEALTH NORTHWEST MISSISSIPPI; CLINTON HMA, LLC D/B/A ALLIANCEHEALTH CLINTON; CLINTON HOSPITAL CORPORATION D/B/A LOCK HAVEN HOSPITAL; COLLEGE STATION HOSPITAL LP D/B/A COLLEGE STATION MEDICAL CENTER; CRESTVIEW HOSPITAL CORPORATION D/B/A NORTH OKALOOSA MEDICAL CENTER; CRESTWOOD HEALTHCARE LP D/B/A CRESTWOOD MEDICAL CENTER; DEACONESS HEALTH SYSTEM LLC D/B/A ALLIANCEHEALTH DEACONESS; DEMING HOSPITAL CORPORATION D/B/A MIMBRES MEMORIAL HOSPITAL; DURANT HMA LLC D/B/A ALLIANCEHEALTH DURANT; DYERSBURG HOSPITAL COMPANY LLC D/B/A TENNOVA HEALTHCARE-DYERSBURG REGIONAL; EAST GEORGIA REGIONAL MEDICAL CENTER, LLC; EMPORIA HOSPITAL CORPORATION D/B/A SOUTHERN VIRGINIA REGIONAL MEDICAL CENTER; EVANSTON HOSPITAL CORPORATION D/B/A EVANSTON REGIONAL HOSPITAL; FOLEY HOSPITAL CORPORATION D/B/A SOUTH

BALDWIN REGIONAL MEDICAL CENTER; FORREST CITY ARKANSAS HOSPITAL COMPANY LLC D/B/A FORREST CITY MEDICAL CENTER; FORT PAYNE HOSPITAL CORPORATION D/B/A DEKALB REGIONAL MEDICAL CENTER; FRANKLIN HOSPITAL CORPORATION D/B/A SOUTHAMPTON MEMORIAL HOSPITAL; GAFFNEY HMA LLC; GALESBURG HOSPITAL CORPORATION D/B/A GALESBURG COTTAGE HOSPITAL; GRANBURY HOSPITAL CORPORATION; GRANITE CITY ILLINOIS HOSPITAL COMPANY LLC D/B/A GATEWAY REGIONAL MEDICAL CENTER; GREENBRIER VMC LLC D/B/A GREENBRIER VALLEY MEDICAL CENTER; GREENVILLE HOSPITAL CORPORATION D/B/A LV STABLER MEMORIAL HOSPITAL; HAINES CITY HMA LLC D/B/A HEART OF FLORIDA REGIONAL MEDICAL CENTER; HAMLET HMA LLC D/B/A SANDHILLS REGIONAL MEDICAL CENTER; HARTSVILLE, LLC D/B/A CAROLINA PINES REGIONAL MEDICAL CENTER; HERNANDO HMA LLC; HMA FENTRESS COUNTY GENERAL HOSPITAL LLC; HMA SANTA ROSA MEDICAL CENTER LLC; HOSPITAL OF BARSTOW INC D/B/A BARSTOW COMMUNITY HOSPITAL; HOSPITAL OF LOUISA, INC. D/B/A THREE RIVERS MEDICAL CENTER; HOSPITAL OF MORRISTOWN LLC D/B/A LAKEWAY REGIONAL HOSPITAL; JACKSON HMA LLC; JACKSON HOSPITAL CORPORATION D/B/A KENTUCKY RIVER MEDICAL CENTER; JACKSON TENNESSEE HOSPITAL COMPANY LLC; JOURDANTON HOSPITAL CORPORATION D/B/A SOUTH TEXAS REGIONAL MEDICAL CENTER; KENNETT HMA LLC; KEY WEST HMA LLC; KIRKSVILLE MISSOURI HOSPITAL COMPANY, LLC; LAKE SHORE HMA,

LLC; LAKE WALES HOSPITAL CORPORATION; LANCASTER HMA LLC D/B/A HEART OF LANCASTER REGIONAL MEDICAL CENTER; LAS CRUCES MEDICAL CENTER LLC; LEA REGIONAL HOSPITAL LLC; LEBANON HMA LLC; LEHIGH HMA LLC D/B/A LEHIGH REGIONAL MEDICAL CENTER; LEXINGTON HOSPITAL CORPORATION D/B/A HENDERSON COUNTY COMMUNITY HOSPITAL; LONGVIEW MEDICAL CENTER LP D/B/A LONGVIEW REGIONAL MEDICAL CENTER; MADISON HMA LLC; MARION HOSPITAL CORPORATION D/B/A HEARTLAND REGIONAL MEDICAL CENTER; MARSHALL COUNTY HMA, LLC; MARTIN HOSPITAL COMPANY LLC D/B/A TENNOVA HEALTHCARE-VOLUNTEER MARTIN; MARY BLACK HEALTH SYSTEM LLC D/B/A MARY BLACK HEALTH SYSTEM SPARTANBURG; MAT-SU VALLEY MEDICAL CENTER LLC D/B/A MAT-SU REGIONAL MEDICAL CENTER; MAYES COUNTY HMA, LLC D/B/A ALLIANCEHEALTH PRYOR; MCKENZIE TENNESSEE HOSPITAL COMPANY LLC D/B/A MCKENZIE REGIONAL HOSPITAL; MCKENZIE WILLAMETTE REGIONAL MEDICAL CENTER ASSOCIATES LLC D/B/A MCKENZIE-WILLAMETTE MEDICAL CENTER; MCSA LLC D/B/A MEDICAL CENTER OF SOUTH ARKANSAS; MELBOURNE HMA, LLC D/B/A WUESTHOFF MEDICAL CENTER - MELBOURNE; MIDWEST REGIONAL MEDICAL CENTER, LLC D/B/A MIDWEST REGIONAL MEDICAL CENTER; MMC OF NEVADA LLC D/B/A MESA VIEW REGIONAL HOSPITAL; MOBERLY HOSPITAL COMPANY LLC D/B/A MOBERLY REGIONAL MEDICAL CENTER; MONROE HMA, LLC D/B/A CLEARVIEW REGIONAL MEDICAL CENTER; MOORESVILLE HOSPITAL

MANAGEMENT ASSOCIATES LLC D/B/A LAKE NORMAN REGIONAL MEDICAL CENTER; NAPLES HMA LLC D/B/A PHYSICIANS REGIONAL MEDICAL CENTER; NATCHEZ COMMUNITY HOSPITAL LLC D/B/A NATCHEZ COMMUNITY HOSPITAL; NATIONAL HEALTHCARE OF LEESVILLE, INC. D/B/A BYRD REGIONAL HOSPITAL; NATIONAL HEALTHCARE OF MT VERNON INC D/B/A CROSSROADS COMMUNITY HOSPITAL; NAVARRO HOSPITAL LP D/B/A NAVARRO REGIONAL HOSPITAL; NHCI OF HILLSBORO INC D/B/A HILL REGIONAL HOSPITAL; OAK HILL HOSPITAL CORPORATION D/B/A PLATEAU MEDICAL CENTER; OSCEOLASC LLC; PAINTSVILLE HOSPITAL COMPANY, LLC D/B/A PAUL B HALL REGIONAL MEDICAL CENTER; PASCO REGIONAL MEDICAL CENTER, LLC; PHILLIPS HOSPITAL CORPORATION D/B/A HELENA REGIONAL MEDICAL CENTER; PINEY WOODS HEALTHCARE SYSTEM, L.P. D/B/A WOODLAND HEIGHTS MEDICAL CENTER; POPLAR BLUFF REGIONAL MEDICAL CENTER LLC; PORT CHARLOTTE HMA LLC D/B/A BAYFRONT HEALTH PORT CHARLOTTE; PRIME HEALTHCARE SERVICES MESQUITE LLC; PUNTA GORDA HMA LLC; QHG OF ENTERPRISE INC D/B/A MEDICAL CENTER ENTERPRISE; QHG OF SOUTH CAROLINA INC D/B/A CAROLINAS HOSPITAL SYSTEM MARION; RED BUD ILLINOIS HOSPITAL COMPANY LLC D/B/A RED BUD REGIONAL HOSPITAL; RIVER OAKS HOSPITAL LLC D/B/A MERIT HEALTH RIVER OAKS; ROCKLEDGE HMA, LLC D/B/A WUESTHOFF MEDICAL CENTER - ROCKLEDGE; ROH LLC; ROSE CITY HMA LLC D/B/A LANCASTER REGIONAL MEDICAL CENTER; RUSTON

LOUISIANA HOSPITAL COMPANY LLC D/B/A NORTHERN LOUISIANA MEDICAL CENTER; SALEM HOSPITAL CORPORATION D/B/A THE MEMORIAL HOSPITAL OF SALEM COUNTY; SAN ANGELO HOSPITAL LP D/B/A SAN ANGELO COMMUNITY MEDICAL CENTER; SAN MIGUEL HOSPITAL CORPORATION D/B/A ALTA VISTA REGIONAL HOSPITAL; SEBASTIAN HOSPITAL LLC D/B/A SEBASTIAN RIVER MEDICAL CENTER; SEBRING HOSPITAL MANAGEMENT ASSOCIATES LLC D/B/A HIGHLANDS REGIONAL MEDICAL CENTER; SEMINOLE HMA, LLC D/B/A ALLIANCEHEALTH SEMINOLE; SHELBYVILLE HOSPITAL COMPANY LLC D/B/A TENNOVA HEALTHCARE-SHELBYVILLE; SILOAM SPRINGS ARKANSAS HOSPITAL COMPANY LLC D/B/A SILOAM SPRINGS REGIONAL HOSPITAL; STARKE HMA, LLC D/B/A SHANDS STARKE REGIONAL MEDICAL CENTER; STATESVILLE HMA LLC D/B/A DAVIS REGIONAL MEDICAL CENTER; SUNBURY HOSPITAL COMPANY LLC D/B/A SUNBURY COMMUNITY HOSPITAL; THE HEALTH CARE AUTHORITY OF THE CITY OF ANNISTON D/B/A STRINGFELLOW MEMORIAL HOSPITAL; TOOELE HOSPITAL CORPORATION D/B/A MOUNTAIN WEST MEDICAL CENTER; TULLAHOMA HMA LLC D/B/A TENNOVA HEALTHCARE-HARTON; TUNKHANNOCK HOSPITAL COMPANY LLC D/B/A TYLER MEMORIAL HOSPITAL; VAN BUREN HMA LLC D/B/A SPARKS MEDICAL CENTER- VAN BUREN; VENICE HMA LLC D/B/A VENICE REGIONAL BAYFRONT HEALTH; VICTORIA OF TEXAS LP D/B/A DETAR HOSPITAL NAVARRO; WATSONVILLE HOSPITAL CORPORATION D/B/A WATSONVILLE COMMUNITY HOSPITAL; WEST GROVE

HOSPITAL COMPANY LLC D/B/A JENNERSVILLE REGIONAL HOSPITAL; WHITE COUNTY MEDICAL CENTER D/B/A UNITY HEALTH HARRIS MEDICAL CENTER; WILLIAMSON MEMORIAL HOSPITAL LLC D/B/A WILLIAMSON MEMORIAL HOSPITAL; WILLIAMSTON HOSPITAL CORPORATION D/B/A MARTIN GENERAL HOSPITAL; WINDER HMA LLC D/B/A BARROW REGIONAL MEDICAL CENTER; WOMEN & CHILDRENS HOSPITAL LLC D/B/A LAKE AREA MEDICAL CENTER; WOODWARD HEALTH SYSTEM LLC D/B/A ALLIANCEHEALTH WOODWARD; YAKIMA HMA LLC D/B/A TOPPENISH COMMUNITY HOSPTIAL; YAKIMA HMA LLC D/B/A YAKIMA REGIONAL MEDICAL AND CARDIAC CENTER; and MEDHOST, INC.,

Defendants.

COMPLAINT

Plaintiff-Relators Derek Lewis and Joey Neiman, through their attorneys, on behalf of the United States of America (the "Government"), for their Complaint against Defendants Community Health Systems, Inc. ("CHSI"), CHSPSC, LLC, the CHS hospitals identified in Exhibit A and incorporated by reference herein (collectively, with CHSI and CHSPSC, "CHS"), and Medhost, Inc. ("Medhost") (collectively, "Defendants"), allege based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendants and/or their agents and employees, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("the FCA").

2. This action alleges that Defendants submitted or caused to be submitted hundreds of millions of dollars in false claims to the Department of Health and Human Services ("HHS") for federal incentive payments through the Electronic Health Record ("EHR") Incentive Programs.

3. Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), HHS established the Medicare and Medicaid EHR Incentive Programs (also known as the "Meaningful Use program"), which provided incentive payments to healthcare providers who demonstrated "meaningful use" of certified EHR technology.

4. Defendant CHS is one of the largest hospital operators in the nation, with 127 hospital facilities located in twenty states. The incentive payments in the HITECH Act were an important revenue stream for CHS, which received $544 million in incentive payments. With large amounts of money at stake, CHS made it a business priority for as many of its hospitals as possible to submit attestations for Meaningful Use incentive payments. Through the use of special implementation teams, CHS aimed to maximize the number of its hospitals receiving Meaningful Use incentive payments.

5. Defendant Medhost developed the EHR technology that CHS implemented at many of its hospitals.

6. Medhost's software suffers from pervasive flaws that make it ineligible for certification under the Meaningful Use program, including multiple design failures in its software for computerized physician order entry ("CPOE") and clinical decision support. These flaws prevent healthcare providers from providing clinical care in multiple CHS hospitals safely and reliably. Many of the flaws create an acute risk to patient health and safety.

7. Based on information and belief after a reasonable investigation, Medhost knowingly and falsely attested to its certifying body that its software complied with the requirements for Stage 2 certification and for the payment of incentives under the Meaningful Use program.

8. Medhost's software would not have been eligible for certification if the certifying body had known that Medhost could not perform many of the critical functions it falsely represented it could perform.

9. As a result of the use of Medhost software, CHS and its hospitals presented, or caused to be presented, false attestations to the Government about hospital compliance with required Meaningful Use objectives and measures to obtain Meaningful Use subsidies.

10. CHS knows, and knew, that the Medhost software deployed in its hospitals is defective and unreliable and does not meet the requirements for certified EHR technology. Nonetheless, CHS and its hospitals presented or caused to be presented attestations to the Government representing eligibility for Meaningful Use incentive payments.

11. CHS's implementation of Medhost's software compounded problems with the software making the Medhost system even more unreliable and often dangerous.

12. CHS implemented Medhost's software at a rapid pace so as to be able to submit attestations for Meaningful Use Stage 2 incentive payments. In its haste, CHS took shortcuts and additional defects with performance of the software resulted. Among other things, CHS mapped many order sets incorrectly to hospital formularies, causing doctors to inadvertently place orders for incorrect medications and medication dosages. One CHS employee warned these flaws had "a very high potential for causing a catastrophic event."

13. Even though the flaws and lack of reliability with both the Medhost software and CHS's implementation of the software should have made the CHS hospitals ineligible for Meaningful Use incentive payments, CHS and CHS hospitals knowingly misrepresented to the Government that the hospitals were eligible for subsidy payments.

14. CHS also knowingly misrepresented its eligibility for Meaningful Use incentive payments for sixty hospitals that CHS acquired through a merger with Health Management Associates ("HMA"). These sixty hospitals used a modular electronic health record software known as PULSE. The PULSE EHR modules at these sixty hospitals were not integrated properly and these hospitals could not, and in many cases, cannot, perform tasks that required

more than one EHR module without resorting to paper. Basic workflows, such as admitting a patient from the emergency department or transferring a patient from one inpatient department to another, have required hospital staff to print out the patient's medical records for delivery to the new department.

15. The former HMA hospitals using PULSE technology could not meet the requirements for demonstrating Meaningful Use of certified EHR technology and should have been ineligible for MU incentive payments.

16. CHS knowingly misrepresented to the Government that the CHS hospitals using Medhost and PULSE met all required Meaningful Use objectives and measures and were eligible for Meaningful Use incentive payments.

17. The Government would not have made Meaningful Use subsidy payments to the CHS hospitals that used the Medhost or the PULSE software if it has known of the flaws with the software and problems with implementation of the software that resulted in failure to perform required functions.

18. Defendants' false and fraudulent statements and conduct alleged in this Complaint violate the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq*. The FCA allows any person having information about an FCA violation (referred to as a *qui tam* plaintiff or "relator") to bring an action on behalf of the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

19. *Qui tam* Plaintiff-Relators Derek Lewis and Joey Neiman seek through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged herein in every jurisdiction to which Defendants' misconduct has extended.

II. PARTIES

A. Plaintiffs

20. Plaintiff United States of America is the real party in interest herein. The United States, acting through HHS, administers the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (Medicare), and administers grants to states for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq*. (Medicaid). The United States, acting through HHS, also administers the Meaningful Use program and a certification program for EHR technology.

21. *Qui tam* Plaintiff-Relator Derek Lewis ("Relator Lewis") is a resident of Murfreesboro, Tennessee. Relator Lewis worked for Defendant CHS from January 2009 to December 2016. Between December 2012 and February 2015, Relator Lewis was CHS's Manager of Design and Midrange Engineering, Technology. In that role, he helped to provide infrastructure strategy and management to support CHS's upgrade of 130 facilities to Medhost's HMS 12.0 software. In February 2015, Relator Lewis became CHS's Manager of Product Engineering, Deployment, where he was responsible for the configuration management, automation, and user experience components of CHS's EHR product strategy. In August 2015, he was promoted to Director of Technology Adoption, Deployment, where he was responsible for managing EHR implementation projects at CHS hospitals.

22. *Qui tam* Plaintiff-Relator Joey Neiman ("Relator Neiman") is a resident of Thompson's Station, Tennessee. Relator Neiman worked for Defendant CHS from March 2012 to December 2016. He joined CHS as a Technical Specialist for CHS's Tier 1 Clinical Systems (CHS hospitals that utilized Medhost's EHR software) and was responsible for leading technical projects involving the clinical systems at CHS's hospitals. In February 2014, Relator Neiman was promoted to CHS's Manager of Health Information System Delivery, Deployment Services. In that role, he was responsible for building EHR systems as part of hospital conversions and acquisitions, as well as program management for various projects involving CHS's EHR software.

B. Defendants

1. Community Health Systems, Inc.

23. Defendant Community Health Systems, Inc. ("CHSI") is one of the largest publicly traded hospital companies in the United States and a leading operator of general acute care hospitals. CHSI is incorporated under the laws of the state of Delaware and headquartered at 4000 Meridian Boulevard, Franklin, Tennessee 37067. Through its wholly owned direct or indirect subsidiaries, CHSI owns, leases, or operates 127 hospitals in 20 states with an aggregate of approximately 26,000 licensed beds. Together, CHSI and its directly or indirectly owned affiliate companies are referred to herein as "CHS."

2. CHSPSC, LLC

24. Defendant CHSPSC, LLC (formerly Community Health Systems Professional Services Corporation) is a Delaware corporation headquartered at 4000 Meridian Boulevard, Franklin, Tennessee 37067. CHSPSC is a subsidiary of CHSI that manages CHS's hospitals and other affiliates.

3. CHS Hospitals

25. The Defendant CHS hospitals are identified in Exhibit A and incorporated by reference herein. CHSI and/or its wholly-owned direct and indirect subsidiaries owned, leased, or operated each of the hospitals during the relevant time period. Each hospital attested to Meaningful Use of certified EHR technology based on their use of Medhost or PULSE software.

4. Medhost, Inc.

26. Defendant Medhost, Inc., ("Medhost") is a health information technology company that provides enterprise, departmental, and healthcare engagement solutions to over 1,100 healthcare facilities in the United States. It is headquartered at 6550 Carothers Parkway, Suite 100, Franklin, TN 37067. Medhost's suite of EHR software consists of multiple applications, including an Enterprise System for inpatient care, an EDIS system for Emergency Departments, a Perioperative Information Management System ("PIMS") system for surgical operations and scheduling, and a business intelligence system for tracking and reporting Meaningful Use.

27. CHS is one of Medhost's largest customers. Medhost's other significant customer is the Brentwood, Tennessee-based LifePoint Health, Inc. ("LifePoint"), another large hospital chain. LifePoint hospitals have also certified to Meaningful Use, and received incentive payments, based on the use of Medhost's suite of EHR software.

III. JURISDICTION AND VENUE

28. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relators' knowledge there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e), as amended by Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02. Regardless of whether such a disclosure has occurred, Relators qualify as "original sources" of the information on which the allegations or transactions in this Complaint are based. Before filing this action, Relators voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relators have direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds to any publicly disclosed allegations or transactions relevant to their claims.

29. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, one or more Defendants can be found in and/or transact business in the Southern District of Florida.

30. Venue is proper in the Southern District of Florida pursuant to 28 U.S.C. §§ 1391(b)-(c) and 31 U.S.C. § 3732(a) because one or more Defendants can be found in and/or transact business in this District, and because violations of 31 U.S.C. §§ 3729 *et seq*. alleged herein occurred within this District. CHS, for example, operated hospitals within this District, including the Lower Keys Medical Center located in Key West, Florida. As discussed below, the

Lower Keys Medical Center submitted false attestations to the Government to claim incentive payments for its use of PULSE and other EHR modules.

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

31. The FCA imposes civil liability on any person who, *inter alia*: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government; or (4) conspires to violate the FCA. 31 U.S.C. §§ 3729(a)(l)(A), (B). (C), and (G).

32. The FCA defines a "claim" to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that - (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest ...." *Id.* at § 3729(b)(2).

33. The FCA defines the terms "knowing" and "knowingly" to mean "that a person, with respect to information - (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. *Id.* at § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id.* at § 3729(b)(l)(B).

34. The FCA provides that the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4).

35. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id.* at § 3729(a)(l).

B. The Anti-Kickback Statute

36. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), provides, in pertinent part:

> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -
>
> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) To purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

37. Accordingly, manufacturers of products paid for in whole or in part by federal healthcare programs may not offer or pay any remuneration, in cash or in kind, directly or indirectly, to induce physicians, medical practices, or others to order or recommend products paid for in whole or in part by Federal healthcare programs such as Medicare and Medicaid.

38. The Patient Protection and Affordable Care Act ("PPACA"), Publ. L No. 111-48, 124 Stat. 119 (2010), provides that violations of the AKS are *per se* violations of the FCA: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]."

39. The PPACA also clarified the intent requirement of the Anti-Kickback Statute, and provides that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation." *Id.*

C. Certified EHR Technology and the Meaningful Use Program

1. Certification of EHR Software

40. On February 17, 2009, the HITECH Act was enacted to promote the adoption and meaningful use of certified EHR technology. Under the HITECH Act, the HHS Office of the National Coordinator for Health Information Technology ("ONC") established a certification program for EHR technology. As part of the certification program, EHR vendors attest to ONC authorized certification bodies ("ACB") and accredited testing laboratories ("ATL") that their

software meets the certification requirements established by ONC. The certification bodies and testing laboratories test and certify that vendors' EHRs are compliant with the certification requirements.

41. To obtain certification, EHR vendors must attest to an ACB that their EHR product satisfies the applicable certification criteria, submit to certification testing by an ATL, and pass such testing.

42. After obtaining certification, an EHR vendor must maintain that certification by complying with all applicable conditions and requirements of the certification program. Among other things, the EHR product must be able to accurately, reliably, and safely perform its certified capabilities while in use in hospitals and doctors' offices. EHR vendors must cooperate with the processes established by ONC for testing, certifying, and conducting ongoing surveillance and review of certified EHR technology.

2. Meaningful Use of Certified EHRs

43. Through the Meaningful Use program, CMS makes incentive payments and applies penalties to healthcare providers based on whether the providers demonstrate meaningful use of certified EHR technology. The healthcare providers eligible to receive incentive payments under the program include hospitals ("Eligible Hospitals"), critical access hospitals ("CAHs"), and individual practitioners ("Eligible Professionals"). Incentives are available under both the Medicare and Medicaid programs.

44. To qualify for incentive payments under the Meaningful Use program, Eligible Hospitals, CAHs, and Eligible Professionals are required, among other things, to: (1) use an EHR system that qualifies as certified EHR technology; and (2) satisfy certain objectives and measures relating to their meaningful use of the certified EHR technology.

45. HHS implemented the EHR certification criteria and incentive payment requirements in multiple stages. On January 13, 2010, HHS published in the Federal Register interim final rules setting forth the "2011 Edition" certification criteria and a proposed rule setting forth the "Stage 1" requirements for incentive payments. HHS finalized these

rulemakings by publication in the Federal Register on July 28, 2010. In Stage 1, Eligible Hospitals and CAHs needed to satisfy fourteen "core objectives" and five out of ten "menu set objectives." An Eligible Professional's use of certified EHR technology generally needed to satisfy fifteen "core objectives" and five out of ten "menu set objectives."

46. On September 4, 2012, HHS published in the Federal Register the final rules setting forth the "2014 Edition" certification criteria and "Stage 2" requirements for incentive payments. In Stage 2, Eligible Hospitals and CAHs needed to satisfy sixteen "core objectives" and three out of six "menu set objectives." An Eligible Professional's use of certified EHR technology generally needed to satisfy seventeen "core objectives" and three out of six "menu set objectives."

47. On October 16, 2015, CMS published in the Federal Register a final rule with comment period setting forth the "Modified Stage 2" requirements for incentive payments. For years 2015 through 2017, Modified Stage 2 eliminated the concept of "menu set objectives" and required all Eligible Hospitals, CAHs, and Eligible Professionals, to attest to a single set of objectives and measures.

48. In October 2015, CMS also released a final rule that established Stage 3 in 2017 and beyond, which focuses on using certified EHR technology to improve quality, safety, and efficacy of health care, including promoting patient access to self-management tools and improving population health.

49. Starting in 2015, all providers were required to use technology certified to the 2014 Edition. For 2016 and 2017, providers can choose to use technology certified to the 2014 Edition or the 2015 Edition.

50. To qualify for incentive payments in each Stage of the Meaningful Use program, healthcare providers are required each year to attest that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures. Use of certified EHR technology and satisfaction of applicable Meaningful Use objectives and measures are material to payment under the Meaningful Use program.

3. Incentives Available Under the Meaningful Use Program

51. In general, Hospitals and CAHs are eligible for Medicare's Meaningful Use incentives if they are paid using the Medicare Inpatient Prospective Payment System ("IPPS"), and are eligible for Medicaid's Meaningful Use incentives if they have a Medicaid patient volume of at least 10 percent. Hospitals can be dual-eligible and receive incentives under both programs.

52. The incentive payments from Medicare and/or Medicaid are the product of three factors: (1) an "initial amount" between $2,000,000 and $6,370,200, which is determined based on the number of discharges; (2) the Medicare or Medicaid "share percentage," which is based on the hospital's ratio of Medicare or Medicaid inpatient days to total inpatient days (modified by charges for charity care); and (3) a "transition factor" based on the year the hospital began receiving incentive payments.

53. Medicare payments to Eligible Hospitals under this formula ended after 2016. Medicaid payments to Eligible Hospitals can continue until 2021, although hospitals may not gain eligibility after 2016.

54. Meanwhile, Eligible Hospitals that fail to meaningfully use Certified EHR technology are subject to negative payment adjustments under the Medicare program. Each year, Medicare adjusts the IPPS for inflation. Hospitals that fail the criteria are penalized by a reduction in this increase. The payment adjustment occurs two years after the EHR reporting period, and was a 25% reduction in 2015, a 50% reduction in 2016, and will be a 75% reduction for 2017 and after. There are no payment adjustments under the Medicaid program.

55. Critical Access Hospitals ("CAHs") are also eligible for Medicare and Medicaid incentives under the program; however, the Medicare incentives are calculated differently. CAHs could qualify for an incentive payment from Medicare equal to the product of: (1) the CAH's reasonable costs incurred for the purchase of certified EHR technology; and (2) the CAH's Medicare share percentage, which in this instance is the Medicare share percentage as computed

for Eligible Hospitals plus 20 percentage points, subject to a maximum share percentage of 100%. Medicare incentive payments under this formula for CAHs ended after 2015.

56. Eligible Professionals, under the Meaningful Use program, could qualify for up to $43,720 over five years from Medicare (ending after 2016) or up to $63,750 over six years from Medicaid (ending after 2021).

57. Starting in 2017, the Medicare EHR Incentive Program for Eligible Professionals was incorporated into the Merit-based Incentive Payment System ("MIPS") under the Quality Payment Program created by the Medicare Access and CHIP Reauthorization Act ("MACRA"), 42 U.S.C. § 1395ee.

D. Certified EHR Technology and the IQR Program

58. The Hospital Inpatient Quality Reporting Program ("IQR") is a voluntary reporting program that provides a financial incentive for hospitals to submit data to CMS on specified quality measures for services furnished to Medicare beneficiaries. The Program's goal is to drive quality improvement through measurement and transparency by publicly displaying data that helps consumers make more informed decisions about health care. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care.

59. Similar to the negative payment adjustment for failure to meet Meaningful Use requirements, failure to report the data required under the IQR Program results in a negative payment adjustment to the hospital, calculated as a percentage reduction in Medicare's annual increase to the IPPS. The payment adjustment occurs two years after the IQR reporting period. In 2005-2006, the penalty was a .4% reduction, in 2007-2014 it was a 2% reduction, and from 2015 onward, the penalty is a 25% reduction.

60. Originally, hospitals had to manually compile all of the data for submission to the Program. However, beginning in 2014, CMS gave hospitals the option of reporting some of the IQR data to CMS electronically in the form of electronic clinical quality measures ("eCQMs"). To submit eCQMs, CMS required hospitals to use Certified EHR technology. In 2016, CMS made the submission of eCQMs for the IQR Program mandatory, and required that hospitals

submit the data using either 2014 Edition or 2015 Edition Certified EHR technology. These rules for the Program will continue at least through the 2018 reporting period.

V. ALLEGATIONS

61. This case concerns fraud in obtaining hundreds of millions of dollars in incentive payments under the Meaningful Use program by CHS and Medhost.

62. Beginning in 2012, CHS represented to the Government that dozens of its hospitals met the objectives and measures for Meaningful Use of certified EHR technology. Based on those representations, CHS received over $450 million in Meaningful Use incentive payments between 2012 and 2015.

63. CHS's attestations were false. The EHR technologies that CHS implemented contained serious flaws that endangered patients and made its hospitals ineligible for incentive payments under the Meaningful Use program. Medhost's EHR, which dozens of CHS hospitals used, failed to perform critical functions safely and reliably. Some of the defects in the software, including an inability to calculate weight-based dosing accurately, exposed patients to mistakes that were easily missed in institutional settings and potentially catastrophic. The providers who relied on Medhost software often viewed it as an impediment to care, rather than an improvement.

64. Similar problems existed for the CHS hospitals that used PULSE, a modular EHR. The hospitals failed to integrate the different PULSE EHR modules, forcing providers to print clinical information when patients transitioned from one care setting to another, as well as when doctors entered medication orders. Many workflows have required nurses to enter the same patient information into the EHR multiple times, with the risk of patient harm increasing with each unnecessary step.

65. The Government would not have made Meaningful Use incentive payments to CHS, or any other providers that used Medhost's software, had it known of the serious flaws in its EHR systems.

A. Background

1. Background on Medhost's Software and Certifications

66. Medhost is a healthcare technology company. Founded in 1984, Medhost originally limited its business to developing software for use in emergency departments with a program called Emergency Department Information System ("EDIS"). In 2010, the parent of a Nashville-based technology company, Healthcare Management Systems ("HMS"), acquired Medhost and incorporated the EDIS product into a wider suite of healthcare technology products. Following the Medhost acquisition, the products were integrated into a single EHR system and certified as a "complete" EHR, which means an EHR that meets all mandatory certification criteria for inpatient settings.

67. The EHR system that resulted did not function well as an integrated system, however, but was, instead, a series of modules of varying quality. As each module of Medhost was developed, Medhost found that the system did not function well and was unreliable, including with computerized physician order entry ("CPOE") and clinical decision support ("CDS") functions. A systemic problem was that the modules did not communicate information well within the EHR, making it difficult for users to perform tasks that relied on multiple modules. For patients in an inpatient setting, risks arose at each step through the inpatient experience including for ordering of medications and laboratory studies.

68. In addition to poor integration, the Medhost system is shoddily designed and lacks required functionalities. For example, for a physician using the CPOE function to place an order for a drug, there is no standard or comprehensive drug database triggered. Instead, Medhost triggers only the hospital formulary drugs and does not recognize non-formulary drugs. If a provider enters a drug into the EHR that the hospital does not list on its formulary, the software will not recognize it. When that happens, the EHR will treat the drug as unstructured "free text" that exists within the system but will not engage the EHR's functionality. Due to this limitation and others, many of the providers who use Medhost's EHR regard it as substandard.

2. CHS's Implementation of the Medhost EHR

69. CHS was one of Medhost's largest customers and used its EHR at dozens of hospitals in its network. Beginning in 2012, CHS implemented Medhost's 2011 Edition software and attested to Meaningful Use at 78 hospitals during the Stage 1 reporting period. In late 2013, CHS began to implement Medhost's 2014 Edition software at the hospitals that had used the 2011 Edition for Stage 1, while concurrently implementing 2011 Edition software at hospitals that had not attested to Meaningful Use in Stage 1. CHS's goal was to implement certified EHR technology at as many of its hospitals as possible ahead of the 2014 Meaningful Use attestation reporting period.

70. The senior CHS executive responsible for the implementation project was CHS's Senior Vice President and Chief Information Officer, J. Gary Seay. Seay managed a large team from CHS's corporate-level clinical operations and IT departments, including a deployment team that implemented Medhost's EHR software at CHS hospitals as well as a clinical applications team that was responsible for testing new software releases and working support tickets from the field. The clinical applications team reported to CHS Deputy CIO Manish Shah and was led by Vice President of Clinical Applications Jay Sbinski, Director of Clinical Application Systems Gary Fritz, and Senior Manager of Physician Tools Tim Moore. The deployment team reported to Mr. Seay and was led by Vice President Michael Yzerman, Senior Director Steve Hernandez, and Program Management Director Teri Mitchell. Together, the teams were responsible for deploying EHRs at CHS hospitals and for ensuring that the hospitals were prepared to submit Meaningful Use attestations to the Government.

71. In the months leading up to the 2014 Meaningful Use attestation reporting period, CHS rolled out updated versions of Medhost software at numerous CHS hospitals, which included new CPOE functionality intended to satisfy the Stage 2 Meaningful Use criteria. During the rollout, CHS was focused primarily on implementation of the software with the speed necessary to ensure receipt of tens of millions of dollars in Government awards through the EHR incentive programs. CHS's focus on speed came at the expense of patient safety. As it became

apparent to CHS that the Medhost EHR software was incapable of safely performing CPOE, CHS did not halt the rollout, and instead chose to move forward so as not risk receipt of the Meaningful Use incentive payments.

72. Soon after the Medhost rollout began, doctors and hospital administrators began to report that the updated Medhost software was not able to perform, and that the flaws with the system were putting the safety of CHS patients at risk. For example, on July 8, 2014, the Director of Physician Services at CHS's Deaconess Hospital wrote to the hospital CEO regarding physician frustration with the system: the doctors are "frustrate[ed] regarding the fact that the issues with Medhost are still a way from being resolved through upgrades, etc. … [and] they are expected to practice safety but the system has created an unsafe practice." Another doctor at Deaconess, responding with a message that was forwarded on July 9 to CHS Chief Medical Information Officer Anwar Hussain, went further:

> Please pass this along to any and every person who can leverage this. There are 'known issues' from many months ago from previous deployments which have not been addressed. We are finding new issues every, and I mean every, day. I realize it would be convenient if all these could be addressed in a single massive upgrade later. Many of these cannot wait two or three or six months. An easy example of "safety issue" is there is no warning mechanism when meds have been duplicated, or tests duplicated. We cannot push safety as we have been doing for the last 2 years as a priority if we give no priority to a safe [EHR]. Things we identified a month ago are still unresolved. Our list is growing, and frustration is not lessening.

73. As more and more hospitals sounded the alarm, CHS instituted weekly "critical issues" calls to discuss the problems the hospitals were experiencing with Medhost's EHR. The calls were led by corporate-level executives, including Mr. Fritz and Mr. Moore, and included IT and clinical informatics personnel from each of the Medhost hospitals. The calls began in approximately August 2014 and continued into at least November 2014. On the calls, the hospitals repeatedly voiced their concern about the EHR's lack of functionality and safety.

74. In conjunction with the calls, CHS issued regular advisory memoranda to the hospitals. Many of the advisories came from CHS Vice President and Chief Medical Information Officer Anwar Hussein as well as CHS Vice President and Chief Nursing Officer Pam Rudisill. The advisories were directed to the medical staff and senior executives (e.g.,

Chief Executive Officers and Chief Nursing Officers) at the hospitals. The advisories warned of serious, unresolved problems with the Medhost EHR software and instructed CHS hospitals to implement additional safety checks because of them. For example, Ms. Rudisill sent advisories to the hospitals titled "Double Checking Multi-Dose medication administration," "Double Checking of Medications with Multiple Tablets Dispensed," and "IMPORTANT ACTION REQUIRED: Medhost/HMS Order Sets."

75. In their capacity as Managers working on CHS teams to roll out and support health IT software, Relators were notified by physicians and other hospital personnel of the functional and safety issues with the CPOE software, including, as described further below, errors in medication selection and dose calculation, failure to trigger delivery of medication at the correct time, inability to reliably perform drug-drug, drug-allergy, and duplicate therapy checks, and an inability to lock patient charts while open. Relators believe that this list of issues represents only a sample of the CPOE-related flaws that exist and existed in CHS's Medhost EHR software. Taken together, these flaws reveal an EHR that is not able to perform as required by federal law and is dangerously broken.

76. The Government created the EHR incentive program to facilitate the use of software to enhance public health and achieve superior health outcomes, and it chose the specific criteria required under the program to advance that goal. The ability of EHR software to meet the basic criteria for CPOE and CDS—and to do so safely—are material to the government's decision to pay awards under the EHR incentive programs.

B. Medhost's Computerized Physician Order Entry ("CPOE") Software Failed to Meet the Requirements for Certified EHR Technology

77. To be certified as a Complete EHR under 2014 Edition certification criteria, an EHR must be able to perform computerized provider order entry ("CPOE") in accordance with CMS standards and implementation specifications. Among other things, the EHR must enable users to electronically record, store, retrieve, and modify medication orders, laboratory orders,

and radiology/imaging orders. The EHR must be able to perform these functions accurately, reliably, and safely.

78. The Medhost software installed at CHS's hospitals was incapable of performing CPOE in a safe and reliable manner and thus did not meet the requirements for certified EHR technology. The defects included flaws that existed within Medhost's software, thus affecting all healthcare providers that used the software, as well as flaws that CHS introduced in configuring and deploying the software at its hospitals. Many of the defects remain unaddressed, as Medhost has laid off staff from its development teams and repeatedly delayed the release of critical fixes.

1. Medhost EHR Flaws Relating to Medication Order Entry

a. *Flaws in the Java Clinical View Medication Entry Portal*

79. Medhost's EHR software suite, implemented at CHS, is made up of many separate applications, which are supposed to work together as a single integrated system. Several of the Medhost applications can be used by providers to place medication orders, including the Java-based Clinical View portal ("ClinView"), the web-based "PhysDoc" module, the Clinical Reconciliation module ("ClinRec"), and the Pharmacy module ("GUI"). During the time period relevant to this Complaint, physicians and nurses at the CHS Medhost hospitals primarily used PhysDoc and ClinView to enter medication orders into the Medhost system.

80. ClinView's medication ordering functionality contains numerous dangerous flaws, which can cause and have caused medication orders to be incorrectly entered and recorded in the system, rendering it unsafe for CHS patients and non-compliant with the Meaningful Use CPOE criterion. These flaws include, but are not limited to, the following:

(1) *Weight-Based Dosing Feature Calculates Incorrect Drip-Rate for Medications*

81. Under certain circumstances, the ClinView module fails to calculate the correct dose for weight-based medications. The issue occurs when the software calculates a dosage for weight-based medications requiring a "drip-rate"—the measurement of rate at which medications are to be administered through an intravenous (IV) drip.

82. For example, CHS found errors in how ClinView calculated the drip rate on an order for Sodium Chloride 0.9% Bag 1000 ml Solution, for an individual weighing 158 lbs. The correct drip-rate for a 158 lb. individual is 5.991 ml per hour. However, the ClinView module instead created an order for the medication with a drip-rate of 41.666 ml per hour, nearly seven times too high.

83. On learning of this flaw in the system, CHS instructed its pharmacists not to rely on the Medhost EHR's drip-rate calculations, and to instead manually calculate a new rate.

(2) *Weight-Based Dosing Window Can Display Incorrect Medication*

84. Under certain circumstances, the ClinView application suffers a medication name mismatch in its weight-based dosing window. The issue can occur when a doctor utilizes the module to calculate the dose for a weight-based medication. After the doctor enters the name of the desired medication, the ClinView application calculates the dosage for an entirely different medication.

85. On May 5, 2014, following a training associated with the rollout of the Medhost software updates, the Director of Pharmacy at CHS's DeTar Healthcare System alerted CHS's software deployment team to the problem: "I tried out the weight based dosing and got some scary results. Please see the screen shots I have attached. It is not always pulling the right drug for the dosing, if [sic] fact it is wrong more that [sic] it is right. Is this a known issue?"

86. The Director of Pharmacy illustrated two separate instances of the issue through screenshots attached to her email. One screenshot showed a medication order entry for the drug Clindamycin Phosphate. The other screenshot showed an entry for the drug Cefazolin Sodium. However, both screenshots revealed that the weight-based dosage feature had pulled the wrong medication, Gentamicin Sulfate, for the calculation.

(3) *"Send Dose Now" Checkbox Created Medication Orders Scheduled for Delayed Delivery*

87. Medhost provided a "Send Dose Now" checkbox in the ClinView order entry window that doctors could select while making a medication order. The purpose of the checkbox was so physicians could indicate that they wanted the medication to be immediately delivered to the patient. However, the "Send Dose Now" checkbox did not, in fact, create medication orders designated for immediate delivery, but instead created orders scheduled for normal delivery at the next scheduled frequency.

88. For example, if a physician entered a medication order to be administered every three hours, and checked the "Send Dose Now" checkbox, the Medhost software created an order for the medication specifying administration of the medication every three hours, with the first dose scheduled to be delivered three hours in the future. The tool therefore did not trigger the immediate administration of a dose. Physicians who relied on the tool for that purpose were at risk of unwittingly delaying treatment.

89. CHS and Medhost became aware of this issue no later than April 2014. Rather than disable the broken feature, however, CHS instructed doctors to either call the pharmacy to clarify their orders, or to enter two separate orders for the medication thereby circumventing the requirement of placing medication orders through the EHR system.

90. Despite being flagged as "high priority" and "impacting all sites," Medhost was unable to fix the flaw. Medhost did not disable the feature until the end of July 2014 allowing providers to attempt to use a broken feature for medication ordering for over four months without notifying them of the problems with the ordering mechanism. An August 2014 issue log reported the issue was resolved by disabling the broken feature, stating: "Send Dose Now is disabled with sites trained to not use button."

b. *Other Medication Ordering Flaws in the Medhost EHR Software*

(1) *Medhost's EHR Can Calculate Incorrect Doses for Medications Based on Static Clinical History Profile Data*

91. Medhost's EHR software is incapable of reliably calculating correct medication doses based on the patient's weight, body surface area ("BSA"), or creatinine ("CrCl") levels.

The EHR uses information from the patient's Clinical History Profile ("CHP") to determine the weight, BSA, and CrCl used in the dosage calculation. Providers typically complete the CHP when the patient is admitted to the hospital.

92. Over the course of an inpatient stay, a patient's measurements can change significantly, often enough to yield relevant changes in medication dosage. When a hospital takes new measurements from the patient, Medhost's software will save the new measurements in the EHR but will not update the information in the patient's CHP. Even though the information in the CHP is no longer current for the patient, the software will continue to use the CHP to calculate the patient's medication dosages. Consequently, a patient who suffers weight loss or declining renal function while in the hospital is at risk of receiving medications at doses the EHR calculated based on his or her condition upon admission. Patients who receive such doses may be at risk of significant overdosing or underdosing.

(2) *Medhost Lacks the Capability to Accurately Create PRN Medication Orders*

93. Medhost's EHR is also incapable of reliably creating PRN medication orders orders—orders to be administered "as needed." When a physician enters a PRN medication order that includes an expiration time for the order and a maximum number of doses, Medhost's EHR may terminate the order early (i.e., prior to the expiration date the physician chose) or fail to display the maximum number of doses.

94. On July 30, 2014, the Director of Pharmacy Services at CHS's Fallbrook Hospital wrote to CHS Pharmacy Informatics Manager Jeannie Bennet and others regarding "flawed PRN frequencies in CPOE represent a medication safety risk." In the email, the Director used the example of an order for 6mg of the migraine medication Sumitriptan, to be administered every hour as needed for migraine headache, but with a maximum of 3 doses to be administered over not more than 12 hours. The Director warned that the EHR was incapable of recording the order as the provider had intended—depending on how the provider entered the order into the Medhost EHR, the software would either create an order for a maximum of 3 doses to be administered

over not more than 3 hours, or for unlimited doses to be administered over not more than 12 hours. "Either way," the Director wrote, "the order as entered would not actually reflect what was ordered."

95. Medhost acknowledged to CHS that the problem with PRN medication orders was a "limitation of the system." Medhost refused to fix the problem, however, with one employee writing CHS that: "at some point nurses treating patients have to take some 'clinical responsibility' because [Medhost software] cannot be made fool proof." To the Relators' knowledge, Medhost had not corrected the problem as of late 2016.

(3) *Physician Favorites Feature Can Cause Hospital Pharmacies to Fill Medication Orders Incorrectly*

96. The Medhost EHR does not reliably create medication orders entered using a feature called "Physician Favorites," which allows doctors to create a list of the medication configurations they commonly order from the hospital formulary. The purpose of the list is to allow the doctor to quickly select and order the configurations they tend to use in practice. The feature contains a flaw, however, that in certain circumstances can cause the hospital pharmacy to fill the order incorrectly.

97. When a doctor sets a Physician Favorite, the EHR displays a description of the medication (type, dose, route, etc.) in the doctor's Physician Favorites list and assigns it a "mnemonic" text string that corresponds to the text string used for the medication in the hospital's formulary. The EHR uses the text string to record and place orders for the Physician Favorite. When a doctor enters an order, the EHR compares the mnemonic string to the list of strings in the formulary database, and places an order for the resulting match.

98. Medhost does not connect the information displayed to the provider in the Physician Favorite list with hospital formularies. Hospitals can, and do, change the configuration of drugs in the formulary without changing the mnemonic code that identifies the drugs on the formulary. In such instances, the EHR will display the original configuration to the doctor on the Physician Favorite list. When the doctor orders the medication, however, the EHR

will match the text string to the text string in the formulary for the new configuration. The EHR will trigger an order for the new configuration, not the configuration that the doctor intended to order. The EHR does not alert the doctor to the change in the formulary or remove the medication from the Physician Favorite tool.

99. This problem occurs most commonly when a hospital changes a medication's unit of measurement (*e.g.*, from grams to milligrams). At CHS, the text string for a medication will not change when a hospital changes the unit of measurement for the medication in its formulary. If a doctor enters an order for such a drug using the EHR's normal CPOE interface, the interface will display the new unit of measurement, alerting the doctor to the change. If the doctor uses the Physician Favorite tool, however, the EHR will display the old unit of measurement. The dose the doctor orders, therefore, will be based on an incorrect unit of measurement for the drug. Making the problem especially dangerous, the pharmacist who fills the order may have no reason to suspect that the dose is based on an outdated unit of measurement.

100. The danger posed by this flaw was amplified by a series of flawed formulary changes, described below, which CHS implemented at its hospitals during the same timeframe and that included many unit of measurement changes.

(4) *Medication Orders to Automated Medication Dispensing Systems Have Yielded Incorrect Doses*

101. The Medhost EHR software fails to reliably ensure that patients receive proper doses when a hospital dispenses medications using an automatic dispensing system.

102. CHS hospitals use the Pyxis automated medication dispensing system to dispense some medications, and providers can route medication orders to Pyxis using Medhost's EHR. Pyxis dispenses medications based on the dose information in the hospital's formulary. When a doctor orders a "partial dose" of a medication—a dose that is less than the full dose found in the hospital's formulary (*e.g.*, 50 mg of drug X, when 100 mg is the smallest dose available from the Pyxis machine)—the Pyxis machine will fill the order for the full dose unless a pharmacist notices the conflict and intervenes.

103. The Medhost EHR does nothing to alert providers when an order calls for a partial dose. The EHR does not alert the doctor who creates the order, the pharmacist who verifies the order, or the nurse who administers the medication. Furthermore, the hospital's eMAR system, which serves as a last line of electronic defense against medication errors, will not alert the nurse to the dosing issue when the nurse scans the patient's barcode prior to administering the medication. If providers do not affirmatively check that the order the doctor entered matches the order that Pyxis dispensed, the patient may receive an overdose of the medication.

104. This flawed system led at least one CHS patient to receive an overdose of Potassium. The error occurred in CHS's Lake Wales, Florida facility and was raised by the hospital's pharmacy director during an October 16, 2014 issues call.

2. Medhost's EHR Software Cannot Reliably Perform Drug-Drug, Drug-Allergy, Duplicate Therapy, or Dose Range Checks

105. To meet the requirements for a certified EHR, the EHR must check all medication orders for drug-drug and drug-allergy interactions, which require that it automatically and electronically indicate to the user prior to completing and acting upon the medication order any drug-drug and drug-allergy contraindications based on the patient's medication list and medication allergy list. The EHR must perform the drug interaction checks accurately, reliably, and safely.

106. Safe CPOE also requires similar electronic capabilities regarding checks for duplication of medication therapy (i.e. that the patient has not already been prescribed the same medication) and that medication orders fall within safe dose ranges.

107. Medhost's EHR does not reliably perform the drug interaction checks required for certified EHR technology.

a. *Medhost EHR's Drug Interaction Checks Fail to Consider "Free-Text" Medication and Allergy Entries*

108. CHS Medhost hospitals use a codification scheme for their formularies that is based on the Medi-Span Electronic Drug File ("Medi-Span"). Each medication available in a hospital's pharmacy will be listed in the hospital's formulary database and identified by a unique

Medi-Span identifier code (RxNorm). The Medhost EHR uses the Medi-Span identifiers to perform a variety of its CPOE functions, including all of its drug interaction checks. Only medications or allergies that are mapped to Medi-Span identifiers in the formulary can be considered for interactions by the system.

109. Though Medhost relies on Medi-Span identifiers to perform drug interaction checks, CHS and Medhost allow users to enter medications and allergies into the EHR system without mapping them to Medi-Span identifiers ("free-text entries"). When medications and allergies are entered into the system without Medi-Span identifiers, the EHR system does not include them in drug interaction checks, increasing the risk that patients will receive contraindicated medications. By not checking for medications and allergies in the patient's medical record in a reliable manner, the hospitals did not meet CMS requirements for Meaningful Use.

(1) *Medhost's EHR Cannot Reliably Map Medicine and Allergy Lists from the Emergency Room Module to Medi-Span Identifiers*

110. The Medhost "EDIS" EHR module that CHS uses for its emergency departments uses a different drug codification scheme than the Medhost "Enterprise" modules used in CHS's inpatient departments. Instead of the Medi-Span vocabulary, EDIS refers to drugs using a codification scheme created by First Databank ("FD").

111. When a patient is admitted to a CHS emergency room, the emergency department will record the patient's home medications and allergies in EDIS, which assigns them FD codes. If the patient is admitted to the hospital, the hospital must import the patient's home medications and allergies from EDIS into Medhost Enterprise. Because Medhost Enterprise uses a different codification scheme, Medi-Span, it must translate the patient's FD codes into Medi-Span identifiers.

112. Medhost's translation mechanism applies a basic text-matching algorithm to the FD codes, looking for a textual match to the formulary database in Medhost Enterprise. When

Medhost Enterprise successfully matches an FD code to the formulary database, it will map that code to a Medi-Span identifier. If Medhost Enterprise is unable to match the FD code, however, it will import the code as unstructured "free text."

113. Like all free-text entries, Medhost Enterprise excludes the unmatched codes from the medication and allergy lists it uses for drug interaction checks. Moreover, when Medhost Enterprise imports a code as free text, it fails to import any information on the route, frequency, or unit of measurement for the relevant medication, which can lead to errors if the doctor continues the medication while the patient is in the hospital.

114. The text-matching algorithm has a high failure rate. Even after multiple revisions, for example, the algorithm works less than seventy percent of the time under test conditions in the case of home medications. Consequently, CHS excludes a significant percentage of home medications from its drug interaction checks.

(2) *Medhost's EHR Cannot Reliably Map Custom and Local Medications to Medi-Span Identifiers*

115. The Medhost EHR's drug interaction checks do not function reliably with custom and local medications. Custom medications are medications that are modified by a doctor to suit a particular patient's needs. Local medications are those that doctors or patients provide themselves, outside of the normal hospital pharmacy process.

116. The Medhost EHR contains an incomplete database of Medi-Span identifiers, with most included only as needed for the hospital formularies. However, custom medications and local medications are frequently not on the hospital formulary, and therefore do not have available Medi-Span identifiers in the Medhost database. Without available Medi-Span identifiers, providers are forced to enter the medications as free-text entries, which are not considered by Medhost drug interaction checks.

b. *Medhost's EHR Fails to Flag Medication Allergies If the Medication Order Is Already in the System*

117. Medhost's EHR software only runs medication allergy checks when a medication order is first entered into the system. A patient's allergy list is typically compiled at admission, and stored in the patient's CHP.

118. If new allergies are subsequently added to a patient's CHP, the Medhost EHR software fails to run a new drug interaction check for the allergy against the patient's outstanding medication orders, such as orders that have not yet been administered or orders that are scheduled for administration in the future.

c. *Medhost's EHR Fails to Lock Open Patient Charts, Risking Duplicate Medication Orders*

119. Medhost's EHR software fails to lock open patient charts, allowing multiple providers to open a patient's chart at the same time. Under such circumstances, both providers (for example a doctor and a pharmacist) can make medication orders for the patient at the same time, which overrides the EHR's ability to perform duplication therapy or dose range checking.

120. Similarly, the EHR does not synchronize the information displayed in PhysDoc and ClinView. If a provider has both applications open in separate windows, the provider's workflow in one application will not be reflected in the other. For example, if a provider is working on charts for multiple patients, switching from one patient to the next in PhysDoc will not prompt ClinView to switch as well, resulting in the applications displaying information on different patients. If the provider does not catch that the patients are different, the provider may make clinical decisions for one patient based on information listed in the other patient's chart.

121. Multiple CHS hospitals have reported these defects to CHS management as presenting a serious risk to patient safety, however CHS and Medhost have not resolved the issue.

d. *Medhost's EHR Fails to Run Drug Interaction Checks on Medications Ordered at Discharge*

122. Providers at CHS hospitals perform a clinical reconciliation at discharge ("discharge reconciliation"), in which the provider can continue or discontinue medications that

the patient received during the inpatient stay and can restart any home medications that had been discontinued upon admission.

123. Medhost's EHR software is incapable of performing drug interaction checks when a provider continues or discontinues a medication during discharge reconciliation. Medhost only screens for drug-drug or drug-allergy contraindications at the time a provider creates a medication order, not when the provider continues or discontinues a medication during discharge reconciliation. Consequently, if a provider continues a medication at discharge, the EHR will not indicate drug-drug or drug-allergy contraindications to the provider, contrary to CMS requirements. Instead, the EHR simply instructs the provider to select "continue" or "discontinue" for each medication order in the discharge reconciliation form, without identifying any contraindications. CHS and Medhost configured the discharge reconciliation form not to display contraindications because providers commonly order patients to continue home medications at discharge and Medhost's EHR frequently stores those medications as free text. Because the EHR cannot screen such drugs for contraindications, the Relators believe that CHS and Medhost disabled screening altogether for discharge reconciliations so that providers would not mistakenly rely on the EHR for that function.

C. CHS Contributed to the CPOE Issues by Rolling Out Order Sets That Conflicted with Hospital Formularies, Causing Additional Medication Order Errors

124. CHS compounded the problems with Medhost's software by taking dangerous shortcuts when deploying the system. One of the most serious shortcuts involved CHS's deployment of electronic order sets.

125. An order set is a curated selection of related medication and other orders—designed for application in a specific scenario—that a doctor can select quickly and easily using CPOE. When used correctly, order sets can reduce medical errors, standardize hospital procedures, and increase efficiency. CHS and Medhost intended to use order sets as the primary method for medication ordering in the Medhost EHR.

126. During the deployment, CHS rolled out a series of electronic order sets that doctors were supposed to use with the EHR software. To make the order sets function with Medhost's CPOE, each medication order embedded within an order set must be mapped to the hospital formulary using mnemonics. To create the mapping for the order sets, CHS started from templates created by Zynx Health, a source of evidence-based clinical information. CHS modified the Zynx templates and then mapped them to each hospital's formulary using a software tool created by Medhost.

127. The CHS process failed to account for the numerous differences in hospital formularies, and CHS did not designate pharmacists or others with subject-matter expertise to oversee the mapping process. As a result, order sets were rolled out to the hospitals with a large volume of dangerous errors in the mapping of individual orders.

128. CHS and Medhost learned of the issues almost immediately, as members of the CHS implementation team and practitioners at individual hospitals began to flag concerns. For example, on March 10, 2014, CHS Manager of Pharmacy Informatics Cliff Kolb wrote to others on the CHS implementation team in an email with subject line: "Serious concerns on Order sets and model build." The email detailed concerns from a review that Mr. Kolb had conducted of the build at the first six sites scheduled to go live with the new order sets:

> Within a few minutes, we found some glaring issues. Zofran 4 mg was mapped to the 40mg vial not the 4mg vial which could cause a 10 fold overdose. When looking at the Hydromorphone and Morphine, they were mapped to regular form when the mapping should have been preservative free. With this brief review, it brought up red flags as to what else is out there that we did not have time to find....
>
> We are seeing this at the other 5 facilities as well...
>
> We have been asking who is completing the quality review. We were told today that the sets are being reviewed by analyst not pharmacists. We have concerns that this should only be done by clinical staff... However, [they do] not currently have access to the order sets so they can review....
>
> In the above example, the Zofran would never be in the Pyxis machines as [described].... [T]he nurse would not be able to get it and the pharmacist will have to edit it. This would not meet MU standards.
>
> We need someone to go in and clean up the [model order set] before more sets are pushed to any sites.... Based on comments from Medhost folks, this is a one to two week process to clean up. I am not sure we have time but it is a patient safety issue.

129. Two weeks later, CHS had not begun to address the issue. On March 25, CHS Director of Pharmacy Operations, Jerry Reed, sent an email expressing his alarm to CHS Vice President of Operations Support Tim Park:

> I am not sure where my authority stops, but will push forward until I get a cease and desist.
>
> -None of my pharmacists are involved in the build.
>
> -Most of the issues go back to the [model order set]. I think urgent cleanup is necessary. The order sets are being mapped out of the [model order set] to the facilities and until this is cleaned up we are going to continue to experience this.... Examples: Acetaminophen suppositories is mapped to orally. Normal saline is asking for weight based dosing.
>
> -Pharmacists must oversee the drug component of the [model order set] and model build.
>
> -Cliff and Jeannie have been bringing up these issues for the last month.
>
> -The readiness documentation does not even include pharmacy directors because the deployment team still seems to think that pharmacy had nothing to do with CPOE.

130. In response to the email, Mr. Park acknowledged that the issue created fertile ground for patient harm, writing that "These medication sentences have **a very high potential** for causing a catastrophic event."

131. Despite acknowledging the danger of rolling out flawed order sets, however, CHS continued to push forward with deploying the order sets at additional hospitals in advance of the 2014 attestation period with its intended purpose being to collect Meaningful Use subsidies for those hospitals. CHS did not assign pharmacists or subject-matter experts to correct the problems it had identified at the hospitals that had already received the order sets. Instead, CHS instructed non-clinical staff, including Relator Neiman, to resolve the safety issues while prioritizing strategies to meet the target dates for implementation to ensure that CHS would receive Meaningful Use incentive payments.

132. The inaccurate mapping between order sets and hospital formularies prevented physicians from creating orders safely, accurately, and reliably using the EHR. Because there was no assurance that the medication information in the order sets would match the medication

information that pharmacists used to fill medication orders, CHS's hospitals did not meet the objective of using CPOE for medication orders.

D. Medhost's EHR Cannot Reliably Perform Clinical Decision Support

133. Clinical Decision Support ("CDS") is a process designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific interventions, assessments, recommendations, or other forms of guidance that are then presented to a decision-making recipient or recipients that can include clinicians, patients, and others involved in care delivery.

134. ONC has identified CDS as a key functionality of health information technology that—when effectively applied—contributes to "improved care quality, enhanced health outcomes, error and adverse event avoidance, improved efficiency, reduced costs, and enhanced provider and patient satisfaction." ONC, *Clinical Decision Support: More than Just 'Alerts' Tipsheet*, July 2014 (noting that "Congress included CDS as a centerpiece of the Medicare and Medicaid EHR Incentive Programs").

135. To be certified under 2011 or 2014 Edition certification criteria, CMS requires EHRs to be capable of implementing automated, electronic CDS rules based on data in problem lists, medication lists, demographics, vital signs, and laboratory test results. EHRs must further be capable of automatically and electronically generating and indicating in real time notifications and care suggestions based on CDS rules.

136. To meet these requirements, EHRs must enable "users to select (*i.e.*, activate) one or more electronic clinical decision support interventions" based on patient data and to "enable interventions to be electronically triggered" based on patient data and during transitions in care. 45 CFR § 170.314(a)(8)(i), (iii). Such interventions "must automatically and electronically occur when a user is interacting with EHR technology." § 170.314(a)(8)(iv). ONC has issued guidance providing that "the best method of tracking CDS interventions is to capture when they are enabled" and that "it should be apparent [from the software] when these users [specified in

§ 170.314(a)(8)(i)] have enabled certain interventions." 77 Fed. Reg. 54163, 54213 (Sept. 4, 2012).

137. For healthcare providers to receive incentive payments, they must attest to having implemented CDS rules. In Stage 1, providers were required to implement one CDS rule relevant to their specialty, high clinical priority, or high priority hospital condition, along with the ability to track compliance with that rule. In Stage 2, providers were required to implement five CDS interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period.

138. As discussed below, Medhost's EHR software is unable to reliably perform CDS or track when and whether CDS rules have been enabled.

1. Medhost's EHR Did Not Enable Users to Implement CDS Rules During the 2014 Attestation Period

139. Medhost's EHR software contains a programmable "rules engine" that determines when to "fire" CDS interventions using simple logical operations based on data in the EHR system (*e.g.*, if X is true and Y is false then display popup Z on the screen). In addition to the rules engine, the EHR software contains a CDS audit tool to track and record information about the CDS interventions, including when rules were first created and enabled, and every time a rule fired in the system.

140. In early 2014, CHS programmed CDS interventions into the Medhost EHR rules engine in preparation for the Stage 2 attestation period. Problems with the Medhost CDS functionality arose soon thereafter. In April 2014, CHS Director of IT Internal Audit Kristi Meyer noticed gaps—unexplained periods of time during which the CDS rules did not fire—in hospitals' CDS audit log reports. In June 2014, Ms. Meyer raised the issue directly with Medhost Corporate Account Manager Nate Miller:

> After looking at the [audit log and CDS] data, we would like to get a better understanding of the stability of these logs. It appears as if the logs did not check the status for several days. I want to understand why that is. Also, I want to get an [sic] perspective on if these logs are something my team can rely on from an Audit perspective.

Medhost subsequently identified a credentialing issue with the CDS audit tool and issued an update that purportedly resolved the problem.

141. On July 1, 2014, CHS began its first of two planned waves of Meaningful Use attestation. For each wave, a set of hospitals would undergo a three-month Meaningful Use reporting period, during which time the CDS functionality had to be continuously enabled.

142. In mid-August 2014, after Medhost issued an update to its EHR software, the software stopped triggering CDS interventions at CHS's hospitals.

143. CHS management did not learn of the CDS failures until September, two thirds of the way through the first reporting period. On September 12, 2014, CHS Director of Program Informatics Connie Senseney sent an email to Relator Neiman: "On 8/18 apparently all of the CDS rule acknowledge reports were turned off. It shows that the rules are still active. Did something happen?"

144. One week later, the Ms. Senseney followed up with Relator Neiman about the issue, writing that "[a]pparently the CDS rules actually quite [sic] firing on or around the 15th of August. . . . So, it may not be the report that stopped, but the rules are no longer firing. . . . This needs immediate attention since it affects all sites in Stage 2."

145. On September 24, 2014, CHS Director of Information Systems for the Medhost Deployment Team Teri Mitchell circulated a problem summary by email:

> - To Meet Core Measure, we need to prove 1) It's built and 2) the rules are active and continuously firing during the reporting period (7/1 thru 9/30)
>
> Last week, Internal audit was conducting a "trial" run of the report prior to submission for 10/1 attestation. During that trial run, it was discovered the report wasn't working. Connie S. reached out to Medhost for assistance. Medhost fixed the report. After reviewing the report, it was discovered that at several sites the rules were not acknowledged, which means the rules did not fire, or show a gap in firing....
>
> ...
>
> - Based on the report results, CDS rules are not firing/firing consistently at multiple facilities. Status: OPEN.
>
> What is Impacted
>
> - Core measure meeting attestation requirements
>
> Who is Impacted

- During a quick spot check of 17 facilities by Joey's team, all 17 show a gap…

Next Steps

- Medhost is confirming if the rules are firing and report is wrong

- If firing and the report is wrong, a different method of proof will be required to attest

- If not firing, according to Connie, we can't attest.

146. In another email, sent to Relator Neiman the same day as the problem summary, the Clinical Systems Coordinator at CHS's Cedar Park Regional Medical Center confirmed that the CDS rules were not firing in his hospital's system during tests: "[I]t does not appear that any of our rules have been firing since August 14th. I tried several rules on several patients and nothing happened…. Checked [the CDS interventions] for stroke, diabetes, ischemic stroke and AMI."

147. CHS discussed the problem with Medhost during a weekly/biweekly issue call on September 30, 2014. Medhost acknowledged the issue on the call and informed CHS that Medhost would have to re-build the CDS code to resolve the problem. Medhost further explained that the CDS interventions would not fire until the re-build was complete.

148. Medhost "re-built" the CDS functionality in its EHR software in early October, and CHS again planned to rely on the functionality for its second wave of attestation, which began its reporting period October 1.

149. By late October, CHS management learned that Medhost's CDS functionality was still failing. On October 28, 2014, a CHS Regional Clinical Informaticist, who had previously reported CDS issues at hospitals during the first wave, emailed the implementation team regarding further failures:

> I have another one. I was at [the hospital in] Selmer today and we took a look at the CDS rules to make sure they were running. I am seeing a similar scenario as I saw at [the hospital in] Lexington a few weeks ago. It appears, according to the Acknowledgement report that the triggers stopped firing on the 15th. However, according to the status report the rules have not been active for 0 of 28 days….
>
> We could really use some help in identifying if the rules have indeed stopped and if so why this keeps occurring.

150. On November 20, 2014, in an email responding to an issue ticket submitted by a CHS hospital, Medhost confirmed that the CDS reporting problem was a known issue with the

software, and that it affected facilities beyond just CHS. Medhost also indicated that it had no estimate for when it could provide a fix:

> [T]he issue you are having with established Clinical Decision Support rules not showing on the ODS Acknowledgement Report is a known issue. This has happened on several other facilities in our system. . . .
>
> There is a program fix that is being developed and tested to resolve this issue, PIF 1711. At this time, we do not have an ETA on the completion and implementation of this PIF, but we do believe that it will be soon. We apologize for any inconvenience this has caused for you as you are working through your Attestation.

151. As of late December 2014, Medhost had two software enhancement requests (PIRs) open to address the issue, however it did not implement a fix for the software until it released Version 2014 R2 SR3 of the EHR in March 2015. Even after the release, as late as May 2015, CHS facilities were still reporting that the CDS audit reports were not working reliably. CHS did not begin to implement Version 2014 R2 SR3 until June 2015.

2. CHS Did Not Meet Meaningful Use Objectives for CDS

152. CHS did not meet Meaningful Use objectives in Stage 1 or Stage 2. In Stage 1, CHS did not implement Medhost's rules engine and falsely attested to Meaningful Use compliance on the basis of a software feature that resembled, but was not, a CDS intervention. In Stage 2, CHS attested to Meaningful Use compliance despite the fact that Medhost's rules engine had not triggered CDS interventions during the reporting period. To conceal its failure to meet a core objective of the program, CHS took the position in its attestations that the order sets it had built into the EHR met the requirements for CDS, when it knew they did not.

a. *CHS's Use of the Fall Risk Assessment Failed to Meet the CDS Objective in Stage 1*

153. In Medhost's EHR, the CDS rules engine is designed for use with the CPOE application. Because CHS did not implement CPOE in Stage 1 (it was not yet a core objective), it did not program a single CDS intervention using Medhost's rules engine. Despite not using the CDS functionality in Medhost's EHR, CHS attested to meeting the objectives and measures for CDS on the basis of a "workaround." CHS's workaround was to cite an unrelated function of the EHR—a protocol that nurses used to perform fall risk assessments—as though it were CDS.

154. In late 2011 or early 2012, CHS distributed a guide to instruct nurses on the workflow for the fall risk "intervention." Under the workflow, nurses were responsible for identifying the need to perform a fall risk assessment on the patient. Once the nurses decided to perform the assessment on a patient, they were to select the assessment in the EHR, which would display a series of quantitative questions based on a common method to calculate fall risk. The nurses were to assign a score for each question. At the end of the assessment, the software would automatically total the scores, producing a single "Fall Risk" score that it displayed in an output field entitled "Score Total."

155. At this point, in a step the guide described as "mandatory for the Meaningful Use requirements," the software would display a window in which the nurse would select a checkbox indicating whether the Score Total was more or less than 25. If the nurse selected the checkbox for a score less than 25, the assessment ended. If the nurse selected the checkbox for a score over 25, the EHR prompted the nurse to select a care plan for the patient from a list (one of the plans the nurses could choose was "fall risk"). The nurse then had to manually add the care plan to the patient's profile.

156. Thus, CHS fabricated a CDS "intervention" by creating an extra, unnecessary step in the nurses' workflow concerning fall risk assessments, indicating to the nurse that a score under 25 did not require further action while a score over 25 warranted the selection of a care plan.

157. This fall risk "intervention" was insufficient to meet the core objective for CDS in Stage 1 and did nothing to improve the quality, safety, or efficiency of patient care. CHS did not use demographic information, problem lists, medication lists, vital signs, or laboratory results to determine which patients needed a fall risk assessment upon admission, nor did it use that information to trigger the "intervention" in the assessment workflow. Instead, nurses remained responsible for identifying the need for a fall risk assessment when a patient was admitted to the hospital, as well as for identifying any issues in the patient's medical record. Because CHS's

workaround did not constitute a CDS rule under the Meaningful Use program, CHS did meet the core objective and measure for CDS in Stage 1 and its attestations of Meaningful Use were false.

158. CHS knew that the fall risk assessment workaround did not meet the objective and measure for CDS. As one CHS employee explained:

> For stage 1 we did not have any actual CDS rules built [in the Medhost rules engine] because CPOE was not active. So, what we did was, we used the Nursing Fall risk assessment within Pt care. When a nurse completed the fall risk assessment then the assessment would prompt the nurse to create a risk specific care plan based on the fall risk score.

159. In addition to the assessments not constituting "actual CDS rules" within the EHR, CHS knew that it lacked the ability to track providers' compliance with the "intervention" in the assessments. On April 8, 2014, Lisa Fitts, CHS's Clinical IS Team Lead—Physical Tools, emailed several CHS employees about their efforts to map the workaround to a CDS audit report, which would enable CHS to determine if the "intervention" was operative. In her email, Ms. Fitts wrote: "It does not sound like the care plan would be captured on a CDS audit report. I say this because I don't know that a care plan can be designated as a CDS rule [in the rules engine]."

b. *CHS's Use of Static Order Sets Failed to Meet the CDS Objective in Stage 2*

160. CHS developed five CDS interventions using Medhost's rules engine in advance of the Stage 2 reporting period. On July 1, 2014, at the start of the reporting period for CHS's first wave of hospitals, the required five interventions had been programmed into the system.

161. As discussed above, the CDS rules engine failed at CHS's Medhost hospitals beginning in August 2014. Many of the hospitals that no longer generated CDS interventions were in the middle of the Stage 2 attestation period.

162. Within its corporate offices, CHS acknowledged that it could not attest to meeting the core objective during the attestation period because its rules engine had been broken for much of it. In a September 24, 2014 email to CHS management, CHS Director of Information Systems Teri Mitchell wrote that "we can't attest" if the CDS rules were not firing.

163. CHS, however, was unwilling to forego incentive payments for the hospitals, and decided to attest to meeting the CDS objective even though the hospitals had not used CDS for

much of the attestation period. As in Stage 1, CHS turned to a "workaround" to support its attestations. In this instance, CHS submitted attestations on the basis of order sets. CHS selected five order sets that related to four or more clinical quality measures and treated them as CDS interventions for purposes of its attestations.

164. CHS's order sets did not meet the requirements for a CDS intervention. Unlike a CDS intervention, the content of the order sets was static and did not change (or trigger alerts) based on the patient's problem list, medication list, demographics, vital signs, or lab results. The EHR also did not suggest particular order sets to providers based on patient information. Instead, providers had to choose the order sets manually from a wider list of available order sets in the system. Consequently, the order sets did not meet the objectives or measures for CDS.

165. On October 3, 2014, Relator was directed by CHS Senior Manager of IT Internal Audit and Compliance Kristi Meyer to ensure that the order sets were installed at the hospitals in the first attestation wave:

> Meagan and connie agree that the [order set] extract is exactly what we need as a starting point. We will use that extract for the Medhost hospitals to validate we have 5 that apply for CDS Rules.
>
> Can you help run these for us for every 7/1 [first wave] Stage 2 site?

166. On October 6, 2014, a week after the end of the reporting period for the hospitals, Ms. Meyer realized that several of the hospitals did not have the five order sets that they intended to use for attestation. She asked Relator Neiman to investigate.

> [A]fter reviewing the evidence, we identified 8 hospitals that only had 3 of the "approved" order sets active the entire time. Therefore, could your team provide us with a listing of all active order sets from 7/1-9/30 for those 8 hospitals? Based on your output, we will work with OPS to determine the other order set to use for attestation.

167. Three weeks later, on October 30, 2014, Ms. Meyer sent another update regarding the issue, stating that the eight facilities mentioned were still in "limbo," lacking sufficient order sets for attestation. She subsequently determined to add the fall risk assessment, which CHS had relied upon for Stage 1, as a final intervention. Soon after, CHS submitted attestations to CMS for all the hospitals.

168. While CHS was preparing to attest to CDS functionality using static order sets for the first-wave hospitals, members of the implementation and audit teams still believed that the hospitals in the second wave, for which the reporting period began on October 1, 2014, would be able to attest using the actual CDS interventions in Medhost's EHR.

169. However, as described above, CHS learned in October 2014 that the MedHost CDS functionality had again failed. On November 20, 2014, CHS Director of Clinical Informatics Implementation Connie Senseney wrote to her colleagues: "We are going to have to use the order sets again I believe."

170. Indeed, CHS subsequently attested for the wave two hospitals using the order sets to purportedly satisfy the Stage 2 CDS objective.

171. While CHS submitted attestations based on the order sets, it failed to inform the providers at its hospitals that the EHR could not generate CDS interventions and that CHS had substituted the broken CDS functionality with order sets. Even though the issue was known within CHS's headquarters, CHS never released an advisory to alert physicians that they could not rely on the CDS rules to provide potentially critical intervention information. Thus, CHS did not alert providers to a known defect in the EHR, even as it was developing a workaround in order for the hospitals to submit Meaningful Use attestations.

E. Medhost Illegally Provided Free Software to Induce CHS to Purchase Medhost's EHR Software

172. CHS's use of Medhost's software was partly the result of illegal kickbacks. No later than 2013, Medhost began to provide CHS with free financial software for the purpose of inducing CHS to purchase full licenses of its EHR software suite. The financial software, known as Medhost Enterprise Financials ("Medhost Financials"), is a suite of financial applications, capable of performing hospital accounting, billing, and other management functions. The products include Accounts Payable, General Ledger, Materials Management, Payroll/Human Resources, Patient Accounting, and Health Information Management applications. A license for

Medhost Financials is worth approximately $250,000. Medhost provided free licenses to at least 19 CHS hospitals, totaling kickbacks with a value of over $4,750,000.

173. For nearly three decades prior to the kickback scheme, CHS had used—and paid for—the Medhost financial software at most of its hospitals.

174. Medhost initiated the illegal kickback scheme at the same time it expanded the Medhost Enterprise software suite to include Medhost's clinical package, which CHS later used to attest to Meaningful Use. It offered to provide Medhost Financials for free to all CHS hospitals, both those that utilized the full Medhost Enterprise EHR suite and those that used third-party EHRs. For each hospital, Medhost only required that CHS pay approximately $137,000 for accompanying software products and interfaces, including Advanced Security, eArchive, Insurance Eligibility, and SSI Electronic Billing.

175. During the relevant time period, Relators both worked as direct reports to Steve Hernandez, CHS's Senior Director of Information Systems, who was responsible for finalizing software pricing with Medhost. During that time, it was commonly known and discussed among CHS employees that Medhost's offer was intended to induce CHS to continue doing business with Medhost and, specifically, to purchase Medhost Enterprise. Even for CHS hospitals that continued to use third-party EHRs, Medhost's goal was to maintain a software presence at the hospitals to increase the likelihood that CHS would convert those hospitals to the Medhost EHR in the future.

176. CHS not only accepted Medhost's kickbacks, but also purchased additional licenses of Medhost's EHR as a result. CHS knew that Medhost's offer of free product was intended to induce it to purchase EHR software. On multiple occasions, CHS corporate leadership chose the Medhost EHR for hospitals over the objection of CHS implementation and hospital staff, who were concerned about the Medhost EHR's poor track record and a strong preference by doctors for other EHRs that were of similar cost. The explanation that CHS gave to Relators and other employees was that CHS needed to "take care of its friends," referring to Medhost, and "make sure they get some business."

177. The EHR that CHS acquired from Medhost is funded in part by Medicare and Medicaid through the EHR incentive programs.

F. CHS Falsely Attested to Meaningful Use of Certified EHR in Legacy HMA Hospitals

178. In January 2014, CHS acquired Health Management Associates ("HMA"), a competing for-profit hospital chain. The transaction expanded CHS's hospital network from 135 to 206 facilities.

179. The hospitals that CHS acquired from HMA (the "HMA hospitals") used modular EHR technologies rather than complete EHRs. Under the Meaningful Use program, eligible hospitals may combine EHR modules to meet the definition of certified EHR technology, provided they ensure that the modules are interoperable and can properly perform in their expected operational environment to support the hospitals' achievement of meaningful use.

180. The EHR modules that the HMA hospitals deployed during the Stage 2 reporting period were not interoperable. Despite relying on multiple EHR technologies for patient care, the HMA hospitals failed to integrate the technologies so that the clinical information stored in one system was reliably accessible to the other systems. In particular, the HMA hospitals did not develop key software interfaces—protocols by which the applications could exchange information—that would allow the hospitals to transfer information on medication orders electronically from one department to another. Without the interfaces, providers could not move a patient from one EHR module to another without printing the patient's medical record and entering the contents by hand into the new module.

181. First, the hospitals' emergency department information system, Medhost EDIS, did not interface with the hospitals' inpatient EHR system, PULSE, to transmit information on medication orders. When the hospitals admitted a patient from the emergency department, the emergency department would have to print the patient's chart so that an inpatient nurse could enter the chart information into PULSE.

182. Second, PULSE did not provide a medication order interface with the hospitals' CPOE application, PatientKeeper. At the HMA hospitals, physicians entered medication orders using a proprietary application called the Medical Access Portal ("MAP"). When a physician created an order using MAP, the application would communicate the order to PatientKeeper via a software interface. Nurses at the HMA hospitals used PULSE for their workflows and did not have access to MAP or PatientKeeper. There was no interface to communicate information from PatientKeeper to PULSE, which prevented nurses from viewing the medication orders in the patient's EMR. When physicians signed medication orders, the hospitals had to print the orders in the appropriate hospital department for review by the nursing staff. Because the problem affected every medication order entered in the hospital, the HMA hospitals programmed PatientKeeper to print medication orders automatically. Therefore, the HMA hospitals did not have a CPOE process that was truly electronic.

183. Third, the HMA hospitals lacked an interface from PatientKeeper to their pharmacy management system, Horizon Meds Manager ("HMM"). When a physician entered a medication order, the order would not appear in HMM. Instead, PatientKeeper would generate an email to the pharmacist, who would have to transcribe the contents of the email into HMM. Manually copying medication order information from PatientKeeper to HMM increased the risk of medication errors. Moreover, it made the hospitals' Meaningful Use reporting less accurate, as pharmacists who received orders via email had to guess whether those orders originally had been entered using CPOE.

184. Because PULSE did not communicate with Medhost EDIS or PatientKeeper, and because HMM did not communicate with PatientKeeper, the HMA hospitals were unable to safely and reliably maintain patients' problem lists, active medication lists, and medication histories for the duration of the patient's entire hospitalization.

185. The lack of interoperability also prevented users from using EHR technology to reconcile clinical information. The hospitals store active medication lists, problem lists, and medication allergy lists in PULSE. Physicians do not have access rights to PULSE. Physicians

also cannot access the information in PULSE indirectly because their applications—MAP and PatientKeeper—do not interface with PULSE. For physicians to reconcile the clinical information in PULSE with clinical information from other sources, a nurse must print the patient's medication reconciliation form for the physician to complete by hand. Once the form is complete, the nurse must manually re-enter the contents of the form into PULSE.

186. Because physicians cannot electronically reconcile the clinical information in PULSE, the HMA hospitals did not, and, in many cases, do not meet the requirement that providers safely and reliably electronically reconcile a patient's active medication list at admission and other relevant encounters.

187. Because the EHR modules at the HMA hospitals did not meet CMS requirements for certified EHR technology, the hospitals were ineligible for incentive payments under the Meaningful Use program. Despite their ineligibility, 60 of the HMA hospitals submitted Meaningful Use attestations during Stages 1 and/or 2 and were paid a total of $206 million in incentive payments.

188. CHS knew that the EHR technology at the HMA hospitals was seriously flawed. Prior to its acquisition, HMA hired a consulting firm, Accenture, to evaluate HMA's readiness to meet Stage 2 requirements. In a December 3, 2013 report, Accenture warned that "HMA's complex application portfolio results in excessive potential points of failure and limits key functionality." One of the failure points Accenture identified was the processing of medication orders, which it found were "highly fragmented involving duplicate data entry and manual workarounds that increase the potential for errors." Accenture noted that "[t]he number of order entry systems and complex set of clinical workflows that have been created increase the opportunity for more gaps in care and patient safety risks."

189. Due in part to these flaws, Accenture concluded that HMA was not close to meeting Stage 2 requirements. It found that HMA had deployed PatientKeeper at only 32 of its 71 hospitals and was not scheduled to complete deployment at the remaining hospitals until May 27, 2014. Accenture also found that "Clinical Decision Support, a key functionality of MU

Stage 2, is currently not implemented in MAP nor evident in product roadmap." Accenture warned that "[t]he fragmentation of applications, workflows and clinical processes impacts patient safety and potentially creates significant financial risks (MU Stage 2 and HIPAA compliance)."

190. In a subsequent report to CHS dated January 6, 2014, Accenture found that significant applications remained in development. PULSE, for example, lacked functionality for transitions of care, data portability, C-CDA, and interfaces with other applications. Accenture wrote that PULSE was "still in the planning phase" for C-CDA and "still in development and testing" for integrating CDS with other EHR modules. For transitions in care, Accenture found that PULSE's "business requirements for this functionality are still in review," while "[i]nterfaces for vendor software such as MEDHOST, Patient Safe Systems and Medicity need to be developed." For the HMA hospitals to attest to Meaningful Use in Stage 2, Accenture advised that CHS deploy the applications no later than April 1, 2014, leaving only three months to develop core functionality from scratch.

191. Despite knowing that the HMA hospitals lacked the functionality necessary for meaningful use, CHS decided it would be too costly to convert the hospitals to a different EHR system. Even before completing the acquisition, however, CHS and HMA reduced the number of the developers responsible for PULSE and MAP and did not allocate other resources to developing the applications. As a result, CHS did not develop the functionality needed to meet Stage 2 requirements and the problems that Accenture had identified prior to the HMA acquisition persisted through the Stage 2 reporting period and beyond.

192. The HMA hospitals knew that their EHR systems were defective and alerted CHS to the defects. In June 2015, for example, Relator Lewis joined two of the leaders of CHS's deployment team, Mr. Yzerman and Mr. Hernandez, on a visit to Midwest Regional Medical Center, an HMA hospital located in Midwest City, Oklahoma. CHS had received numerous complaints from the hospital about PULSE's cumbersome workflows, unsafe functionality, and unstable infrastructure, with physicians threatening to no longer refer patients to Midwest

Regional if the problems continued. The purpose of the visit was to evaluate whether to transition Midwest Regional to a different EHR system.

193. During the visit, physicians told the CHS executives that the hospital was relying on paper to bridge its disparate EHR systems and that this "hybrid system" posed a significant safety concern. The physicians said that the lack of an integrated EHR system forced the hospital to print and re-enter chart information whenever patients were admitted from the ER or transferred from one department to another. The physicians also said that the hospital was forced to chart medications on paper at the same time it was using PULSE to administer medications. The physicians warned that if there was an error or delay in entering a medication order from a paper chart into PULSE, a nurse using the hospital's eMAR system could miss the medication order or administer a duplicate dose.

194. Physicians in the cardiology department, meanwhile, identified medication reconciliation as a "huge patient safety concern" that they feared would "kill a patient." One cardiologist told the CHS executives that physicians were using paper to reconcile medication lists because they did not have access to PULSE and that nurses were entering the completed reconciliation forms into PULSE by hand. According to the cardiologist, physicians had caught errors in the re-entered forms that would have sent patients home with the wrong drugs, doses, or instructions. The cardiologist said that physicians at Midwest Regional required nurses to print the re-entered forms so that they could check for such errors.

195. At the time of the visit, Midwest Regional had attested to its meaningful use of certified EHR technology on four occasions and received $5.95 million in Meaningful Use incentive payments from the Government. Because Midwest Regional had never implemented EHR technology that met CMS's certification requirements, each of the hospital's attestations had been knowingly false.

VI. DEFENDANTS VIOLATED THE FALSE CLAIMS ACT

196. Medhost knowingly misrepresented to customers that its EHR products satisfied federal Meaningful Use requirements. These misrepresentations foreseeably caused customers,

including CHS, to purchase its EHR technology. The misrepresentations also foreseeably caused the purchasers to attest to compliance with Meaningful Use requirements when they were not in compliance with those requirements, and foreseeably caused the purchasers to submit claims to the Federal Government for EHR incentive payments to which they were not entitled. In this manner, Medhost knowingly caused false claims, and false statements material to false claims, to be submitted to the Government.

197. Medhost has caused federal Meaningful Use incentive payments to be paid for its EHR system even though its software is flawed and unreliable and does not meet fundamental requirements for performance as defined by the Meaningful Use criteria. These standards for performance are core requirements for any EHR system. Every claim for payment submitted to the Government for incentive payments for use of EHR software that is defective and/or does not meet Meaningful Use requirements is a false or fraudulent claim in violation of the FCA.

198. CHS knew that Medhost's EHR technology was defective and did not satisfy federal Meaningful Use requirements. CHS and CHS hospitals knowingly presented and caused to be presented submission of false claims to the Government for EHR incentive payments to which they were not entitled. CHS and CHS hospitals also presented and caused the presentment of false attestations of compliance with Meaningful Use requirements, which were material to their false claims for EHR incentive payments.

199. CHS knew that the modular PULSE EHR software used by the former-HMA hospitals also did not satisfy Meaningful Use requirements. CHS and the former-HMA hospitals knowingly presented and caused the presentment of false claims, and made and caused to be made false records and statements material to false claims, for EHR incentive payments to which they were not entitled.

200. By arranging for Medhost to provide CHS with valuable financial software for free in return for CHS's purchase of full licenses of Medhost's EHR software suite, Medhost and CHS knowingly and willfully offered and accepted unlawful remuneration in violation of the AKS. Compliance with the AKS is material to the Government's decision to pay the claims that

CHS submitted for payment or approval under the Meaningful Use program. All claims made to the Government under the Meaningful Use program as a result of services tainted by these unlawful payments are false and/or fraudulent within the meaning of the FCA.

201. Through the conduct discussed above, the Defendants knowingly caused the submission of false claims and false statements material to false claims to be submitted to the Government in violation of the False Claims Act.

False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), (B), (C), & (G)

202. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 201 above as though fully set forth herein.

203. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

204. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

205. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the Government.

206. By virtue of the acts described above, Defendants knowingly caused the concealment or improper avoidance or decrease of an obligation to pay or transmit money or property to the Government;

207. By virtue of the acts described above, Defendants knowingly conspired with others to violate the FCA. Moreover, Defendants took substantial steps toward the completion of the goals of that conspiracy by the conduct alleged herein.

208. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by several separate entities.

Relators do not have access to the records of all such false or fraudulent statements, records, or claims.

209. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

210. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

211. Additionally, the United States is entitled to the maximum penalty for each and every violation arising from Defendants' unlawful conduct alleged herein.

PRAYER

WHEREFORE, *qui tam* Plaintiff-Relators Derek Lewis and Joey Neiman pray for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty for each violation of 31 U.S.C. § 3729;

3. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

4. That Relators be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relators recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Date: January 31, 2018

By: Jeffrey W. Dickstein

Colette G. Matzzie
Luke J. Diamond
PHILLIPS & COHEN LLP
2000 Massachusetts Ave., NW
Washington, DC 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Edward Arens
PHILLIPS & COHEN LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
Fax: (415) 836-9001

Jeffrey W. Dickstein (FL Bar No. 434892)
PHILLIPS & COHEN LLP
Southeast Financial Center
200 S. Biscayne Blvd., Suite 2790
Miami, Florida 33131
Tel: (305) 372-5200
jdickstein@phillipsandcohen.com

Attorneys for Qui tam Plaintiffs Derek Lewis and Joey Neiman