IN THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

THE UNITED STATES OF AMERICA ex rel. Megen Duffy Plaintiffs, v. LAWRENCE MEMORIAL HOSPITAL Defendant	CIVIL ACTION CASE NO. 2:14-cv-02256-SAG-JPO *FILED IN CAMERA and UNDER SEAL* FALSE CLAIMS ACT COMPLAINT

SECOND AMENDED COMPLAINT

INTRODUCTORY STATEMENT

The Plaintiff, MEGEN DUFFY, by and through her counsel of record, brings this action on behalf of the United States of America against LAWRENCE MEMORIAL HOSPITAL (hereinafter "Defendant") pursuant to the Qui Tam provisions of the Federal False Claims Act, 31 U.S.C. §§3729-33 ("Federal FCA" or "FCA"),(referred to herein as "Qui Tam Action"). Pursuant to 31 U.S.C. §3730(b)(2), this action is brought in camera and under seal.

Plaintiff alleges that Defendant has violated the Federal FCA, by submitting or causing to be submitted false claims for reimbursement from Medicare and from Medicaid, and by making false certifications upon which payments from the federal government were based.

The fraud scheme utilized by Defendant included, but was not limited to, submitting knowingly false performance reports to the Centers for Medicare and Medicaid Services. These included knowingly false IQR (inpatient quality of care) reports required to be made under the Medicare Modernization Act of 2003, OQR (outpatient quality of care) reports required to be made under the Tax Relief and Health Care Act of 2006, and reported performance measures tracked by the Hospital Value-Based Purchasing Program established under the Affordable Care Act of 2010.

Provisions under the Medicare Modernization Act of 2003 and the Tax Relief and Health Care Act of 2006 require hospitals to make these reports, known as the Inpatient Prospective Payment System report and the Outpatient Prospective Payment System report, respectively.

These statutes, as well as the relevant section of the Deficit Reduction Act of 2005, provide compensation to hospitals, including Defendant, for "satisfactorily reporting" specific key quality measures. "Satisfactorily reporting" required the timely reporting of accurate information each hospital was required to track and knew, or reasonably believed, to be true.

These payments for "satisfactorily reporting" gave hospitals, including Defendant, an increase of 2% of its annual market basket update for each of these required reports. And a hospital could receive a total of 4% of its total annual market basket update from the government each year for satisfactorily tracking and reporting the measures required each year on the Inpatient Prospective Payment System and Outpatient Prospective Payment System reports. But by submitting knowingly false reports, Defendant was not entitled to these increased annual payments from Medicare because the reports were knowingly and materially false.

The Federal False Claims Act makes it a false claims act violation to submit a knowingly false claim for payment, or to make or to cause to be made a false statement upon which a claim for payment by the government is based.

Among the reasons Defendant apparently chose to falsify records and reports was to make it appear Defendant was meeting better performance standards than Defendant actually was. And it was further motivated by the fact that some of the measures tracked on the Inpatient and Outpatient Prospective Payment System reports were connected to reimbursement under Medicare's new Value-Based Purchasing program.

And it was important in avoiding detection when fraudulently seeking the millions of dollars at stake under that program for all of the reported numbers under the Inpatient and Outpatient Prospective Payment System reports to also remain consistent with what Defendant falsely reported in securing the Value-Based Purchasing program's incentive payments for performance.

As identified above, the Value-Based Purchasing program was established under the Affordable Care Act of 2010. It was the outgrowth of efforts beginning with the Medicare Modernization Act of 2003, and continuing with the Tax Relief and Health Care Act of 2006, to phase in a pay-for-performance reimbursement system for Medicare to replace the fee-for-service model.

The Value Based Purchasing program withheld 1% of the total annual Medicare payments to hospitals nationally, which was then placed in a fund managed by the Centers for Medicare and Medicaid Services. That fund was then used to pay up to the full 1% back, as incentive payments, to hospitals who met specific performance measures.

The percentage annually withheld from hospitals under this program was 1% of total annual Medicare payments in Fiscal Year 2013, 1.25% in FY 2014, 1.5% in FY 2015, and will increase further in future years.

The total number of dollars at stake for an acute care hospital, such as the Defendant, which reports receiving more than $60 million annually in total Medicare payments, already exceeds $2.25 million from the first three years alone of the program, with roughly $1 million more to come in the next fiscal year, in potentially lost revenue or increased incentive payments under this program. And the means provided for getting the money returned is by meeting the required performance measures, or by making it appear on reports that those performance measures have been met.

These false records were then submitted to the Centers for Medicare and Medicaid Services and used to obtain higher incentive payments than Defendant was actually entitled to under the Hospital Value-Based Purchasing Program.

This started by falsifying patient "arrival times" in the Emergency Department to appear to coincide exactly with the time of the automatically-generated time produced by the EKG monitor. All quality measures, under the Hospital Value-Based Purchasing Program, which were based on these falsified arrival times also then became false when reported and used to obtain a higher incentive payment.

Most notably, the Centers for Medicare and Medicaid Services published a Final Rule to hospitals in 2011 clearly stating that Emergency Department arrival times for Acute Myocardial Infarction patients could not be recorded as the time the EKG was performed, but instead must be recorded as the time of the patient's actual physical arrival at the hospital or Emergency Department.

This is because best outcomes for a patient presenting with acute myocardial infarction requires, fibrinolytic therapy to be received within 30 minutes of hospital arrival or Primary PCI to be received within 90 minutes of hospital arrival, when either of those procedures are required.

These time measures were so important that they were included among the only 12 performance measures hospitals were made to report in order to receive their incentive payments under the Value Based Purchasing program in 2013.

In its Final Rule in 2011 regarding Value Based Purchasing payments and performance measures, CMS cited to the American College of Cardiology guidelines established earlier which prohibited using the EKG time as a patient's hospital arrival time when tracking these crucial 30 minute and 90 minute windows of time.

CMS stated in that Final Rule in 2011 that Value Based Purchasing performance scores and incentive payments are *not* to be based on the use of EKG times as a patient's hospital arrival time.

Nevertheless, Defendant went to great lengths to ensure its Emergency Department staff falsely recorded and reported EKG times as patient arrival times, with elaborate and complex schemes at times, as described herein, to guarantee that no record would be kept to provide any earlier indication of a "chest pain" patient's arrival than the EKG automatically-generated time showing that the patient had arrived, while concealing any time the patient spent in the waiting room, at registration, or in triage.

The EKG monitor automatically generates a time that cannot be changed. But every other prior indicator of a patient's arrival in the Emergency Department can be changed or concealed. And those measures were directed by Defendant to be changed or concealed as described herein.

The stated reason Emergency Department staff members were given by supervisors and the Chief Operating Officer of the hospital for having to go to such lengths to falsely document arrival times, and other specific times, was "to maximize reimbursement from CMS."

When employees questioned the practice and balked at falsifying these records, they were told that if they did not want to follow the policy that there were other hospitals where they could go work.

At least one employee who worked as a Triage Tech was removed from that position for failing to follow this policy.

Reporting the EKG time as the patient arrival time violated CMS' clearly stated rule with regard to meeting the requirements of AMI performance measures associated with Value Based Purchasing incentive payments.

Making these false records and statements in order to falsely and artificially increase Defendant's Performance Score and resulting increased incentive payment under the Value Based Purchasing program constitutes a False Claims Act violation.

Defendant has continued since FY 2011 to falsely report EKG times as the arrival times of these patients. And Medicare's "Hospital Compare" website published for prospective patients confirms that, as of the most recent reporting period ending in FY 2014, Defendant continues to report Median Times to EKG of "0" minutes, which beats the national average reported next to it on the website by 8 minutes.

Not only does this continue to violate the pay-for-reporting requirements regarding the Outpatient Prospective Payment System report, which includes "Median Time to EKG", and the pay-for-reporting requirements of the Inpatient Prospective Payment System report, which includes false arrival times of AMI patients who supposedly received fibrinolytic therapy within

30 minutes from arrival or Primary PCI (balloon) within 90 minutes from arrival, but it also continues to create false Performance Scores to be calculated for Defendant's Value Based Purchasing incentive payments, and it lures Medicare patients who live between Defendant's location and competing neighboring hospitals who have reviewed the Hospital Compare website to take their Medicare dollars to Defendant for the quick care and zero minute wait times this false public report on Medicare's website implies.

Defendant engaged in other practices as well in order to create false records upon which reimbursement or incentive payments were premised. These included, but were not limited to, falsifying "throughput" times. Throughput measures the time from a patient's arrival at the Emergency Department to the time that patient is admitted and in a room in the main hospital. It also measures the time from the point when the Emergency Room physician makes the decision to admit a patient to the time when the patient is actually admitted and in a room in the main hospital.

Throughput is a quality measure reported on the Inpatient Prospective Payment System report, it is a tracked quality performance measure, and "meaningful use" dollars are also connected to its reporting and the hospital's performance under the HITECH act.

Finally, Defendant violated the Federal FCA by falsely certifying to State and Federal Medicaid officials in writing that Defendant was in full compliance with the false claims act training and education requirements of the Deficit Reduction Act of 2005, which made full compliance with this requirement a condition of receiving any Medicaid payments after March 2007.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. §§1331 and 1345, and 31 U.S.C. §§3732(a) and 3730.

2. Venue is appropriate as the Defendant can be found in, resides in, and/or transacts business in this judicial district. Therefore, within the meaning of 28 U.S.C. §1391(b) and (c) and 31 U.S.C. §3732(a), venue is proper.

3. To Relator's knowledge, jurisdiction over this action is not barred by 31 U.S.C. §3730(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party; there has been no "public disclosure" of these allegations or transactions; and Relator is the "original source" of the information on which these allegations are based.

THE PARTIES

4. Plaintiff Megen Duffy is a citizen of the United States of America and a resident of Kansas. From August 2009 until October 31, 2013, Plaintiff was employed by Defendant as an Emergency Department nurse. Plaintiff brings this action based upon direct and unique information obtained during the period of her employment with Defendant in this capacity. As characterized by the Federal False Claims Act, Plaintiff will often be referred to as "Relator" hereafter. Ms. Duffy has provided some of this information to the United States and will provide additional information through a Relator's "Disclosure Statement" to be served on the United States.

5. Defendant Lawrence Memorial Hospital is a municipal hospital located in Lawrence, Kansas, and is a Kansas Medicaid (KMAP) Provider, and also is recognized by the Centers for Medicare and Medicaid Services as an Acute Care Hospital. Defendant contracts

with Medicaid, Medicare, and other taxpayer funded healthcare plans and private insurance to provide healthcare services to patients.

6. At all relevant times herein Defendant has operated as a hospital and healthcare provider in Lawrence, Kansas.

THE FEDERAL-STATE MEDICAID PROGRAM

7. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §1396-1396v (hereinafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States (and territories) and is funded by State and Federal taxpayer revenue. In Kansas, Medicaid funding remained roughly 40% state-funded and 60% federally-funded throughout the relevant time periods herein. The Medicaid Program is overseen by the United States Department of Health and Human Services through the Centers for Medicare and Medicaid Services (hereinafter "CMS"). Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needing individuals who qualify for Medicaid.

THE DEFICIT REDUCTION ACT OF 2005

8. Section 6032 of the Federal Deficit Reduction Act of 2005, signed into law in February 2006, and codified at 42 U.S.C. §1396(a)(68) requires that, as of January 1, 2007, all healthcare providers who receive $5 million or more annually from Medicaid, as a condition of receiving Medicaid payments: shall (A) establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31,

administrative remedies for false claims and statements established under chapter 38 of title 31, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal healthcare programs (as defined in section 1320a 7b(f) of this title); (B) include as part of such written policies detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and (C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

9. As a Kansas Medicaid (KMAP) Provider, Defendant is required each year since 2007 to sign and submit the following "Attestation of Compliance with Section 6032 of the Federal Deficit Reduction Act":

10. "I hereby attest that, as a condition for receiving payments, I have read Section 6032 of the Deficit Reduction Act of 2005 (the Act), and have examined the above-named provider/entity's policies and procedures. Based on that review the provider/entity is in compliance with the requirements of the Act to educate employees and contractors concerning the Federal False Claims Act established under sections 3729 through 3733 of Title 31, United States Code, administrative remedies for false claims and statements established under Chapter 38 of Title 31, United States Code, State laws pertaining to Medicaid fraud, abuse, civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste and abuse in Federal healthcare programs. Furthermore, the provider/entity will continue to comply with these provisions to remain eligible for payment under the Kansas Medical Assistance

Program. I understand that if any statements in this declaration are false, they may be subject to prosecution under the Kansas perjury law, K.S.A. 21-3805, as well as the laws cited in this declaration. I declare under penalty of perjury under the laws of the state of Kansas that the foregoing is true and correct." (Emphasis added).

11. This attestation is then signed and dated, as a condition of receiving Medicaid funds, by the entity's Chief Executive Officer, President or Vice President.

12. Compliance with these requirements is mandatory. Any provider or provider entity that fails to comply with the annual attestation or the submission of information will be subject to sanction, including suspension of Medicaid payments or termination from participation in the Kansas Medical Assistance (Medicaid) Program.

13. The Centers for Medicare and Medicaid Services (hereinafter "CMS") extended the deadline for compliance with this requirement of the Deficit Reduction Act from January 2007 to March 2007. Because this compliance was statutorily made a "condition of receiving such [Medicaid] payments," the receipt of Medicaid payments by any such healthcare provider after March of 2007 required certification of compliance with this requirement of the Deficit Reduction Act. And any false certifications of such compliance made in order to receive Medicaid payments would constitute false records or statements material to a false or fraudulent claim, in order to get a false or fraudulent claim paid or approved by Medicaid, which would be a violation of the federal False Claims Act.

14. It is important to note that there are 4 key elements that an employee must be educated about under this requirement. These include, 1) that the False Claims Act exists, what it is, what it does; 2) the administrative remedies for false claims and statements established under Chapter 38 of Title 31 of the United States Code; 3) State laws pertaining to Medicaid fraud,

abuse, civil or criminal penalties for false claims and statements; and 4) whistleblower rights and protections under such laws, including the role of such laws in preventing and detecting fraud, waste and abuse in Federal healthcare programs.

15. The education component of this requirement means that it is not sufficient to merely post this information on a link to a website on which employees may not ever know to look. Nor is it sufficient if the content on that website or link fails to include all 4 key elements.

16. Additionally, it is not a sufficient program under the purposes of the Act if the information given to employees is that "where to report suspected fraud" consists only of reporting that fraud to an employee who is a subordinate of the individuals within the company or business who are directing the fraud, because the individual the fraud is reported to is equally subject to retaliation, and equally lacks the authority to stop the fraudulent conduct.

THE FEDERAL MEDICARE PROGRAM

17. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395-1395ccc, (hereinafter "Medicare"), is a Health Insurance Program administered by the Government of the United States and is funded solely by Federal taxpayer revenue. The Medicare Program is overseen by the United States Department of Health and Human Services through the Centers for Medicare and Medicaid Services (CMS). Medicare provides funding for healthcare services and supplies for individuals age 65 and older, those with end stage renal failure, and for individuals with certain permanent disabilities. Medicare Part B provides funding for hospital care for all such individuals.

THE MEDICARE MODERNIZATION ACT OF 2003

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM ("IQR")

18. Section 501(b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173, and Section 5001(a) of the Deficit Reduction Act of 2005, Public Law 109-171, provide incentives to encourage hospitals to report to CMS data about inpatient care. (*See Social Security Act Section 1886(b)(3)(B)(vii) and (viii).)* The Inpatient Quality Reporting ("IQR") program does not provide for evaluation of the hospital's quality of inpatient treatment. This law merely establishes a requirement for the hospital to report accurate information to CMS. The reward for accurate reporting is a higher annual update to the standardized amount for hospital inpatient operating costs, sometimes called the market basket update. The Deficit Reduction Act of 2005 increased this to 2.0% of market basket update. However, a hospital is penalized with a reduction in its annual Medicare payment rates when it fails to meet reporting requirements.

19. The hospitals are required to report data on specific quality measures of patient care as set out by CMS. For its initial quality for IQR reporting, CMS chose information concerning four topics: Acute Myocardial Infarction (AMI), Heart Failure (HF), Pneumonia (PN), and Surgical Care Improvement (SCIP). *See 42 CFR Parts 422 & 480, 76 Federal Register 26492 (May 6, 2011).*

20. CMS will ultimately expand the quality measures required for reporting, but initially targeted these areas because they involve "(a) conditions that result in the greatest mortality and morbidity in the Medicare population, (b) conditions that are high volume and high cost for Medicare, and (c) conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines." *See 42 CFR Parts 422 & 480, 76 Federal Register 26496 (May 6, 2011).*

21. For purposes of IQR, CMS initially adopted the standards for health care quality measurement development by the National Quality Forum ("NQF"). The standards set by NQF for AMI treatment require that a hospital perform an electrocardiogram ("EKG") of a possible AMI patient within three minutes after the patient's arrival at the hospital ("Median Time To EKG"), provide Fibrinolytic Therapy (administration of clot-busting medications) within thirty minutes after the patient's arrival at the hospital (fibrinolytic therapy time), and provide the Primary Percutaneous Coronary Intervention (PCI, a balloon angioplasty) within ninety minutes of the patient's arrival at the hospital ("door-to-balloon" time).

22. Additionally, CMS publishes the Specifications Manual to set the national hospital quality measures for a given period and to assist hospitals in tracking and reporting requisite information.

23. In the Dictionary portion of its Specifications Manual, CMS defines "Arrival Time" as "[t]he earliest documented time (military time) the patient arrived at the hospital." At pages 1-72 through 1-73.

24. To determine arrival time, the hospital should carefully examine all medical record documentation from the acceptable sources recognized by CMS. These documents are: any emergency department documentation, nursing admission assessment/admitting note, observation record, procedure notes, and vital signs graphic record. Id at I-74. (emphasis added)

25. The Emergency Department (ED) documentation specifically includes "ED vital sign record, ED/Outpatient Registration form, triage record and EKG reports, laboratory reports, x-ray reports, etc. if these services were rendered while the patient was an ED patient." CMS directs that "[a]rrival time should NOT be abstracted simply as the earliest time in the acceptable sources, without regard to other (i.e. ancillary services) substantiating documentation. If

documentation suggests that the earliest time in the acceptable sources does not reflect the time the patient arrived at the hospital, this time should not be used." Id. at 1-73. (emphasis added)

26. In other words, a hospital is not allowed to simply rely on or report the EKG time as the determining measure of arrival time in isolation while ignoring all other acceptable sources recognized by CMS, including any emergency department documentation, registration record, nursing assessment/admitting note, observation record, procedure notes and vital sign records, or triage record.

27. Because one or more of these "other acceptable sources" virtually always precedes the administration of an EKG for any patient presenting with chest pain in an Emergency Department, to simply report the EKG time as though it is every patient's "arrival time" is, therefore, both factually inaccurate and in violation of express CMS rules, guidelines and definitions.

28. But, specifically with regard to acute myocardial infarction patients and this measured 30 minute window for fibrinolytic therapy and the 90 minute window for receiving Primary PCI (balloon), CMS has expressly adopted the standards set out by the American College of Cardiology, which states that the EKG time shall not be used in determining the patient's arrival time, and that arrival time is determined instead by the patient's physical arrival at the hospital or Emergency Department.

29. And fibrinolytic therapy and PCI times from arrival are reportable measures on the IQR's IPPS, and these two measures for AMI patients are components then used for calculating a hospital's Performance Score in determining the amount of any incentive payment the hospital may receive under the Value Based Purchasing program.

30. In fact, the Inpatient Prospective Payment System as of 2012 included the requirement to track and report the following measures:

1- AMI-7: Median Time to Thrombolytics for STEMI
2- AMI-7a: Thrombolytics within 30 minutes of Hospital Arrival for STEMI
3- AMI-8: Median time to PCI for STEMI
4- AMI-8a: Primary PCI within 90 Minutes of Hospital Arrival for STEMI
5- PN-3a: Blood cultures Performed for ICU Admission within 24 hours
6- PN-3b: Blood Cultures Performed in the ED Prior to Initial Antibiotic Received in Hospital
7- PN-6: Pneumonia Patients Given the Most Appropriate Initial Antibiotic
8- STK-4: Acute ischemic stroke patients who arrive within 2 hours of time last known well and w/t-PA initiated within 3 hours of time last known well
9- ED-1: ED Throughput—Median time from ED Arrival to ED Departure for Admitted Patients

   a. Reporting began in 2011 for those hospitals applying for meaningful use dollars through the HITECH act
   b. Optional reporting for those hospitals no applying for meaningful use until 2014 when reporting is required

10- ED-2: ED Throughput—Median time from Admit Decision to ED Departure for Admitted Patients

   a. Reporting began in 2011 for those hospitals applying for meaningful use dollars through the HITECH Act
   b. Optional reporting for those hospitals not applying for meaningful use until 2014 when reporting is required.

31. Falsely reporting the EKG time as a patient's arrival time would then violate requirements in federal law for hospitals to satisfactorily (accurately) report each of these measures under this pay-to-report program, including patient arrival times; door to STEMI times; Primary PCI times, and Throughput times, among the affected measures that are inaccurately reported, in violation of federal law, when patient arrival times are falsely reported as being the same as the patient's EKG time.

32. And when Emergency Department staff is specifically and intentionally directed to have the triage nurse make "chest pain patients" which the nurse has determined to likely be "cardiac" then wait as unregistered patients for an EKG so that the "arrival time" can be recorded

as the EKG time, this not only jeopardizes patient safety, it also constitutes knowingly manufacturing false and fraudulent records which were then used to get false claims paid by the government.

33. Submitting knowingly false records to the government when those records are the basis upon which reimbursement or payment is to be made by the government constitutes a false claims act violation.

THE TAX RELIEF AND HEALTH CARE ACT OF 2006

HOSPITAL OUTPATIENT QUALITY **REPORTING PROGRAM ("OQR")**

34. The 2006 Tax Relief and Health Care Act (Public Law 109-432, Section 109) mandated the creation of the Hospital Outpatient Quality Report ("HOQR" or "OQR"). As with the IQR established by the Medicare Modernization Act of 2003, the OQR was created to track quality measures in this next phase of transitioning from fee-for-service to pay-for-performance for Medicare providers. And national standards and future payment rates are determined by what is reported in the OQR.

35. The OQR, like the IQR, is a pay-for-reporting program, set up and funded by CMS where payment is based on satisfactorily (timely and accurately) reporting numbers involving specific measures. These measures are contained in the Outpatient Prospective Payment System ("OPPS") report.

36. To receive the full Annual Payment Update (APU) under the OPPS, hospitals must meet administrative, data collection and submission, and data validation requirements of

the OQR. Hospitals that fail to successfully participate in the OQR receive reduced payments through a reduction of 2.0 percentage points to the hospital market basket update.

37. As of 2012, the OPPS consisted of 23 measures. Number 19 was suspended by CMS due to concerns over HIPAA, and number 15 was called into question by the Quality and Performance Committee of ACEP.

38. The OPPS, however, only requires the reporting of any 9 of the remaining 21 measures, and a hospital was allowed choose which ones to report based upon which numbers were most favorable to the hospital.

39. And a hospital reporting false arrival times in order to maximize HVBP incentive reward payments would not merely falsely report a "majority of measures" making the OPPS report materially false. Instead, the hospital could selectively report 9 measures that were all false, which would make the OPPS entirely false.

40. The opportunity then exists to create an entirely false OPPS report using only the 9 measures that most benefit the hospital's HVBP incentive reward payments, using knowingly falsified arrival times and resulting measures that not only cause the OPPS report to be falsified, but also the numbers upon which calculations are based in determining a hospital's "Total Performance Score" and HVBP incentive payments.

41. And, if all other records of a patient's actual arrival time at the hospital are destroyed, the only evidence of when they arrived is found in the printed time automatically generated by the EKG and the knowingly falsified OPPS report.

42. "Aspirin at Arrival" remained a reportable measure, but was later deemed by CMS to be a "topped out" quality measure to report because it was so standard as to no longer need reporting or tracking at this level.

43. There was a total 21 potential measures a hospital could choose from in selecting which 9 measures it would report on the OPPS. These consisted of 11 measures that were connected to a patient's arrival time, including such things as:

OP-1: Median Time to Fibrinolysis

OP-2: Fibrinolytic Therapy Received within 30 minutes

OP-3: Median time to Transfer to Another Facility for Acute Coronary Intervention

OP-4: Aspirin at Arrival

OP-5: Median Time to ECG

OP-6: Timing of Antibiotic Prophylaxis (which relator says was also often falsified)

OP-16: Tronopin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received within 60 Minutes of Arrival

OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients

OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional

OP-22: ED- Patient Left Before Being Seen

OP-23: ED Head CT Scan Results for Acute Ischemic Stroke or Hemmorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival.

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44. Falsifying arrival times, including by reporting EKG as the time of arrival, would cause 11 of these measures to be false, and the entire report to be materially non-compliant. Moreover, because time from arrival to fibrinolytic therapy is one of the performance measures for determining incentive payments under the Value Based Purchasing program, falsifying this report then allows for performance measures for determining Value Based incentive payments to also be falsified and inflated.

45. Knowingly submitting materially or entirely false reports is not "satisfactorily reporting" under the requirements of the statute for pay-for-reporting reimbursement.

46. Any payment received from CMS for a report that was materially, knowingly, and intentionally false would constitute a False Claims Act violation.

THE AFFORDABLE CARE ACT AND CMS' HOSPITAL VALUE-BASED PURCHASING PROGRAM

47. The Patient Protection and Affordable Care Act of 2010, in the next phase of this effort to shift away from the fee-for-service model that rewarded providers for quantity of care, established the Hospital Value-Based Purchasing Program ("HVBP" or "Hospital VBP"), found in section 1886(o) of the Social Security Act, which affects payment for more than 2,985 hospitals across the country. Under the HVBP, Medicare makes incentive payments to hospitals based on quality of care as measured by either 1) How well they have and continue to perform on each tracked measure, or 2) How much they improve their performance on each measure compared to their performance during a baseline period.

48. Hospitals submit some of the same information for the HVBP program that they submitted for the IQR and OQR programs described above. But, under HVBP, CMS rewards hospitals based on actual quality performance on measures, rather than simply reporting data for those measures." *See 42 CFR Parts 422 and 480, 76 Federal Register 26490 (May 6, 2011).*

49. Although the HVBP program began tracking hospital performance in 2010 (FY 2011), incentive payments were not available until 2012 (FY 2013). To determine incentives for Fiscal Year 2013, CMS looked to the information reported in FY 2011 as the base year and then compared it to the information reported in FY 2012. If the records reflected that the hospital

performed well both years, or that the hospital showed improved performance in 2012 over 2011, the hospital was eligible for an incentive payment in fiscal year 2013.

50. The HVBP reduced payments to hospitals initially by 1% and placed the savings of more than $800 million per year into a fund which then goes to rewarding hospitals based on how well they meet these performance measures, standards and goals. The HVPB Program also utilizes the standards for health quality measurement recognized in the IQR and OQR programs via OPPS and IPPS.

51. In 2014, this percentage increased to 1.25% and secured $1.1billion nationally for value-based incentive payments.

52. The Final Rule for 2015 increases the applicable percent reduction to fund the program to 1.5% of Medicare reimbursement, which will garner $1.4 billion for value-based incentive payments.

53. While the earlier Proposed Final Rule for performance measures under HVBP included all of the Measures the Final Rule contained, the Final Rule for performance measures upon which these incentive payments would be based for FY 2013 was given by CMS in 2011, *76 Federal Register 26510 (May 6, 2011).*

54. This Final Rule set out the following performance measures for FY 2013.

FINAL MEASURES FOR FY 2013 HOSPITAL VBP PROGRAM
Clinical Process of Care Measures

Acute myocardial infarction

AMI–7a ..... Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.

AMI–8a ..... Primary PCI Received Within 90 Minutes of Hospital Arrival.

Heart Failure

HF–1 ..... Discharge Instructions.

Pneumonia

PN–3b ..... Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.

PN–6 ..... Initial Antibiotic Selection for CAP in Immunocompetent Patient.

Healthcare-associated infections

SCIP–Inf–1 ..... Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.

SCIP–Inf–2 ..... Prophylactic Antibiotic Selection for Surgical Patients.

SCIP–Inf–3 ..... Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.

SCIP–Inf–4 ..... Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.

Surgeries

SCIP–Card–2 ..... Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.

SCIP–VTE–1 ..... Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.

SCIP–VTE–2 ..... Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.

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55. While there is a complex calculation structure for weighting and valuing these 12 measures, the process essentially involves adding up the hospital's weighted scores on these 12 measures. Each measure is weighted differently, and providers are scored on their achievement on each measure relative to national or other appropriate benchmarks. That total combined score for those measures becomes the hospital's Performance Score. The Total Performance Score then determines the amount of the hospital's 1%, which was withheld from its Medicare payments, will be returned to the hospital as an incentive payment under the Value Based

Purchasing program. And, in subsequent years, this 1% amount would increase to 1.25%, 1.5%, etc. as noted above.

56. Some of these measures are procedural and merely require that the measure was performed, such as providing discharge instructions to heart failure patients.

57. Other measures require urgent action such as the receipt of Fibrinolytic Therapy within 30 minutes of hospital arrival or Primary PCI Received within 90 minutes of hospital arrival for patients with Acute Myocardial Infarction.

58. Accordingly, some of these 12 measures are weighted more heavily than others as well when determining the Performance Score.

59. For example, most hospitals are going to be running blood labs before giving an antibiotic to a pneumonia patient. And most hospitals, hopefully, are going to give discharge instructions to heart failure patients. These and other "check the box if you did it" measures, therefore, are going to matter only in the loss of HVBP dollars if those measures are not performed, and not in maximizing what a hospital receives back in incentive payments.

60. This is because the Total Performance Score is based on performance measured against the performance of other hospitals and national standards. And a performance score cannot be increased by simply doing what every other hospital is already doing, and is expected to do.

61. But if few or no other hospitals are falsifying arrival times and falsifying the resulting time-sensitive measures upon which Total Performance Score and maximum HVBP incentive payments are premised, then a hospital that is falsifying those times has a chance to max out its Total Performance Score and incentive payments by surpassing national averages on

the timed measures, which is where the size of incentive payments is determined. That is where a hospital sets itself apart.

62. And, when the national average Median to EKG time is 8 minutes, a hospital falsely reporting theirs as 0 minutes has given itself an 8 minute advantage on all other hospitals in regard to all resulting timed performance measures, and in securing the top possible Total Performance Score and maximum HVBP incentive payments.

63. During the Comments Period regarding the Final Rule, CMS reports that "One commenter suggested that we review the technical specification for AMI-7a and AMI-8a to ensure that intervention timing is based on diagnosis by EKG." *76 Federal Register 26500 (May 6, 2011).*

64. CMS' response to this comment was that:

> The intervention timing for both AMI-7a and AMI-8a runs from the time of arrival, not the time of diagnosis by EKG. Specifically, the specifications for the AMI-7a measure state that AMI patients with ST-segment elevation or Left bundle branch block (LBBB) on the EKG closest to arrival time receiving fibrinolytic therapy during the hospital stay have a time from hospital arrival to fibrinolysis of 30 minutes or less. Similarly, the specifications for the AMI-8a measure state that AMI patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay have a time from hospital arrival to PCI of 90 minutes or less.
>
> These specifications can be found on the Quality Net Web Site (http://www.qualitynet.org). We note that these specifications are based on clinical guidelines adopted by the American College of Cardiology (ACC) clinical guidelines for ST elevation MI." *76 Federal Register 26501 (May 6, 2011).(emphasis added)*

65. In other words, CMS is saying in this Final Rule on Value Based Purchasing that a hospital shall not report the EKG time as a patient's arrival time at the hospital/emergency department. Using EKG diagnosis as the arrival time and the starting of the clock on the 30

minute and 90 minute measured times violates best practice, and runs contrary to the guidelines already known by hospitals and established by the American College of Cardiology.

66. The progression of damage to heart tissue and other parts of the body is not suspended in time while a patient remains in the Emergency Department waiting to be seen, or registered, or triaged before receiving an EKG. And CMS will not pay incentive payments under Value Based Purchasing when hospitals are not following best practice in order to reduce costs and harm to patients.

67. Having this knowledge earlier from the American College of Cardiology, and having it repeated clearly and in no uncertain terms by CMS in its Final Rule regarding Value Based Purchasing payments and performance measures no later than May 6, 2011, makes it particularly egregious as a knowing violation of the False Claims Act for any hospital to have continued falsely and unlawfully reporting the EKG time as the hospital arrival time of AMI patients.

68. And when a hospital reports to CMS that it was meeting the requirements of any performance measures, including heavier weighted performance measures, under Value Based Purchasing, such as arrival and action times with regard to acute myocardial infarction patients, in order to falsely and artificially increase its Total Performance Score upon which Value Based Purchasing payments are calculated and paid, a False Claims Act violation has occurred with regard to that Value Based Purchasing incentive payment.

THE HITECH ACT, ELECTRONIC HEALTH RECORD REPORTING ("EHR") AND "MEANINGFUL USE" INCENTIVE PAYMENTS

69. The HITECH Act (Title IV of Division B of the American Recovery and Reinvestment Act of 2009 ("ARRA"), together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011.

70. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology.

71. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Social Security Act, as added by section 4102 of the HITECH Act, the Secretary is given authority to select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments.

72. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act.

73. All clinical quality measures selected for the EHR Incentive Program for eligible hospitals must be proposed for public comment prior to their selection, except in the case of measures previously selected for Hospital IQR program under section 1886(b)(3)(B)(viii) of the Act.

74. The final rule for the Medicare and Medicaid EHR Incentive Programs includes 15 clinical quality measures for eligible hospitals and critical access hospitals (75 FR 44418), two of which have been selected for the Hospital IQR program under 1886(b)(3)(B)(viii) of the Act for the Fiscal Year 2014 payment determination (75 FR 50210 through 50211) and include

the "throughput" measures identified under the Hospital IQR section above. (See paragraphs under heading for IQR.)

75. Thus, the Hospital IQR and Hospital Value Based Purchasing programs have important areas of overlap and synergy with respect to the EHR-based reporting of quality measures under the HITECH Act.

76. The financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals were intended to encourage greater EHR-based reporting of clinical quality measures under the Hospital IQR program, which are subsequently used for the Hospital Value Based Purchasing program.

FEDERAL FALSE CLAIMS ACT

77. The Federal False Claims Act, 31 U.S.C. §3729(a)(1)(A) makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law.

78. The Federal FCA, 31 U.S.C. §3729(a)(1)(B) makes "knowingly" making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, in order to get a false or fraudulent claim paid or approved by the Government, a violation of federal law.

79. The Federal FCA, 31 U.S.C. §3729(a)(1)(C) makes conspiring to commit any of the above acts under the Federal False Claims Act, a violation of federal law.

80. The Federal FCA, 31 U.S.C. §3729(a)(1)(D) makes having possession, custody, or control of property or money used, or to be used, by the Government and knowingly

delivering, or causing to be delivered, less than that amount of money or property, a violation of federal law.

81. The Federal FCA 31 U.S.C. 3729(a)(1)(G) makes knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or to knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law.

82. The Federal FCA defines "knowing" as that a person, with respect to information, 1) has actual knowledge of the information, 2) acts in deliberate ignorance of the truth or falsity of the information, or 3) acts in reckless disregard of the truth or falsity of the information, and requires no specific intent to defraud.

83. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property, whether or not the United States has title to the money or property, which is presented to an officer, employee or agent of the United States; or which is made to a contractor, grantee, or other recipient (including a state or local governmental agency), if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, *and if the United States Government provides or has provided any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.* (Emphasis added.)

FACTS AND ALLEGATIONS

84. Relator began working for Defendant in or about August 2009. Relator's job title was Registered Nurse, and she worked in Defendant's Emergency Department.

85. In the years that followed during Relator's employment with Defendant she became certified in TNCC, ENPC and ACLS and became board-certified in emergency nursing. Relator received multiple accolades and positive performance reviews, with no negative reviews until her abrupt termination.

86. On a typical day during Relator's employment, Defendant's Emergency Department treated many patients with complaints of "chest pain." At that time, it was standard practice to properly and accurately record both the arrival times of patients and the times when EKGs were obtained, as with any other presenting patient and complaint.

87. After enactment of the Affordable Care Act, reporting and reimbursement rules changed. Defendant, then, also changed its standard practices for Emergency Department documentation.

88. In 2010, the Emergency Department Staff members received their first training from their Department Educator, Elaine Swisher, regarding new hospital policies that would require the staff to falsely report patient arrival times by delaying their registration to appear as though this time coincided with the time those chest pain patients received an electrocardiogram ("EKG" or "ECG").

89. This was to be done in order to make it appear that those patients were immediately receiving an EKG upon arrival, with the stated intent from supervisors and administrators that it would allow the hospital to maximize their reimbursement rates or incentive payments under the new Value-Based Payment program.

90. Additionally, once this "arrival time" was falsified, it bought the hospital time and allowed for the falsification of subsequent procedures for that patient in the hospital, including, but not limited to Primary PCI (balloon) times for heart patients who required angioplasty. Maximum incentive payments from HVBP required Primary PCI (balloon) times to be less than 90 minutes from the time of hospital arrival. And the falsified "arrival time" created in the Emergency Department under these directives allowed that goal to be reached more than if the actual arrival time had been documented in the patient's record and in the records submitted to CMS by Defendant upon which these HVBP incentive payments were based.

91. Beginning about this same time, employees were threatened with disciplinary action if they failed to follow this directive in falsely reporting these arrival times, and the Staff received training at monthly Staff meetings on how to falsely record and report these times.

92. In one such Staff meeting, one of Relator's associates, Jeanine McCullough, RN, asked how the hospital could ethically discipline employees for not committing fraud as directed. No answer was given.

93. If a patient presented to triage with a complaint of chest pain, the triage tech was to notify the triage RN immediately.

94. The triage RN was to decide whether the "chest pain" was likely to be cardiac. If it was, then the patient was not to be registered, but was to instead wait as an unregistered patient for an EKG.

95. After an EKG was obtained, ER registration was notified and then proceeded to register the patient. Through this procedure, the hospital ensured that the earliest recorded patient arrival time was the time on the automatically recorded EKG report rather than the time the patient actually arrived at the hospital.

96. Falsely recording the EKG time as the patient's "arrival time" then allowed the hospital to falsely report "Median Time to EKG" times for patients, as well as Primary PCI (balloon) times, fibrinylotic therapy times, "throughput" times, time from arrival to being seen by a medical professional, and each other measure that relied upon reported patient arrival times in pay-for-reporting programs such as IPPS and OPPS, as well as those measures used in determining reimbursement rates and incentive payments by the government to the hospital under Value Based Purchasing.

97. RN training and chart reviews, which were included in yearly personnel reviews, included ensuring that the triage time matched the EKG time in the computer.

98. In or about January 2013, Relator attended a lecture delivered by Karen Schumate, Defendant's Chief Operations Officer, in which Ms. Schumate discussed Meaningful Use and Medicare reimbursement in depth.

99. Closely following this lecture by Ms. Schumate was an Emergency Department Staff meeting in which the then-Director of the Emergency Department, Joan Harvey, made it very clear that failure to fall into the top tiers nationwide would reduce the hospital's reimbursement, or incentive payments. Therefore, employees would be held to stricter standards regarding the points over which the Emergency Department had control, most notably "zero EKG times" and extremely short admission times from the time of the decision to admit.

100. Relator asked again what these repercussions would be and stated that she felt uncomfortable falsifying times, and Ms. Harvey stated that there were plenty of other hospitals where Relator could work.

101. In addition to ethical dilemmas regarding falsifying the data with the explicit goal of defrauding Medicare, these "zero EKG times" ironically resulted in delays in patient care.

102. This is because when patients were not immediately registered, in order to have later registration times to coincide with EKG times, they were treated as though they were not in the Emergency Department at all, and physicians could not order treatment for them during that time as a result.

103. In this way, the hospital attempted to rely solely on the time reflected on the EKG report to establish "Arrival Time" for purposes of the HVBP program. This was contrary to the requirement to consider all information regarding the time the patient arrived at the hospital. It was also a blatant violation of CMS' directives not to use or report EKG times as "arrival times" in violation of guidelines from the American College of Cardiologists, and that CMS would not deem that practice appropriate under its Value Based Purchasing program from which incentive payments for meeting targeted times would come.

104. An email from then-Director of Defendant's Emergency Department, Joan Harvey, in 2011 reads, "The ED physicians have expressed concern with trading 'zero' minute EKGs for a delay in the QTR [Quick Triage Registration] for them to enter orders on the cardiac patients. When it is necessary due to patient acuity, pull an admissions person in ASAP on those patients to get them into the system."

105. In other words, the physicians were fully aware that they were trading patient care for favorable reimbursement data and were concerned about the human consequences of doing so.

106. The intent and result of this conduct was the creation of entirely false IPPS and OPPS reports that were submitted to CMS. The IPPS report would then consist of as many as 8 out of 10 measures being false. And the OPPS report would also then have 9 of the required reported measures falsified.

107. The falsely reported IPPS measures included such items as "Median Time to Thrombolytics," "Thrombolytics within 30 minutes of Hospital Arrival," "Median time for PCI," "Primary PCI within 90 minutes of Hospital Arrival," "Median Time from ED Arrival to ED Departure for Admitted Patients," and "Median Time from Admit Decision to ED Departure for Admitted Patients," as well as falsely reporting under a separate scheme if "Blood Cultures [were] Performed in the ED Prior to Initial Antibiotic [being] Received in Hospital" for pneumonia patients, which is also one of the 10 reported IPPS measures.

108. And the falsely reported OPPS measures included such items as "Median Time to Fibrinolysis," "Fibrinolytic Therapy Received within 30 Minutes," "Median Time to Transfer to Another Facility for Acute Coronary Intervention," "Aspirin at Arrival," "Median Time to ECG," "Tronopin Results for Emergency Department Acute Myocardial Infarction (AMI) Patients or Chest Pain Patients (with Probable Cardiac Chest Pain) Received within 60 Minutes of Arrival," "Median Time from ED Arrival to ED Departure for Discharged ED Patients," and time of "Door to Diagnostic Evaluation by a Qualified Medical Professional."

109. The hospital is only required to report 9 of these measures on its OPPS report. But every one of them is false when the hospital is knowingly, intentionally, and unlawfully starting with an "arrival time" that both the American College of Cardiology and CMS have expressly prohibited using, namely "EKG time" as the patient's arrival time. And Defendant's fraudulent reports are contingent upon unlawfully using the patient's "EKG time" as the arrival time.

110. The motives for these false reports, and the lives and health of patients placed at risk in order to create them, was multi-faceted. But the key issue was in terms of which of these measures were on the list of current performance measures tracked for maximum HVBP incentive payments, and which of these measures were presumed to be on the list of future

performance measures tracked for maximum HVBP incentive payments, and the resulting need to keep all of the measures reported for the IPPS, OPPS and HVBP consistent in order to conceal the fraud that was occurring.

111. For purposes of HVBP incentive payments, only 4 of the 12 measures tracked are based on time, rather than simply on whether or not an act occurred while a patient was in the hospital's or department's care. And because of the way a hospital's "Total Performance Score" is calculated under HVBP, it is only through a hospital's performance on those 4 timed measures, compared to the performance of other competing hospitals and national standards and averages that a hospital can "max out" its Performance Score and resulting HVBP incentive payments.

112. This was Defendant's motive, and Defendant was able to falsify key timed measures for maximizing HVBP incentive payments worth millions of dollars, including how quickly fibrinolytic therapy and Primary PCI were received by AMI patients, all by unlawfully "starting the clock" only at the time of the patient's EKG, when all of Defendant's competitors nationally were instead starting the clock on their patients minutes earlier when the patient actually physically arrived at the hospital, as CMS had expressly directed them to do, with time the patient spent in the waiting room, in triage, or to be registered all counting against them while Defendant, in contrast, was falsely reporting those waiting, registration and triage times for their patients as zero minutes.

113. And, with a reported national average of 8 minutes for "door to ekg," while Defendant was reporting their time as "0" minutes, falsely reporting arrival times as "0" minutes gave Defendant an 8-minute head start compared to other hospitals nationally, and in securing a

maximum "Total Performance Score" in order to receive maximum HVBP incentive payments worth millions of dollars.

114. In 2013, Defendant began experimenting with various ways of falsifying the times patients waited to transfer out of the ER after the decision to admit was made.

115. This is a measure mandated to be reported by hospitals on the IPPS as part of the IQR, and also under the HITECH Act, and it is referred to as "throughput".

116. At one point secretaries entered a "comment" on the electronic tracking board when the decision to admit was made, but they waited to enter the electric order until the patient already had orders written for the floor, at which point an icon turned green, or otherwise notified staff that they now had 30 minutes to get the patient to the floor.

117. The difference between the time of the decision to admit and the time the order was given to move the patient to the floor would then appear to be nearly instantaneous, even though the two points in time could be up to two or more hours apart. But it falsely allowed the record to appear that the patient had waited less than 30 minutes between the time the decision to admit was made and the time the patient was moved into a room upstairs as an admitted patient.

118. This "throughput" wait time could then be reported as 30 minutes or less on the IPPS.

119. At another point, the secretaries kept cheat sheets on all the admissions, including when the Emergency Department physician told them the decision had been made to admit the patient, when the primary RN was notified, and when inpatient orders were finally received, at which point the secretary would order the bed request as before.

120. The basic idea was that they were trying to find a uniform way of letting everyone know who was being admitted, and even possibly to what room, but without using that function

of the tracking board which would have showed "admit" long before inpatient orders were ready and a bed was available.

121. Relator received a verbal coaching from supervisor, Elaine Swisher, about a nursing progress note Relator wrote indicating the patient had no questions on the plan of care and was waiting on admission because Relator's note had been written before the decision to admit order actually appeared in the electronic chart. Relator said that she didn't feel right lying about the times, and Swisher said, "Well, that's the policy," and walked off without further discussion.

122. Relator was terminated on October 31, 2013, but the last she knew, the process was for the unit secretaries in the Emergency Department to wait until the hospitalist had seen the patient and had written orders before entering the decision to admit "starting the clock" on the dictated 30-minute window of time to admit the patient.

123. Relator expressed concern with this as well, because a patient could lie in the Emergency Department for 5 hours after being told she would be admitted, but if the hospitalist was busy and waited up to 5 hours to write orders, it would still appear in the records that the time from decision to admit to transfer was very fast.

124. The goal from the time of the decision to admit to the actual admission was 30 minutes or less.

125. As stated above, Defendant terminated Relator's employment on October 31, 2013. Ryan Jackson, who replaced Joan Harvey as the Director of the Emergency Department in July 2013, along with Carolyn Bowmer, Vice President of Human Resources, and Dana Hale, Vice President of Nursing, were present during Relator's termination.

126. The fabricated reason given at that time for Relator's termination was that Relator had sent a threatening text to another employee, and these supervisors claimed that "people are so afraid of you they have been on administrative leave," and that a "thorough investigation" had been conducted.

127. This claim seemed suspicious from the outset as Relator knew of no such text, nor did she know of any employee or person she had placed in fear, and Relator's attendance at work throughout October had been very limited because of a life-threatening cardiac condition that necessitated surgery that month.

128. Relator asked during her termination whom she had allegedly threatened and asked to see the threatening text she had allegedly sent.

129. Relator pointed out that a thorough investigation should include asking her, as the accused, about the alleged threats. Those present refused to provide the name or show Relator the supposed text.

130. It remains unknown how or why anyone would be afraid or need to take leave given that Relator was a sick cardiac patient at the time who was on medical leave most of the month of October. And relator was terminated almost literally when she walked back in the door to work after recovering from her surgery.

131. After Relator's termination, and after she was able to determine how and where to report the fraudulent activity of Defendant, Relator contacted CMS in November 2013.

132. CMS then referred the case for investigation to a 3rd party contractor, NCI AdvanceMed, which is now investigating the claims.

133. In February 2014, Relator returned to Defendant's Emergency Department as a patient and witnessed that the same fraudulent practices of falsifying arrival times of "chest pain" patients to create the illusion of zero "door-to-EKG times" was still continuing.

134. Defendant is a Kansas Medicaid Provider of healthcare services.

135. On information and belief, Defendant received more than $5 million annually from Medicaid from Calendar Year 2007 through 2014.

136. While several Staff meetings were held by Defendant to instruct Staff members on how to commit fraud against the government and falsify records, and Staff members were instructed on the consequences of what would happen if they failed to comply with these directives, no comparable efforts, nor any efforts at all, were made to inform employees about the Federal False Claims Act or any of the provisions related thereto as required by Section 6032 of the Deficit Reduction Act.

137. At no time during more than four years of employment with Defendant was Relator ever made aware by Defendant of any established or written policies that provide detailed information, or any information at all, about the False Claims Act established under sections 3729 through 3733 of Title 31, administrative remedies for false claims and statements established under chapter 38 of Title 31, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal healthcare programs as defined under 42 U.S.C. §1320a, as required by Federal law for all healthcare providers receiving more than $5 million annually from Medicaid.

138. At no time during more than four years of employment with Defendant was Relator ever made aware by Defendant of any programs, policies or procedures of Defendant for

detecting and preventing fraud, waste and abuse, as required by Federal law for all healthcare providers receiving more than $5 million annually from Medicaid.

139. Other employees of Defendant were also never made aware by Defendant of the Federal and State False Claims Acts, administrative remedies, whistleblower protections under such laws, or the policies or procedures of the Defendant for detecting and preventing fraud, waste and abuse, despite the requirements of the Deficit Reduction Act of 2005 that every employee of Defendant receive such information from Defendant as a condition of Defendant receiving Medicaid payments.

140. It was the specific lack of any such information or training that left Relator searching for months to know how and to whom to report the suspected fraud she had been witnessing as an employee of Defendant.

141. Eventually Relator learned on her own and through her own research how and to whom to report suspected fraud, which she did in November 2013, the month after her employment was terminated by Defendant.

142. Defendant currently has a link on its website, which an employee may or may not happen upon by chance. The information on this link uses what, in the context of these complex fraud schemes apparently crafted and directed from the highest levels of Defendant's Administration, appears to be merely hollow lip service to state the Defendant's intent to take any reports of fraud seriously, along with limited statements regarding what measures Defendant will take if it receives any reports of fraud.

143. The most glaring problem, as far as the Deficit Reduction Act of 2005 and other anti-fraud statutes requiring Defendant to use this language, to have an anti-fraud program, and to have a system for reporting fraud is concerned, is that the only person or office to whom an

employee with knowledge of suspected or actual fraud can report, here, is a subordinate of the very administrators who have crafted and are directing the fraud. Therefore, even if that individual takes the report seriously and tries to act on it, that individual can do nothing to protect the reporting employee from retaliation, nor to stop the reported fraud other than to face potential retaliation himself or herself. This does not meet the requirement of the Deficit Reduction Act.

144. Further, this website contains none of the 4 key elements required for a compliant False Claims Act training program. Instead, the Defendant would need to inform its employees 1) that the False Claims Act exists, what it is, what it does; 2) the administrative remedies for false claims and statements established under Chapter 38 of Title 31 of the United States Code; 3) State laws pertaining to Medicaid fraud, abuse, civil or criminal penalties for false claims and statements; and 4) whistleblower rights and protections under such laws, including the role of such laws in preventing and detecting fraud, waste and abuse in Federal healthcare programs.

145. Based upon the foregoing facts, all Medicaid payments received by Defendant after March 2007 through at least 2015 were based upon false material statements made by Defendant in order to get false claims paid by Medicaid in violation of the Federal False Claims Act in 31 U.S.C. §3729 et seq., and of the Deficit Reduction Act of 2005 as codified in 42 U.S.C. §1396(a)(68).

146. During the course of Relator's employment, in the absence of training or information about the False Claims Act, whistleblower protections and rights, or policies for detecting fraud, waste and abuse, what the Relator and her coworkers did receive training on was how to game the system with false information to maximize reimbursement rates from CMS, and what would happen to them if they failed to follow these directives.

147. Relator cannot identify at this time all of the false claims caused by this Hospital because the Relator worked in only one department of a large, complex hospital.

148. But, on information and belief, Defendant's plan for falsifying records and reports of timed performance measures occurred in other hospital departments as well, particularly in areas such as surgery and post-op that had the only timed performance measures outside of the Emergency Department where a hospital could falsely inflate its "Total Performance Score" to maximize its HVBP incentive payments.

149. Eight of the twelve performance measures upon which HVBP incentive payments are based are simply a matter of marking the box indicating the task was completed. For example, one measure is about whether heart failure patients received discharge instructions. Another measure asks whether pneumonia patients had blood cultures collected prior to receiving an antibiotic.

150. Because "Total Performance Score" is determined by how a hospital performs relative to other hospitals, virtually all hospitals will get the same score on these non-timed performance measures, and can only lose money under HVBP if they fail to perform those measures. But hospitals cannot increase their HVBP performance rewards by falsifying reports with respect to those non-timed measures. Instead, receiving HVBP incentive payments, and the size of them, is secured by performance, compared to other competing hospitals, on these timed measures.

151. Relator has personal knowledge that she and Defendant's entire Emergency Department were directed to falsify records regarding the timed performance measures that determined the level of incentive payments Defendant received under the Value Based Purchasing program.

152. It seems clear from these and other events that the master plan for gaming the system was coming from levels much higher than the Emergency Department supervisors. And the January 2013 lecture given by Defendant's Chief Operating Officer, Karen Schumate, led Relator to believe these directives and this fraud scheme were coming from the very top levels of Defendant's administration, with an overall master plan, of which the Emergency Department was only one part, although a very important part.

153. Relator further has reason to believe, in addition to those false claims of which Relator does have personal knowledge, that investigation of other departments in the Hospital will reveal further violations with reported performance measures upon which HVBP incentive payments and Total Performance Scores are based

154. And the statements by the then-Director of the Emergency Department, Joan Harvey, in the Emergency Department staff meeting which followed Ms. Schumate's lecture further raised this issue when Harvey stated that failure to fall into the top tiers nationwide would reduce the hospital's reimbursement, or incentive payments. The fact that Harvey then stated that employees would be held to stricter standards regarding the points over which the Emergency Department had control, most notably "zero EKG times" and "throughput" times revealed the likelihood that other Departments were similarly being held to stricter standards regarding the points over which *they* had control.

155. As noted above, the list of time-sensitive performance measures used by CMS in determining Total Performance Scores of hospitals and their resulting incentive payments under HVBP shows that those timed tracked measures are centered on the emergency department and on the surgical/post-op department and its reports.

156. Given the level of pressure and coercion to falsify records and reports with regard to HVBP performance measures over which the Emergency Department had control, and that the directives were coming from the highest levels of Defendant's administration in an overriding master plan, it is reasonable to believe that similar pressure was being placed by Administration, Chief Operating Officer Karen Schumate, and department supervisors on employees in the surgical/post-op area to falsify records and reports as well, as that is where the only other time-sensitive measures tracked outside of the Emergency Department for maximum HVBP incentive payments exists. And this was all done "to maximize reimbursement from CMS."

COUNT I

VIOLATIONS OF THE FEDERAL FCA: 31 U.S.C. §3729(a)(1)(A), (B), (C), (D), and (G)

157. Relator restates and realleges the allegations contained in Paragraphs 1 through 156 above as if each was stated herein in its entirety and said allegations are incorporated herein by reference.

158. The False Claims Act, 31 U.S.C. §3729(a)(1), prohibits persons from (A) knowingly presenting, or causing to be presented to the United States Government, false claims for payment, or (B) knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government, or (C) conspiring to commit a violation of subparagraph (A) or (B) identified above.

159. The False Claims Act, 31 U.S.C. 3729(b) defines "knowing" and "knowingly" as that a person, with respect to information, 1) has actual knowledge of the information; 2) acts in

deliberate ignorance of the truth or falsity of the information; or 3) acts in deliberate ignorance of the truth or falsity of the information. And 31 U.S.C. 3729(b)(1)(B) makes clear that no proof of specific intent to defraud is required.

160. The Defendant knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim by falsely attesting and certifying compliance with the requirements of Section 6032 of the Deficit Reduction Act as contained in 42 U.S.C. §1396(a)(68), in order to receive, and to continue to receive, Medicaid funds, despite Defendant's non-compliance with specific requirements of the law upon which receiving Medicaid payments were conditioned, which caused false or fraudulent claims for payment to be presented for approval.

161. The Defendant also knowingly made, used or caused to be made or used, a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. §3729(a)(1)(B), by falsely recording and reporting IQR data on the IPPS which included several quality measures, including but not limited to, Emergency Department "arrival times," "Median Time to Thrombolytics for STEMI," "Thrombolytics Performed Within 30 Minutes of Arrival," "Median Time to PCI," "Primary PCI (balloon) Performed Within 90 Minutes of Arrival," and "Throughput," each in regard to numerous patients on a daily basis beginning as early as October 2010 and continuing to the present time.

162. These IQR records, which Defendant submitted to CMS, were knowingly false.

163. Defendant was reimbursed by CMS, under the Medicare Modernization Act of 2003 and the Deficit Reduction Act of 2005, for making these reports by being allowed to retain from Medicare 2% of Defendant's market basket update in each year that it "satisfactorily reported" under this "pay-for-reporting" system. Because these reports were knowingly

materially false and non-compliant, the compensation for having "satisfactorily reported" them also constitutes a False Claims Act violation each time a false report was made and compensation was provided by the Government.

164. The Federal FCA 31 U.S.C. 3729(a)(1)(G) makes knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or to knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law.

165. Defendant's retention of 2% of market basket update based upon these knowingly false reports violated 31 U.S.C. 3729(a)(1)(G).

166. The Defendant also knowingly made, used or caused to be made or used, a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. §3729(a)(1)(B), by falsely recording and reporting OQR data on the OPPS which included several quality measures, including but not limited to, Emergency Department "arrival times," "Median Time to Fibrinolytic Therapy," "Fibrinolytic Therapy Received Within 30 Minutes of Arrival," "Median Time to EKG," "Primary PCI (balloon) Performed Within 90 Minutes of Arrival," and "Throughput for Discharged ED Patients," "Door to Diagnostic Evaluation by a Qualified Medical Professional," etc., each in regard to numerous patients on a daily basis beginning as early as October 2010 and continuing to the present time.

167. These OQR records, which Defendant submitted to CMS, were knowingly false.

168. Defendant was reimbursed by CMS, under the Tax Relief and Health Care Act of 2006, for making these reports by being allowed to retain from Medicare 2% of Defendant's market basket update in each year that it "satisfactorily reported" under this "pay-for-reporting"

system. Because these reports were knowingly materially false and non-compliant, the compensation for having "satisfactorily reported" them also constitutes a False Claims Act violation each time a false report was made and compensation was provided by the Government.

169. The Federal FCA 31 U.S.C. 3729(a)(1)(G) makes knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or to knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law.

170. Defendant's retention of 2% of market basket update based upon these knowingly false reports violated 31 U.S.C. 3729(a)(1)(G).

171. These acts of knowingly reporting false data on the IPPS and OPPS were done with the specific plan of enabling Defendant to then falsely manipulate its Total Performance Score with regard to performance measures tracked by the new Value Based Purchasing program, in order "to maximize reimbursement from CMS," and obtain larger annual incentive payments than Defendant was entitled to receive.

172. The Defendant further knowingly made, used or caused to be made or used, a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. §3729(a)(1)(B), by falsely recording and reporting its performance on measures tracked and utilized in calculating its "Total Performance Score," in order to falsely inflate the score and unlawfully increase its annual incentive payment under the Value Based Purchasing Program.

173. The Defendant violated American College of Cardiology guidelines and the clearly stated directives from CMS by unlawfully reporting the arrival time of acute myocardial

infarction patients as being the time of the patient's EKG instead of the time of the patient's physical arrival in the hospital. Violating this directive from CMS caused all of Defendant's reported performance for AMI-7a and AMI-8a measures in calculating Defendant's Total Performance Score to be intentionally and knowingly false, to create a false Total Performance Score, and to secure a Value Based Purchasing annual incentive payment amount to which Defendant was not entitled.

174. Defendant received Value Based Purchasing program incentive payments amounts it was not entitled to each year since FY 2013, based upon false reports Defendant began making as far back as October 2010.

175. These were each intentional reporting and billing fraud schemes designed and directed by Defendant's administration and supervisors in a conspiracy to commit violations, and cause others to commit violations, of the False Claims Act in violation of the False Claims Act, 31 U.S.C. §3729(a)(1)(C).

176. Defendant has established procedures within its hospital which have resulted in a pattern and practice of submitting false records for the purpose of obtaining government funds to which it was not entitled. Defendant had actual knowledge of the falsity of these documents. By specifically instructing its staff to falsely document current patient treatment, and falsely alter records of prior patients, in a misleading manner, Defendant designed a system to submit false records and reports that violated best practices, jeopardized patient safety, and defrauded the federal government.

177. The Defendant directed, participated in, or authorized others to take the actions set forth above, on behalf of Defendant, over a period of years, with some violations beginning as early as 2007, and others in 2010, and continuing until at least the present time in 2015.

178. The United States has been damaged as a result of Defendant's violations of the False Claims Act because it paid for certain overpayments and ineligible payments totaling millions of dollars.

179. As set forth in the preceding paragraphs, Defendant has knowingly, with deliberate ignorance, or with reckless disregard for the truth, violated 31 U.S.C. §3729(a)(1)(A), (B) and (C), and has thereby damaged the United States Government by these actions in a specific amount to be determined at trial.

WHEREFORE, Relator Megen Duffy, acting on behalf of and in the name of the United States of America, demands and prays that judgment be entered as follows against Defendant under the Federal FCA Counts as follows:

(a) In favor of the United States against the Defendant for treble the amount of damages to Medicaid and to Medicare from the false claims submitted, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the United States against the Defendant for disgorgement of the profits earned by Defendant as a result of its unlawful conduct.

(c) In favor of the Relator for the maximum amount allowed pursuant to 31 U.S.C. §3730(d) to include all reasonable expenses, attorney fees and costs incurred by Relator;

(d) For all costs of the Federal FCA civil action

(e) In favor of the Relator and the United States for such other and further relief as this Court deems to be just and equitable.

Respectfully submitted,

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DEMAND FOR A JURY TRIAL

Plaintiff/Relator respectfully requests that the issues in this matter be heard by a jury.

DESIGNATION OF PLACE OF TRIAL

Plaintiff/Relator hereby designates the Federal Court in Kansas City, Kansas as the place of trial in this matter.

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