Case 3:17-cv-01-782-K-BK Doutment	2 Filed 07/07/17 Page 1 of 32 PageID 3
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UNITED STATES OF AMERICA, ex rel., SUSAN DE SESSA, an individual	§ FILED UNDER SEAL
Plaintiff,	§ § CIVIL ACTION NO
v.	§
DALLAS COUNTY HOSPITAL DISTRICT d/b/a PARKLAND HEALTH AND HOSPITAL SYSTEM	8-17CV1782-K
Defendant.	х §

COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COMES Qui Tam Plaintiff/Relator, Dr. Susan De Sessa, by and through the undersigned attorneys, and files this Complaint against Defendant, Dallas County Hospital District d/b/a Parkland Health and Hospital System, and respectfully alleges as follows:

I. <u>THE PARTIES</u>

1. The Qui Tam Plaintiff/Relator in this action is Susan De Sessa, an individual. In accordance with 31 U.S.C § 3730(b), a private person may bring a civil action for a violation of 31 U.S.C. § 3729 for the person and for the United States Government. This action is properly brought in the name of the United States Government.

2. Plaintiff/Relator, Dr. Susan De Sessa¹, ("De Sessa"), an individual, is a resident of Tarrant County, Texas. De Sessa has personal knowledge of violations of Medicare, Medicaid, and other Federal health care program requirements by Defendants named herein.

¹ As addressed below, Dr. De Sessa is a Doctor of Public Health and was an Epidemiologist at Parkland. She is not a medical doctor.

3. At all times material hereto, Defendant Dallas County Hospital District d/b/a Parkland Health and Hospital System is a public hospital located at 5200 Harry Hines Blvd., Dallas, Texas, 75235, and may be served with process by serving its registered agent for service of process, Michael L. Silhol.

II. JURISDICTION AND VENUE

4. This action arises under the Federal Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended, related to false or fraudulent claims made against the United States Government and 31 U.S.C. § 3730(h) related to retaliatory action taken in furtherance of an action related to false or fraudulent claims made against the United States Government. Pursuant to 31 U.S.C. § 3730, a private person may bring a civil action for a violation of § 3729 for the person and for the United States Government, jurisdiction is founded on 28 U.S.C. §§ 1331 and 1345.

5. Venue is proper in the Northern District of the United States District Court for the Dallas Division of Texas, pursuant to 28 U.S.C. § 1391(b), because the claim arose there.

III. <u>COMPLIANCE WITH 31 U.S.C. § 3730(b)(2)</u> <u>AND FEDERAL RULE OF CIVIL PROCEDURE 4(i)</u>

6. Pursuant to 31 U.S.C. § 3730(b)(2) and Federal Rule of Civil Procedure 4(i), this complaint is being filed in camera and shall remain under seal for at least 60 days and shall not be served on the Defendants until the court so orders.

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IV. <u>SUMMARY OF THE ACTION</u>

This is an action against Defendant Dallas County Hospital District d/b/a
 Parkland Health and Hospital System ("Parkland") for violating the False Claims Acts of the
 United States.

8. In April 2017, the OIG released a report recognizing the problem of hospitals "gaming the system" when it comes to the accuracy of data. [Appx. p. 301]. The OIG and the Centers for Medicare & Medicaid Services' (CMS) indicate that "gaming the system" is ongoing with the increase of quality-based payment programs over the last several years. Parkland has done just that, resulting in millions in additional, unwarranted Federal funding.

9. From approximately 2012 to 2016, Parkland received over \$38 million in Federal funding for an 1115 Waiver project that was represented as a project to reduce healthcare-associated infections (HAI). [See Appx. p. 162; Exhibit 9 to the Affidavit of Susan De Sessa (hereinafter "Affidavit")]. While this 1115 Waiver project was in place, Parkland's Management developed and implemented practices and procedures designed to manipulate and falsify the number of hospital acquired infections reported to receive achievement based results under the 1115 Waiver project. These practices and procedures include:

- Adjudication: Modifying how employees are taught to report infections solely for the purpose of reducing the number of infections reported;
- Underculturing: Failing to perform cultures on patients in an attempt to avoid detection and/or documentation of infections to the detriment of its patients;
- Falsifying data: Intentionally using incorrect diagnostic codes to avoid reporting surgical site infections post-operation; and

• Retaliation: Threatening to terminate and actually terminating hospital employees who uncovered the falsification of numbers of reportable infection.

10. Additionally, at all times relevant to this Complaint, in order to receive Medicare payments, Parkland had obligations to comply with the following Rules, Regulations and agreements:

- Centers for Medicare & Medicaid Services' ("CMS") Conditions of Participation;
- ii. A Systems Improvement Agreement ("SIA") entered into with CMS;
- iii. A Corporate Integrity Agreement ("CIA") entered into with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS).

11. Parkland represented compliance with these rules, regulations and agreements to the Government to continue to receive Federal funding; however, Parkland was not in compliance. Parkland's internal policies are set up to mask non-compliance and Parkland had a complete disregard of numerous compliance issues. As addressed herein, during De Sessa's time at Parkland she raised numerous issues of non-compliance and blatantly false data being reported. This was met with a blind eye from all at Parkland (including the CEO) and ultimately led to De Sessa's termination. The response and indifference from Parkland indicates a willful falsification and misrepresentation of data to continue to receive this funding and increase overall funding to which Parkland should not be entitled.

12. As a direct result of knowingly making and using these false and misleading records in connection with claims for significant amounts of Federal funding via the Medicare and Medicaid programs, to which these records were material, Parkland has committed

numerous violations of 31 U.S.C. § 3729(a)(1)(B). Additionally, in pursuing the various improper and unlawful practices addressed below, Parkland has committed countless violations of its Corporate Integrity Agreement, which would, were these violations made known to the OIG, result in significant fines and penalties owed by Parkland to the United States Federal Government. Thus, Parkland has committed innumerable further violations of 31 U.S.C. § 3729(a)(1)(G) by knowingly and improperly making and using false records to avoid an obligation to pay money to the Government.

V. <u>STATEMENT OF FACTS</u>

BACKGROUND

13. The Dallas County Hospital District d/b/a Parkland Health and Hospital System ("Parkland"), by and through its directors, officers, and management, have been involved in activities that violate the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended, relative to Medicare and Medicaid claims. As used hereinafter, "Defendant" includes each of Defendant's agents, employees, officers, directors, and management.

14. At all times material hereto, all acts of all Defendant's officers, directors, and management were done while acting in their respective actual and/or apparent authority and within the course and scope of their employment with and under the direction of Defendant. *Background of Relator*

15. Qui Tam Plaintiff/Relator Dr. Susan De Sessa ("Dr. De Sessa") served as a Clinical Epidemiologist in the Infection Prevention department of Parkland Hospital from July 2012 through November 2014. In addition to analyzing the infection statistics at Parkland, Dr. De Sessa's job included "[c]ollaborat[ing] with clinicians and hospital staff regarding the collection and entry of data, data analysis, and the dissemination/presentation of research results," and "[d]irect[ing], perform[ing], and/or support[ing] Infection Prevention improvement and outcome analyses." [See Appx. p. 1; Affidavit ¶ 2 and Appx. p. 15; Exhibit 1 to Affidavit]

16. Dr. De Sessa is a Doctor of Public Health (DrPH) which she earned from the University of North Texas Health Science Center. She has a Masters in Public Health (Epidemology) from the University of North Texas Health Science Center. She is certified in Public Health (CPH) by the National Board of Public Health Examiners. She is a Certified Professional in Healthcare Quality (CPHQ) by the National Association for Healthcare Quality. In addition, Dr. De Sessa also has a Bachelor of Science degree in Biology from Texas A&M University – Kingsville and completed coursework towards a Masters in Psychology. Previously, De Sessa worked as an Epidemiologist focusing on infection prevention at the Nueces County Public Health District in Corpus Christi, Texas. [See Appx. p. 2; Affidavit ¶ 4 and Appx. p. 15; Exhibit 1 to Affidavit]

1115 Waiver Project - Federal Funding Directly Related to Infection Prevention

17. From approximately 2012 to 2016, Parkland received over \$38 million in Federal funding for an 1115 Waiver project that Parkland represented to the Government as a project to reduce healthcare-associated infections (HAI). [See Appx. p. 162; Exhibit 9 to the Affidavit]. The project description is as follows: "Implement measures to reduce the incidence of preventable healthcare-associated infections (HAI) with a focus on central line associated bloodstream infections [CLABSI], catheter-associated urinary tract infections [CAUTI], and surgical site infections [SSI], as well as mortality associated with sepsis." [See Appx. p. 162; Exhibit 9 to the Affidavit].

The 1115 Waiver Project is broken into four distinct categories of additional
 funding to Parkland. The first two categories are to implement a program and innovate/redesign

the program as needed to achieve success. The third and fourth categories are results based. The

Texas Health and Human Services Commission describes the categories as follows:

Category 1 projects – Infrastructure Development lays the foundation for delivery system transformation through investments in technology, tools, and human resources that strengthen the ability of providers to serve populations and continuously improve services.

Category 2 projects – Program Innovation and Redesign includes the piloting, testing, and replicating of innovative care models, such as telemedicine, patient-centered medical home, and innovations in health promotion and disease prevention.

Category 3 outcomes – Quality Improvements assess the effectiveness of Category 1 and 2 interventions for improving outcomes in the Texas health care delivery system. Each project selected in Categories 1 and 2 has one or more associated outcome measures from Category 3.

Category 4 reporting – Population focused Improvements include a series of reporting measures for a hospital to track the communitywide impact of delivery system reform investments made. Reporting includes data related to potentially preventable admissions, readmissions, and complications, patient-centered health care, and emergency department utilization.

Texas Health and Human Services Commission. *Texas Medicaid and CHIP in Perspective* (11th Edition). February 2017; available at https://hhs.texas.gov/sites/hhs/files//documents/laws-regulations/reports-presentations/2017/medicaid-chip-perspective-11th-edition/11th-edition-chapter15.pdf.

Parkland received Federal funds under each category over a four-year period. [See Appx.

p. 162; Exhibit 9 to the Affidavit].

Government Acknowledged Risk of Gaming the System

Both the Centers for Medicare & Medicaid Services ("CMS"), part of the Department of

Health and Human Services, and the Office of Inspector General ("OIG") have warned of

"gaming the system" when it comes to the accuracy of data. As the OIG recognized, "Accurate

data are fundamental to the integrity of the Centers for Medicare & Medicaid Services' (CMS)

quality-based payment programs, several of which rely on data from Hospital Inpatient Quality

Reporting (IQR).... These data are used to adjust payments on the basis of quality measures;

thus, inaccurate data pose risks to payment accuracy." CMS Validated Hospital Inpatient Quality

Reporting Program Data, But Should Use Additional Tools To Identify Gaming, DEPARTMENT

OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL (April 2017), available at

https://oig.hhs.gov/oei/reports/oei-01-15-00320.pdf. One such program is the Hospital-Acquired

Condition Reduction Program. Id.

Two primary concerns for accuracy of data are the following:

Underculturing: Underculturing departs from standard clinical practice by discouraging the ordering of diagnostic tests in the presence of clinical symptoms. Hospitals may engage in underculturing in cases in which a patient has likely developed an infection during the hospital stay. By not ordering the test, the hospital does not learn whether the patient truly has an infection and therefore the hospital does not have to report an infection to the NHSN. Furthermore, to deal with infections that are possible but unconfirmed, hospitals might—in the absence of diagnoses—treat these patients with broad-spectrum antibiotics, contributing to poor antibiotic stewardship.

Adjudication: In the practice known as adjudication, administrative or clinical superiors inappropriately overrule the hospital staff who are responsible for reporting HAIs to the NHSN, with the result that the hospital does not report infections that should be reported per CDC's definitions for reportable HAIs.

Id. As addressed below, Parkland's actions fall squarely within the concerns of CMS and the OIG.

Parkland's Prior Agreements with the Government

19. In September 2011, CMS performed an inspection of Parkland's compliance with

the CMS Conditions of Participation. These CMS Conditions of Participation are the health and safety standards that health care organizations must meet in order to participate in the Medicare and Medicaid programs, including the Emergency Medical Treatment and Active Labor Act. A true and correct copy of the CMS Conditions of Participation is attached as Appx. p. 28; Exhibit 3 to the De Sessa Affidavit. The CMS assessment found that Parkland was not fully compliant. Accordingly, in September 2011, CMS sent a termination notice and notified Parkland that it intended to terminate Parkland's participation in the Medicare and Medicaid programs due to

failure to meet certain standards. Recognizing the role Parkland serves in providing health care to the people of Dallas County, CMS suspended that termination when Parkland entered into a Systems Improvement Agreement ("SIA"). A true and correct copy of the SIA is attached as Appx. p. 66; Exhibit 4 of the De Sessa Affivavit. In addition, in May of 2013, Parkland entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) for a duration of five years. A true and correct copy of the CIA is attached as Appx. p. 77; Exhibit 5 of the Dessas Affidavit. [See Appx. p. 2; Affidavit ¶ 5]

20. Parkland had a huge financial interest in making the Government believe that these agreements and conditions were being complied with and did whatever it took to convince CMS that this was the case. In August of 2013, CMS notified Parkland that Parkland was in substantial compliance with the Conditions of Participation, that Parkland had successfully completed the requirements of the SIA, and that CMS was rescinding its Termination Notice. On August 22, 2013, CMS notified Parkland that it had restored Parkland's deemed status for full participation in the federal healthcare programs. However, in August of 2014, surveyors from CMS again found that Parkland was not in compliance with the CMS Conditions of Participation and found "immediate jeopardy to patient health and safety." Parkland was again notified that CMS intended to terminate Parkland's participation in the Medicare and Medicaid programs. After an additional survey in September 2014, CMS removed the immediate jeopardy to patient health and safety finding but found that Parkland remained out of compliance with the CMS Conditions of Participation. A third survey in October 2014 found Parkland was in substantial compliance with the applicable regulations and in November 2014, CMS formally restored

Parkland's deemed status for full participation in these federal programs. [See Appx. p. 3; Affidavit ¶ 6]

VI. <u>ALLEGATIONS</u>

Manipulating and "Gaming" the Number of Hospital Acquired Infections

21. Under the CMS Conditions of participation, Parkland is required to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. 42 C.F.R. § 482.42. Parkland is further required to maintain an active program for the prevention, control, and investigation of infections and communicable diseases. *Id.* Under such program, a person must be designated as the infection control officer. The infection control officer must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. *Id.* The Chief Executive Officer and the medical staff must ensure that performance improvement and training programs address any problems identified by the Infection Control Officer, as well as be responsible for the implementation of successful corrective action plans in affected problem areas. *Id.*

22. Infection prevention and control is even more significant in the case of Parkland, because of the additional \$38 million in 1115 Waiver project funding directly related to healthcare-associated infections (HAI). [See Appx. p. 162; Exhibit 9 to the Affidavit of Susan De Sessa (hereinafter "Affidavit")]. While this 1115 Waiver project was in place, Parkland's Management developed and implemented practices and procedures designed to manipulate and falsify the number of hospital acquired infections reported to receive achievement based results under the 1115 Waiver project.

23. De Sessa observed and became aware of numerous, ongoing problems with Parkland's infection prevention and control procedures which were the direct result of improper

practices conducted by various Parkland doctors and staff members on a regular and recurring basis. Parkland doctors and staff took intentional steps to conceal and minimize the documentation of various types of infections, communicable diseases, and hospital-acquired conditions. Parkland doctors repeatedly failed to document various types of hospital acquired infections, surgical site infections, and surgical wounds on patients' medical records. Parkland doctors repeatedly failed to culture surgical wounds, thereby preventing the diagnosis of any possible infection. This improper fixing of the numbers produces false and misleading data with respect to various infection levels and other statistics that Parkland is obligated by law to submit to CMS in order to receive Medicare and/or Medicaid funding. The inaccurate and incomplete medical records not only put the patients at risk but also is a violation of the Conditions of Participation. Many of these deficient and/or fraudulent reporting and documentation practices directly resulted in incorrect data being submitted to CMS pursuant to the annual payment update reporting requirements, as well as to the Office of the Inspector General ("OIG"), pursuant to Parkland's obligations under its Corporate Integrity Agreement. [See Appx. p. 4; Affidavit ¶ 11].

24. De Sessa notified numerous Parkland personnel of numerous non-reported reportable diseases; including, but not limited to: Jennifer Masengill, Parkland's Infection Preventionist; Sylvia Trevino, Interim Director of Infection Prevention; Dr. Robert Hendler, Chief of Quality and Safety; Alysha Cartman, Director of Compliance Investigations. Sylvia Trevino specifically instructed De Sessa to stop reviewing for missed infections not assigned to her and others simply ignored De Sessa. [See Appx. p. 5; Affidavit ¶ 12]. When the Texas Department of State Health Services (which controls Federal funding) was coming for an inspection of Parkland in August of 2014, Parkland had advanced warning. De Sessa

specifically instructed Liptak that the State had inaccurate data before it came to audit, yet Parkland turned a blind eye and took no action to correct the data. [See Appx. p. 4; Affidavit ¶ 8].

25. In addition to misleading the Government with regards to infection rates, Dr. Pranavi Sreeramoju, Chief of Infection Prevention, oversaw the final reported numbers and missed multiple surgical site infections that were tracked internally and externally. For example, in fiscal year 2012, one breast infection was reported out of 169 surgeries (only 0.59%); nationally, the average infection rate for breast procedures ranges from 5-20%. Because of this oversight, Parkland had an outbreak of post-operative surgical site infections in mastectomy patients in October of 2012. As a result of this outbreak, previous data were reviewed and an overall infection rate of 5.42% for breast procedures in fiscal year 2012 was calculated. In addition, patients who had a mastectomy with immediate reconstruction were found to have an infection rate of over 40%, but the Chief of Infection Prevention failed to address this outrageously high rate of complication. Dr. Sreeramoju then created new guidelines to replace NHSN guidelines for surgical site infections (SSIs). As an example, Dr. Sreeramoju created a guideline that all surgical site infection diagnoses had to be made by an attending physician, as did all documentation of pus/purulent drainage. This rule is inconsistent with the CDC surgical site infection criteria that includes a broad definition for attending physician. [See the CDC Criteria attached as Appx. p. 201; Exhibit 14 to the Affidavit]. De Sessa confirmed with the CDC that residents' diagnoses meet the CDC criteria. [See copy of an email with a CDC representative attached as Appx. p. 202; Exhibit 15 to the Affidavit]. De Sessa informed Parkland of this but received no feedback or confirmation from them. Multiple infections were not reported simply because a resident physician (as opposed to the specific attending physician)

documented pus or diagnosed post-operative infections. Examples of Parkland records that have clear indications of SSI, but were neither documented nor reported are attached as Appx. p. 204; Exhibit 16 to the Affidavit. Documents that De Sessa hand delivered to Dr. Hendler and Dr. Sreermoju in a meeting that indicated clear infections that were ignored due to using the wrong criteria are attached as Appx. p. 207; Exhibit 17 to the Affidavit. Dr. Sreermoju did not want to re-review this missed infection brought to her attention because she was busy. [See the email from Dr. Sreermoju attached as Appx. p. 212; Exhibit 18 to the Affidavit]. [See Appx. p. 6; Affidavit ¶ 13].

26. De Sessa also observed a repeated and ongoing problem with Methicillin-resistant Staphylococcus Aureus (MRSA) contamination, particularly in the Parkland's intensive care units (ICUs). Parkland understood that MRSA was the leading cause of surgical site infections and the central line associated bloodstream infections as an "Evaluation of Infection Prevention FY13" report to the Board of Managers indicated the problem. [See Appx. p. 214; Exhibit 19 to the Affidavit]. Despite Parklands' awareness of the unacceptably high rate of MRSA infections in the intensive care units at Parkland, both the doctors and the infection control officer failed to perform adequate prevention and control measures to properly and effectively address this problem. Instead, Dr. Pranavi Sreeramoju, Chief of Infection Control, presented misleading data to the Infection Prevention and Control Committee (IPCC) which led to discontinuing all active MRSA surveillance. [See Appx. p. 7; Affidavit ¶ 14]. Attached as Appx. p. 220; Exhibit 20 to the Affidavit, is a copy of an email stopping MRSA screening in ICUs claiming zero MRSA bloodstream infections in the previous fiscal year. However, Parkland's internal records confirm that there were infections in the ICUs in the previous fiscal year. [See Appx. p. 223; Exhibit 21 to Affidavit]. Parkland continued active surveillance in its burn ICU for a limited time after the

other ICUs, but discontinued that shortly thereafter (in the middle of an MRSA outbreak). Parkland began using Chlorhexadine Gluconate ("CHG") on burn patients specifically against manufacturer specifications and warnings. [See Appx. p. 7; Affidavit ¶ 14].

27. Parkland's policy became in effect: don't check for infections; find less infections; report less infections and make more money. In an Infection Prevention Department meeting that De Sessa attended, a Parkland Resident specifically stated that he was frustrated that he was instructed not to culture for infections. Dr. Sreermoju laughed and said that Parkland did not want more infections so it would keep restricting cultures. The internal Parkland data is consistent with the restricted cultures, showing a significant decrease in the amount of "cultured SSIs" reported in Fiscal Year 2014 as a result of these policies. For example, in fiscal year 2012, only 30% of documented infections not being cultured and up to 55% in fiscal year 2014. This failure to properly screen patients for MRSA infections led to a persistent failure to alert other departments within the hospital that patients going into those departments may have been exposed to or colonized with MRSA. [See Appx. p. 8; Affidavit ¶ 15].

28. Despite the ongoing high level of MRSA infections, Parkland discontinued its surveillance and monitoring of the MRSA infections, in contradiction with the infection control program requirements. Rather than address a serious and ongoing risk to the health and well-being of their patients, Parkland doctors and staff took affirmative steps to minimize the documentation of these infections and create the appearance of much lower rates of infection than were actually present. When Parkland discontinued active surveillance, it addressed the MRSA problem merely by instituting daily ("CHG") baths for all patients in the ICUs alleging it was in compliance with CDC recommendations, when, in fact, it was not. Parkland doctors and

staff failed to institute the significant additional component to the procedure mandated by research guidelines – that the patients be given mupirocin in addition to the daily CHG baths. Finally, Parkland failed to put into place and maintain adequate remedial measures and/or ongoing surveillance to ensure that this dangerous condition was resolved. [See Appx. p. 8; Affidavit ¶ 16].

Violation of Reporting Requirements

29. As a condition of receiving the full amount of its annual Medicare payment update, Parkland is required to submit certain data and statistics regarding its quality of care. Specifically, Parkland must submit data documenting its incidence of central line associated bloodstream infections ("CLABSIs") in intensive care units and high-risk nurseries, as well as all surgical site infections ("SSIs"). If Parkland failed to submit the data, it would be subjected to a reduction in the annual Medicare payment update. Thus, while Parkland is not legally obligated to report this data, the receipt of the annual Medicare update funds are directly conditioned upon Parkland's compliance with this reporting requirement.

30. De Sessa discovered numerous instances of incorrect and deficient reporting practices among Parkland doctors and staff. De Sessa made countless efforts to alert her co-workers and other Parkland doctors and staff to these inaccuracies in Parkland's data. Many of these deficient reporting and documentation practices directly resulted in incorrect data being submitted to CMS pursuant to the annual payment update reporting requirements, as well as to the Office of the Inspector General ("OIG"), pursuant to Parkland's obligations under its Corporate Integrity Agreement. For instance, De Sessa discovered that as a matter of routine practice, Parkland doctors would avoid documenting wound infections by using misleading diagnoses that would lead to erroneous International Classification of Diseases (ICD) coding.

Instead of documenting that the patient had a post-operative infection (Code 998.59), doctors would simply document inaccurately that the patient had "wound cellulitis," (Code 682.9). As a result, the data that Parkland reported to both CMS and OIG was false and incorrect, in that it significantly underreported the true number of surgical site infections. [See Appx. p. 9; Affidavit ¶ 17].

31. The effects of these improper reporting practices with respect to surgical site infections are evidenced by the ongoing and significant discrepancies observed by De Sessa between the data recorded in the Parkland records system (called "Theradoc"), the data submitted to NHSN and the data recorded in the log required to be maintained by Parkland's infection control officer. In fact, these discrepancies indicate that the incidence of surgical site infections is not the only data that is being incorrectly documented and reported. Specifically, De Sessa observed constant and ongoing discrepancies between these two databases (and numbers submitted to NHSN) with respect to the incidences of the following conditions: Catheter Associated Urinary Tract Infections ("CAUTIs"), Central Line Associated Bloodstream Infections ("CLABSIs"), Surgical Site Infections ("SSIs"), hospital acquired flu, inpatient flu, and CJD (Mad Cow Disease). [See Appx. p. 9; Affidavit ¶ 18].

Failure to Maintain a Safe Environment

32. Parkland is required to develop and maintain the overall hospital environment in such a manner that the safety and well-being of patients are assured. 42 C.F.R. § 482.41(a). Parkland is also required, to the extent that it chooses to provide surgical services, to provide such services in accordance with acceptable standards of practice. 42 C.F.R. § 482.51. One of the most basic requirements in order to comply with acceptable standards of practice for surgical procedures is to maintain clean and sanitary operating rooms and equipment. Parkland, however,

has consistently failed to meet even minimal sanitation requirements with respect to the condition of its operating rooms and equipment.

33. De Sessa observed daily and persistent violations of the Conditions of Participation such as operating rooms and/or equipment visibly contaminated with blood and other potentially infectious bodily fluids. Continued observation and inspection revealed that the contamination of the operating rooms and equipment was perpetuated as a result of inadequate turnover cleaning, as well as inadequate terminal cleaning. In some instances, De Sessa found that the terminal cleaning logs had been falsified. In April of 2014, as a result of the MRSA outbreak in the Burn ICU, De Sessa submitted cultures to the lab of reportedly clean operating rooms and MRSA was found. [See Appx. p. 9; Affidavit ¶ 19 and Appx. p. 229-230; Exhibits 23-24].

De Sessa reported the problems in the ORs at Parkland to the Director of the ORs, the Director of Environmental Services, the Director of Infection Prevention, Chief of Quality and Safety, and the Senior Vice President of Surgical Services. To back up her reports of contaminated operating rooms, De Sessa provided photographs of the various blood spots and other contaminations in the operating rooms. This would certainly constitute a sufficiently specific disclosure so as to permit a determination of the appropriateness of the alleged improper practice and provide an opportunity to take appropriate corrective action. Thus, upon receiving De Sessa's disclosure, Parkland was obligated under the Corporate Integrity Agreement it entered into with the OIG, to conduct an internal review of the allegations and ensure that proper follow-up was conducted. [See CIA, p. 19-20 (Exhibit 5)]. Of course, Parkland did not report anything. [See Appx. p. 10; Affidavit ¶ 20].

Failure to Maintain a Quality Assessment and Performance Improvement Program

34. Parkland is required to develop, implement, and maintain an effective, ongoing hospital-wide data-driven quality assessment and performance improvement program. This hospital must maintain and demonstrate evidence of its Quality Assessment and Performance Improvement Program (hereinafter "QAPI Program") for review by CMS. 42 C.F.R. § 482.21. This program must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations. 42 C.F.R. § 482.21(a).

35. Further, Parkland is required to use the data collected to monitor the effectiveness and safety of services and quality of care and to identify opportunities for improvement and changes that will lead to improvement. 42 C.F.R. § 482.21(b). Parkland must set priorities for its performance improvement activities that track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. Parkland must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained. 42 C.F.R. § 482.21(c).

36. Despite these requirements, Parkland doctors and staff have continued to engage in various inadequate and misleading documentation and reporting practices, which have led to significantly underreported rates of various adverse events such as SSIs, CLABSIs, and CAUTIs. Thus, Parkland has failed to institute an adequate QAPI program, given that Parkland is not even generating accurate data as to the rates of these various adverse events, much less implementing any actions aimed at improving those rates.

Failure to Abide by the Terms of the Corporate Integrity Agreement

37. Parkland entered into a Corporate Integrity Agreement ("the agreement") with the Office of the Inspector General of the Department of Health and Human Services which imposes numerous requirements on the hospital. Parkland has violated, and continues to violate, multiple obligations under this agreement. These violations fall mostly within two sections of the agreement, Part III-E – addressing the Disclosure Program, and Part III-I – addressing reportable events. Under the terms of the agreement, Parkland is required to establish a disclosure program that includes a mechanism to enable individuals to disclose any identified issues or questions associated with Parkland's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Specifically, the disclosure program must emphasize a policy of non-retribution and non-retaliation, as well as include a procedure to allow anonymous communications.

38. The agreement requires that, upon receipt of a disclosure, Parkland's compliance officer must conduct a preliminary good faith inquiry to determine whether the matter should be further reviewed. For any disclosure that is sufficiently specific so as to permit a determination of the appropriateness of the alleged improper practice and provide an opportunity for taking corrective action, Parkland must conduct an internal review of the allegations, ensuring that proper follow-up is conducted. Additionally, Parkland's compliance officer is required to keep a log of every disclosure received, the status of any internal review, and any corrective action taken in response to the internal reviews.

39. The Agreement also imposes a requirement on Parkland with respect to reporting certain categories of "reportable" events. Included in the definition of reportable events set out

by the agreement is any matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. Thus, each and every one of the violations alleged in the preceding paragraphs of Section IV constitute a "reportable event" under the agreement. If, after having a reasonable opportunity to conduct an appropriate review or investigation of the allegations, Parkland determines that a reportable event has occurred, this must be disclosed by Parkland to the Office of the Inspector General, in writing within thirty days of that determination.

40. Parkland has utterly failed to abide by either of these requirements. With respect to the disclosure program, Parkland has ignored countless disclosures made by Dr. De Sessa, despite the specific and detailed nature of her allegations. In fact, Parkland even went beyond merely refusing to address her disclosures, but began taking steps to prevent Dr. De Sessa from being able to identify other problems in the future. Parkland quickly began imposing numerous limitations on her, including restricting her access to hospital records and documents, as well as prohibiting her from inspecting any operating rooms. [See Appx. p. 4; Affidavit ¶ 7].

41. Most significantly, Parkland failed to address and/or correct the multiple serious problems that Dr. De Sessa uncovered, despite having been provided with an abundance of verifiable evidence to corroborate those disclosures. For instance, to back up her reports of contaminated operating rooms, Dr. De Sessa provided photographs of the various blood spots and other contaminations in the operating rooms. This would certainly constitute a sufficiently specific disclosure so as to permit a determination of the appropriateness of the alleged improper practice and provide an opportunity for taking corrective action. Thus, upon receiving her

disclosure, Parkland was obligated to conduct an internal review of the allegations and ensure that proper follow-up was conducted, in accordance with the mandates of the agreement.

Retaliation and Retribution

42. Parkland engaged in numerous, continuous acts of retaliation and retribution against De Sessa in response to her efforts to identify and correct the problems at Parkland and culminating in De Sessa's termination. During her time at Parkland, De Sessa was consistently given Manager Appraisals with solid or exceptional contribution ratings. [See Appx. p. 261; Exhibit 26 to the Affidavit]. However, in August 2014, De Sessa was suspended by Parkland for a period which was to begin on August 26, 2014, and end on October 3, 2014. During this period of suspension, De Sessa was prohibited by Parkland from speaking to any Parkland employees other than Arthur Ferrell, a member of the Human Resources Department. Despite being the sole Parkland employee that De Sessa was permitted to contact in any way during her suspension, Mr. Ferrell repeatedly ignored multiple attempts by her to contact him. For instance, one of De Sessa's numerous attempts to contact Mr. Ferrell was an email sent on September 11, 2014. Even after waiting a full fourteen days, as of September 25, 2014, De Sessa did not receive any type of acknowledgment or response whatsoever from Mr. Ferrell. She attempted to contact Mr. Ferrell but received no response. In light of the obvious futility of her attempts to contact Mr. Ferrell, De Sessa decided to copy Dr. Hendler, the Chief of Quality, on her email. As a result, De Sessa finally received a response to her communications, however, in a further retaliatory act, this response consisted of an additional ten-day extension of her period of suspension. It is apparent that the additional suspension was solely the product of De Sessa's decision to copy Dr. Hendler on her email. [See Appx. p. 10; Affidavit ¶ 21].

43. On October 13, 2014, prior to her return from this suspension, De Sessa was forced to sign a "final warning" about her alleged improper behavior. Pursuant to this warning, a number of punitive conditions were imposed upon De Sessa. One of these conditions was a requirement that she abide by a "Performance Improvement Plan" (hereinafter "PIP"). [See Appx. p. 276; Exhibit 28]. The PIP contained substantial restrictions on De Sessa's ability to perform her role as a Clinical Epidemiologist. Specifically, she was explicitly instructed via the PIP that she was not permitted to seek out or look into any discrepancies among Parkland's records. Further, if De Sessa happened to discover any such discrepancies in the course of her work, she was prohibited from reporting her findings to anyone at Parkland other than her director. De Sessa was also instructed that she was prohibited from reporting any findings to Dr. Hendler, the Chief of Quality, in particular. The PIP restriction placed upon De Sessa directly violates the Corporate Integrity Agreement with the OIG, which included a Disclosure Program. The Disclosure Program calls for the right of all individuals to be included in the Disclosure Program. [See CIA, p. 19-20 (Exhibit 5)]. [See Appx. p. 11; Affidavit ¶ 22].

44. Early on in De Sessa's employment at Parkland, she sought and received an ADA accommodation. Beyond the restrictions on the ability to perform basic job functions, the retaliation against De Sessa continued in the form of the removal of her ADA accommodation effective immediately upon return from her suspension. In addition, De Sessa's working hours were changed upon her return, despite no similar changes to the working hours of any other employee. Upon becoming aware of the removal of her ADA accommodation, De Sessa contacted the Vice President of the Human Resources Department to ask if Parkland removed the accommodation pursuant to Parkland policy. As a result of this communication, De Sessa was once again suspended, effective October 23, 2014. Upon return from the suspension, on

November 10, 2014, De Sessa was immediately terminated. She appealed the termination. The appeal was heard by a three member panel. Significantly, two of the three members of this panel (Sharon Phillips and Jacqueline Brock), were "Sponsors" of Parkland 1115 Waiver Projects related to 1115 Waiver funding to Parkland. [See Appx. p. 283; Exhibit 29]. [See Appx. p. 12; Affidavit ¶ 23].

45. Significantly, before her termination, on October 14, 2014, De Sessa sent a detailed email to the CEO of Parkland, Dr. Fred Cerise. [See Appx. p. 285; Exhibit 30]. In the email, De Sessa explained in detail the documented violations of Parkland policy, NHSN infection standards, CMS reporting requirement standards, etc. De Sessa offered to provide evidence to Dr. Cerise and encouraged him to speak to her about the issues raised in the email. Dr. Cerise did not contact De Sessa to investigate these allegations (nor anyone else). Rather, De Sessa was terminated shortly thereafter. Additionally, on March 11, 2015, after being put on notice of the inaccuracies in infection rates and Parkland's policies to falsify these numbers, Parkland circulated a press release consciously disregarding the issues raised previously by De Sessa. A copy of an article discussing this press release is attached as Appx. p. 290; Exhibit 31 and quotes two key Parkland Officials:

Such infections "are a major concern for every hospital," said Dr. Fred Cerise, president and chief executive officer of Parkland Health & Hospital System. "And while Parkland's rates of [hospital associated infections] place us in good standing compared to national benchmarks, we are continually focused on this issue."

A statement released by the hospital concluded that "Parkland has already begun to see early successes" in an initiative, called Reduce Infections Together in Everybody. It was launched in 2013 and is being funded by Medicaid through the state's 1115 Waiver program.

"Our goal is to accelerate improvements and achieve much-needed standardization in knowledge, attitudes, practices and cultures of safety related to these potentially preventable complications," said Dr. Pranavi Sreeramoju, chief of infection prevention at Parkland.

In 2014, Parkland saw improvement in all three areas, including a 30 percent reduction in the rate of bloodstream infections, 57 percent fewer catheter-associated infections and an 18 percent fall in sepsis.

"We are pleased with these results, but there are many more things to do," Sreeramoju concluded. "It will continue as an integral part of Parkland's commitment to continuous quality improvement and transformation of health care delivery."

[See Appx. p. 290; Exhibit 31].

26. In reality, there were numerous missed infections in 2014 but they were simply ignored by Parkland. [Attached as Appx. p. 298; Exhibit 32 is a chart made by De Sessa showing the numerous missed infections in only the sample De Sessa was able to review before terminated]. Parkland represents compliance to the public, but the very policies that Parkland brags about, and receives increased Federal funding for, are not designed to help patients and reduce infections but to only improve numbers through willful blindness and falsification of data.

VII. <u>COUNT 1</u>

<u>VIOLATION OF 31 U.S.C. § 3729</u> <u>FALSE OR FRAUDULENT CLAIM MADE TO THE UNITED STATES FOR</u> <u>PAYMENT OR APPROVAL</u>

1. De Sessa adopts, incorporates by reference, and realleges in this count the allegations contained in paragraphs one through twenty-six above, as if fully set forth herein.

2. Through the acts and omissions described above, Defendant knowingly presented and caused to be presented to the United States Government fraudulent claims, records, and statements in order to obtain federal Medicare and Medicaid funds and/or funding.

3. Through the acts described above and otherwise, Defendant knowingly made, used, and/or caused to be made or used false records and statements to get such funds and/or funding granted and approved by the United States Government.

4. The United States and its agents, unaware of the falsity of the records, statements, and claims made or submitted by Defendants, provided and continue to provide federal funds and/or funding to Defendant that would not be provided if the truth were known.

5. By reason of the Defendant's false records, statements, claims, and omissions, the United States Medicare program has been damaged in the amount of millions of dollars in federal funds and/or funding.

6. <u>Manipulating and "gaming the number of hospital acquired infections.</u> As set forth above, Defendant has failed to institute an adequate infection prevention and control program as required by law. 42 C.F.R. § 482.42. Parkland doctors and staff have engaged in numerous improper practices with the goal of reducing the number of infections that are detected and reported for the purpose of receiving increased Federal funds. As a result of these improper practices, Parkland has knowingly submitted false records in support of claims for Medicare and Medicaid funding, in violation of 31 U.S.C. § 3729.

7. Failure to Comply with CMS Reporting Requirements. As set forth above, Defendant has repeatedly employed deficient reporting practices in an effort to reduce its reported numbers of various hospital-acquired conditions. Thus, the data submitted by Defendant to CMS for the purpose of obtaining the maximum possible amount of funding pursuant to its annual Medicare payment update. The submission of these false and misleading records and data to CMS is a violation of 31 U.S.C. § 3729. 8. Failure to Maintain a Safe Environment. As set forth above, Parkland has failed to provide an adequately safe environment, as required by the Medicare conditions of participation, by consistently ignoring contaminated operating rooms and equipment. 42 C.F.R. §§ 482.41(a), 482.51. As a result of these violations, Parkland is not in compliance with the Medicare conditions of participation and therefore is ineligible to participate in Medicare. Thus, each and every bill submitted to Medicare is in violation of 31 U.S.C. § 3729.

9. Failure to Maintain Quality Assessment and Performance Improvement Program. As set forth above, Parkland has failed to implement and maintain an adequate QAPI program, as required by the Medicare conditions of participation. 42 C.F.R. § 482.21. By way of its various attempts to reduce the reported numbers of various hospital acquired conditions, Parkland has failed to identify opportunities for improvement. Additionally, Parkland has failed to implement changes that will lead to improvement, as demonstrated by its continued use of improper reporting methods and repeated refusal to acknowledge or address disclosures identifying problems within the hospital. As a result of these violations, Parkland is not in compliance with the Medicare conditions of participation and therefore is ineligible to participate in Medicare. Thus, each and every bill submitted to Medicare is in violation of 31 U.S.C. § 3729.

10. <u>Failure to Abide by the Terms of the Corporate Integrity Agreement.</u> As outlined above, Parkland has committed innumerable violations of the agreement, namely with respect to the disclosure program and the reportable events requirements. Pursuant to the agreement, Parkland is subject to various fines and penalties in the event that a violation of the terms of the agreement occurs. Each and every violation committed by Parkland generates an obligation to the United States government in the form of the fine or penalty that must be paid, pursuant to the terms of the agreement. Thus, for each and every violation of the agreement which would result in fines or penalties, if discovered, Parkland has improperly avoided an obligation to pay money to the Government, in violation of 31 U.S.C. § 3729.

11. In committing the acts and omissions alleged in Paragraphs one through twentysix above, Defendant has violated and will through the date of trial continue to violate the False Claims Act, 31 U.S.C. § 3729(a)(1), by knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims for payment or approval.

12. In addition, Defendant has separately violated and will through the date of trial continue to violate the False Claims Act, 31 U.S.C. § 3729(a)(1), by knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money to the Government and by knowingly concealing or improperly avoiding an obligation to pay or transmit money to the Government.

13. To the extent, if any, that this case is deemed to be a related action and that facts set forth herein are deemed to be the same as facts underlying any existing Qui Tam False Claims Act action pending at the time of filing of this action, as prohibited by 31 U.S.C § 3730(e)(3), then said factual allegations in common with the pending action, which would cause this to be a related cause of action, are hereby expressly excluded from this action, but only to the limited extent necessary to exclude such preemption.

14. Further, to the extent that the allegations or transaction set forth herein are the subject of an existing civil suit or an administrative civil money penalty proceeding in which the Government is already a party, then the allegations or transactions referred to herein which are the subject of any such civil suit or administrative civil money penalty proceeding are expressly excluded herefrom, but only for the specific time periods and specific allegations or transactions as necessary.

VIII. <u>COUNT 2</u>

<u>VIOLATION OF 31 U.S.C. § 3730(h)</u> <u>RETALIATION FOR ACTING IN FURTHERANCE OF AN ACTION FOR FALSE OR</u> <u>FRAUDULENT CLAIMS MADE TO THE UNITED STATES</u>

15. De Sessa adopts, incorporates by reference, and realleges in this count the allegations contained in paragraphs one through twenty-six above, as if fully set forth herein.

16. <u>Retaliation and Retribution</u>. As stated above, Defendant has suspended, discriminated against, and ultimately terminated Dr. De Sessa because of her lawful acts taken in furtherance of an action under 31 U.S.C. § 3730, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under 31 U.S.C. § 3730.

17. In committing the acts and omissions averred in Paragraphs one through twentysix above, Defendant has violated and will through the date of trial continue to violate 31 U.S.C. § 3730(h), by retaliating against Dr. De Sessa for reporting and investigating Defendant's conduct of knowingly presenting or causing to be presented to the Federal Government false or fraudulent applications for federal funding for payment or approval.

IX. DAMAGES

18. De Sessa adopts, incorporates by reference, and realleges in this count the allegations contained in paragraphs one through twenty-six above, as if fully set forth herein.

19. Pursuant to 31 U.S.C. § 3729(a), Defendants are liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, for each violation of the False Claims Act, plus three (3) times the amount of damages which the United States Government sustained because of the acts of the Defendant. 20. Pursuant to 31 U.S.C. § 3730(h), Defendant is liable to Dr. De Sessa for two (2) times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.

X. <u>PRAYER</u>

WHEREFORE, Plaintiff/Relator Dr. Susan De Sessa respectfully asks for judgment against Defendant for a civil penalty of \$10,000 per false claim under 31 U.S.C. § 3729, plus three (3) times the amount of damages that the government sustains because of Defendant's acts, pursuant to 31 U.S.C. § 3729; plus judgment against Defendant for two (2) times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the retaliation and discrimination; plus reasonable expenses, attorneys' fees, and costs, that this Honorable Court deems necessarily incurred, pursuant to 31 U.S.C. § 3730(d)(1) and (2), and such other relief as may be deemed equitable and just under the circumstances.

XI. DEMAND FOR JURY TRIAL

Plaintiff/Relator in the above-styled cause demands a trial by jury of all issues triable as a matter of right.

Dated this 6th day of July, 2017.

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Respectfully submitted,

/s/ Daniel K. Hagood, P.C. Daniel K. Hagood, P.C. State Bar No. 08698300 FITZPATRICK HAGOOD SMITH & UHL, LLP 2515 McKinney Avenue, Suite 1400 Dallas, Texas 75201 Telephone: 214-237-0900 Facsimile: 214-237-0901

and,

/s/ Thomas E. Shaw Thomas E. Shaw State Bar No. 18152750 THE LAW OFFICES OF THOMAS E. SHAW, P.C. 9304 Forest Lane Suite 252, North Building Dallas, Texas 75243-6238 Telephone: 214-221-7429 Facsimile: 214-221-7447

and,

 \leq /s/ Marc Tecce

Marc C. Tecce State Bar No. 24068652 THE LAW OFFICES OF MARC TECCE 9304 Forest Lane, Suite 251 Dallas, Texas 75243 Telephone: 214-614-8317 Facsimile: 214-221-7447 Email: marc@teccelaw.com

ATTORNEYS FOR RELATOR

CERTIFICATE OF SERVICE

On July 6, 2017, I hereby certify that I have served United States' Attorney General's Office, 950 Pennsylvania Ave., NW, Washington, DC 20530-0001 via Certified Mail and the Northern District of Texas United States Attorney's Office, 1100 Commerce Street, Third Floor Dallas, Texas 75242-1699 via hand delivery.

> /s/ Marc Tecce_____ Marc C. Tecce

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(c) Attorneys (Firm Name.) FITZPATRICK HAGOOD Suite 1400, Dallas, Texas	SMITH & UHL, LLP;		nue,	Attorneys (If Known) Unknown		7 C V.	178	2 -	K
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